Global Efforts to 'Rebalance' Private and Public Interests in Intellectual Property: Chaos IS the New Normal©

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On the Panel

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  - EU Parliament Resolution (2007/2003(INI)) (Environmentally-Sensitive Technology Compulsory Licenses)
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a. United States
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- Public Consultation Launched to Review Copyright Directive 2001/29/EC

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a. Initiatives of the United Nations Secretariat, Agencies, Offices, and Instrumentalities

i. United Nations General Assembly

- World Commission on Environment and Development Report, "Our Common Future" (Aug. 1987)
- UN Conference on Environment and Development (UNCED) ("Earth Summit" 1992), convened pursuant to General Assembly Resolution A/44/228 (Dec. 1989)
- The Rio Declaration on Environment and Development
- Agenda 21 – A Comprehensive Plan of Action to Achieve Sustainable Development, adopted at RIO UNCED
  - Agenda 21 Implementation to Focus on "Economies in Transition"
    - Par. 6.44 – Focus on access to and transfer of technology, know-how and information, consistent with Chapter 34
  - Multiple Agenda 21 Chapters refer to the exchange, dissemination, and/or transfer of scientific, technical and other information, data, knowledge, methods, techniques and technologies
  - Chap. 34 – Transfer of Environmentally Sound Technology, Cooperation & Capacity-Building
    - Pars. 34.3-34.5, 34.7-34.11, 34.14(b), 34.15, 34.18(a) and (d)-(e)
- UN General Assembly - Millennium Declaration - Resolution 55/2 (Sept. 8, 2000)
- Millennium Development Goal ("MDG") Gap Task Force 2013 Report on Implementation of MDGs

- UN Commission on Sustainable Development (CSD) World Summit on Sustainable Development ("Johannesburg Summit", Jan. 2002) Report
  - Johannesburg Declaration on Sustainable Development
  - Plan of Implementation of the World Summit on Sustainable Development (adopted by resolution)

ii. United Nations Secretariat

- Department of Economic and Social Affairs (UNDESA)
  - Post-Rio+20 United Nations Conference on Sustainable Development Study, "Transition to a Green Economy: Benefits, Challenges and Risks from a Sustainable Development Perspective" (2012)
- United Nations Secretary-General
  - UN System Task Team on the Post-2015 UN Development Agenda Report "Science, Technology and Innovation and Intellectual Property Rights: The Vision for Development" (May 2012)

iii. UN Office of the High Commissioner for Human Rights (OHCHR)

- Resolution 2000/7 on Intellectual Property Rights and Human Rights (Aug. 17, 2000)
  - Declares WTO TRIPS Agreement Conflicts With Human Rights

iv. World Health Organization

- Report of WHO Meeting of Senior Officials and Ministers of Health, at World Summit on Sustainable Development (Jan. 2002)
  - Annex 3: Background Paper on Health and Sustainable Development
- World Health Assembly (WHA) Resolution 56.27 (May 2003)
  - Called for Analysis of Scientific, Legal, Economic, Ethical & Human Rights Aspects of Intellectual Property as it Relates to Public Health
  - Called for Creation of Commission on Intellectual Property Rights, Innovation and Public Health (CIPIH)
- WHA Resolution 57.14 (May 2004)
  - Called for Adapting National Legislation for Using Full TRIPS Flexibilities
- CIPIH Report - Public Health, Innovation and Intellectual Property Rights (Apr. 2006)
  - Recommendations
    - WHO, WIPO, etc. Should Establish Training for IP Management in Biomedical Field
    - Developed Countries and Big Pharma Should Take Measures to Promote Technology Transfer and Local Production
    - Developed Countries Should Comply With TRIPS Technology Transfer Obligations Under Article 66.2 and Doha Declaration Para. 7
- WHA Resolution 59.24 (May 2006)
  - Called for Establishment of Intergovernmental Working Group to Draft a Global Strategy and Plan of Action to Implement CIPIH Recommendations
- WHO Intergovernmental Working Group on Public Health, Innovation and

Intellectual Property (WHO IGWG) Draft Strategy and Plan of Action (July 2007)
  - Element 4. Transfer of Technology
  - Element 5. Management of Intellectual Property
- WHO IGWG Convened Public Hearings Soliciting Comments on Draft Strategy and Plan of Action (Sept. 2007)
- WHO IGWG Released its Post-Hearings Report on the Draft Global Strategy and Plan of Action (May 2008)
  - WHA Resolution 61.21 Adopted Global Strategy and Agreed Parts of Plan of Action
  - WHA Resolution 62.16 Resolved Open Items

v. World Intellectual Property Organization
- WIPO Standing Committee on the Law of Patents (SCP) Reports
  - SCP/12/3 Rev.2 - Report on the International Patent System (June 2008; Feb. 2009)
    - Pars. 101, 103-109, 111, 115-117, 119-125
  - SCP/13/2 - Report on Patents and Standards (March 2009)
    - Pars. 5, 8, 16, 117, 139-144, 146
  - SCP/13/3 – Exclusions From Patentable Subject Matter and Exceptions and Limitations to the Rights (March 2009)
    - Pars. 2-3, 5-6, 9-10, 12-15, 27, 31, 53-55, 58, 67, 70, 73, 95, 102-103, 116-117, 127, 129, 134-135, 138, 140-141, 143-144, 158, 160, 164, 167, 180-181, 185
  - SCP/15/3 – Expert's Study on Exclusions From Patentable Subject Matter and Exceptions and Limitations to the Rights (Sept. 2010; Oct. 2010)
    - SCP/15/3 Annex I – Introduction
    - SCP/15/3 Annex II - Computer Programs As Excluded Patentable Subject Matter
    - SCP/15/3 – Annex V - Patent Exceptions and Limitations in the Health Context
    - SCP/15/3 – Annex VI - The Patent System and Research Freedom: A Comparative Study
  - SCP/14/4 Rev.2 – Transfer of Technology (Jan. 2010; Oct. 2011)
    - Pars. 19, 48-49, 51-53, 61-64, 68, 72-74, 77, 83, 85-89, 93, 96-97, 100, 102, 108, 149, 171-173, 178, 182-184, 190, 193, 195, 197
  - WIPO Secretariat Report – Refusals to License IP Rights – A Comparative Note on Possible Approaches (Aug. 2013)
    - Pars. 1, 3, 6, 8-10

b. Initiatives of Economic Intergovernmental Organizations

i. World Trade Organization (WTO)
- Declaration on the TRIPS Agreement and Public Health (Doha Declaration) (Nov. 14, 2001)
  - TRIPS Agreement Does Not Prevent Members from Taking Measures to Protect Public Health

- Members May Grant Compulsory Licenses & Determine Grounds Therefor, Subject to Conditions

- WTO General Council Decision on the Implementation of Doha Declaration Par. 6 (Sept. 2003)
  - Setting Forth a Mechanism for Waiving TRIPS Article 31(f) and (h) Obligations With Respect to Pharmaceuticals Shipped to Developing Countries Without Manufacturing Capacity Pursuant to a Compulsory License
    - WTO Members Approved TRIPS Amendments to Effectuate Decision (Dec. 2005)
    - TRIPS Amendments Have Not Yet Taken Effect for Want of Ratification by 2/3 WTO Membership (Jan. 2014)

ii. World Bank

- World Bank Report – "Inclusive Green Growth: The Pathway to Sustainable Development" (May 2012)
  - Recommends Making it Easier for Developing Countries to Grant Compulsory Licenses to Ensure Access to Green Technologies

iii. BRICS Forum

- First BRICS Summit, BRICS Joint Communique (June 2009)
  - Pars. 5-7, 11
- Third BRICS Summit, Sanya Declaration (April 2011)
  - Pars. 6, 8, 20-21, 23
- Fourth BRICS Summit, Delhi Declaration (March 2012)
  - Pars. 3, 16-17, 30, 32
- Fifth BRICS Summit, eThekwini Declaration (March 2013)
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- Fifth BRICS Summit, BRICS Joint Trade Minister Communique (March 2013)
  - Pages 2-4

2. Copyrights

a. Initiatives of the United Nations Secretariat, Agencies, Offices, and Instrumentalities

i. UN Educational, Scientific and Cultural Organization (UNESCO)

- Copyright Protection Policy
  - Generally
  - UNESCO Report – "Basic Notions About Copyright and Neighbouring Rights"
  - UNESCO Report – "The ABC's of Copyright" (2010)
    - Four Main Categories of Exceptions – To Promote
      - Freedom of Expression
      - Access to Knowledge
      - Public Justice
      - Private or Personal Use
    - Berne Convention "Three-Step Test"

- UNESCO's Contribution to Post-2015 – The Power of Culture for Development

ii. UN Conference on Trade and Development (UNCTAD)

- UNCTAD/ICTSD Project on Intellectual Property Rights and Sustainable Development
  - Report – "The International Copyright System: Limitations, Exceptions and Public Interest Considerations for Developing Countries"
    - Seeks Reform of Berne Convention Annex & a Global Approach to Appropriately Balancing Exceptions & Limitations
- UNCTAD/ICTSD Sidebar Event at WIPO/SCCR (May 2009) Explaining the Munich Declaration on a Balanced Interpretation of the "Three-Step Test" in Copyright Law (2008)
  - The Berne Convention "Three-Step Test" Must Be Reinterpreted Holistically, Not Sequentially; Qualitatively *as well as* Quantitatively; *and* Consistently With the TRIPS Agreement "Three-Step Test" Which Takes Account of the Legitimate Interests of Third Parties
  - *Cf.* Views of Former WIPO Assistant Director General Presentation at Fordham Intellectual Property Conference, Cambridge University, UK (April 15-16, 2009)
    - The "Three-step Test" is Not Broken and Should Not Be Fixed

iii. World Intellectual Property Organization

- Standing Committee on the Copyright and Related Rights
  - SCCR/9/7 - WIPO Study on Limitations and Exceptions of Copyright and Related Rights in the Digital Environment (2003)
    - Exclusions From Copyright Protection
      - For Particular Categories of Work
      - Immunity From Infringement For Particular Kinds of Uses
      - For Particular Uses Subject to Payment of Compensation to the Rightholder – Compulsory Licenses
    - Limitations and Exceptions Under Berne Convention
      - Exceptions to Protection
        - General Exception Concerning Reproduction Rights–the 'Three-Step Test'
          - "Certain Special Cases"
          - "Conflict with the Normal Exploitation of the Work"
          - "Does Not Unreasonably Prejudice the Legitimate Interests of the Author"
      - Compulsory Licenses Allowed Under the Berne Convention
        - Compulsory Licenses in Relation to Developing Countries
          - Appendix Article II - Non-Exclusive, Non-Transferrable Compulsory Licenses for Translation
          - Appendix Article III - Non-Exclusive, Non-Transferrable Compulsory Licenses for Reproduction
    - Limitations and Exceptions Under WIPO Copyright Treaty ("WLT")

- WCT Article 1.4 and Agreed Statement
  - Extends Application of Berne Convention Articles 9(1)-(2) to the use of works in digital form
    - Storage of Protected Works in Digital Form on Electronic Media Constitutes a "Reproduction" Under Berne Convention Article 9
- WCT Article 10 "Three-Step Test"
  - Article 10(1) Applies to Rights Accorded Under WCT
  - Article 10(2) Applies to All Rights Protected in Berne

- Limitations and Exceptions Under the TRIPS Agreement
  - Under TRIPS Article 9(1)
  - Under TRIPS Article 3(1)
  - Under TRIPS Article 13 Within Meaning of TRIPS Articles 7 & 8 to Address Berne Convention "Gap"

- WIPO Intellectual Property Handbook: Policy, Law and Use – Chap. 7, Technological and Legal Developments in Intellectual Property (2004)
  - Pars. 7.17-7.24
- SCCR/15/7 - WIPO Study on Copyright Limitations and Exceptions for the Visually Impaired (Sept. 2006; Feb. 2007)
- SCCR/14/5 - WIPO Study on Automated Rights Management Systems and Copyright Limitations and Exceptions (2006)
  - Application of Technical Protection Measures Seen as Exclusionary
    - Profoundly Changes the Way That Copyright Works by Precluding Unauthorized "Marginal" Uses
- SCCR/24/8/PROV. - WIPO Secretariat - Provisional Working Document Towards an Appropriate International Legal Instrument (In Whatever Form) on Limitations and Exceptions for Educational, Teaching and Research Institutions and Persons With Other Disabilities Containing Comments and Textual Suggestions (July 2012)
  - Based on Developing Country Proposals
    - The African Group – SCCR/22/12 (June 2011)
    - Brazil – SCCR/24/7 (July 2012)
    - Ecuador, Peru & Uruguay – SCCR/24/6 (July 2012)
  - Pars. 4.1-4.3, 4.6-4.7, 5, 7.1-7.2, 7.5-7.6
- SCCR/23/8 – Working Document Containing Comments on and Textual Suggestions Towards an Appropriate International Legal Instrument (In Whatever Form) on Exceptions and Limitations for Libraries and Archives (Aug. 2012)
  - Based largely on Proposal from the African Group - SCCR/22/12 (June 2011)
  - Topics 1-9
- SCCR/24/9 - Revised Working Document on an International Instrument on Limitations and Exceptions for Visually Impaired Persons/Persons with Print Disabilities (July 2012)

- VIP/DC/8 - WIPO – Adoption by Diplomatic Conference of: Marrakesh Treaty to Facilitate Access to Published Works for Persons Who are Blind, Visually Impaired, or Otherwise Print Disabled (July 2013)
  - Relevant Articles
    - Article 2 – Definitions
    - Article 4 - National Law Limitations and Exceptions Regarding Accessible Format Copies
      - Articles 4.1(a), 4.4
    - Article 5 – Cross-Border Exchanges of Accessible Formats
      - Article 5.3 (Addresses Berne Gap)
        - Article 5.4(a)-(b)
        - Article 10 - General Principles of Implementation
        - Article 11 - General Obligations on Limitations and Exceptions

This presentation is divided into three parts. Part I sets forth a general introduction to and overview of the many issues for discussion. Part II focuses on the observed incidents (effects) of change in the world of intellectual property, while Part III focuses on their apparent causes.

I. INTRODUCTION & OVERVIEW

1. **The Apparent Effects**

Incidents of change in the world of intellectual property are all around us, domestically as well as internationally. The extent of patentable and copyrightable subject matter which arguably had been broadening since the 1980's, now appears, suddenly, to be narrowing, as patentability and copyrightability standards have been progressively tightened. And, as efforts have been made to better understand and articulate the public policy grounds for excluding technology or creative-based subject matter from patentability and/or copyrightability (judicially, legislatively and administratively), the bounds of the public domain appear, simultaneously, to be expanding.

In addition, the scope of exclusive patents and copyrights initially granted by the USPTO, the U.S. Copyright Office and analogous foreign national patent and copyright offices and subsequently enforced by specialized courts around the world appear to be narrowing. Simultaneously, the public policy grounds for assessing and determining occurrences of 'abuse' of such rights upon which governments currently appear to more liberally rely - namely, exceptions and limitations to the exercise of such rights - presently also appear to be more numerous. In many cases, the mechanisms to which governments now preemptively resort to prevent perceived 'abuses' are based partly on intellectual property law and partly on antitrust law and unfair competition law.

Furthermore, the ready availability of judicial remedies permitting private interests to enforce their exclusive patent rights and copyrights as against alleged domestic and foreign infringers, including by means of injunctions and exclusion orders in Section 337 trade actions, has more frequently been questioned by governmental authorities and subject to new curtailments potentially deleterious to the sanctity of such IP rights and the economic interests of those who hold them.

Indeed, it would appear that governments around the world have more flexibility and have readily chosen to exercise the option of employing "public interest" grounds beyond the strictures of government product authorization, market access and/or procurement regulations, as the preferred basis for monitoring, overseeing and ultimately governing exclusively private party contractual relations. For example, even where private parties have not otherwise committed an illegal act, governments have increasingly come to view a party's refusal to license an expanding list of technologies as creating a conflict with the public interest that justifies government intervention.

2. **The Apparent Causes**

As with many cause-and-effect analyses, it is more than plausible that there are multiple apparent causes to which these observable effects can be attributed.

One possible cause may lie in the current state of the global economy. The world is still experiencing, to various degrees, the harsh consequences of the 2008 financial crisis. The historical record reflects that during times of severe economic malaise or depression when popular opinion concerning the perceived influence of large corporations (now multinationals) is largely negative (as had occurred during the last two decades of the nineteenth century and during the 1930's), patent rights in the United States were disfavored and curtailed. The public interest was preserved through enactment of antitrust legislation and judicial determinations that strictly construed patent eligibility requirements. Ultimately, as the economy rebounded and prosperity took hold, patent rights were restored (e.g., during the 1980's).[1] This would seem to explain, at least partially, why developed country governments in North America, Europe, Asia and Oceania have sought to curtail perceived 'abuses' of intellectual property rights that could potentially impair competition, innovation and national competitiveness. Since many emerging and developing economies continue to suffer the consequences of the 2008 financial crisis, it is possible that they responded by deploying a growing menu of legislative and judicial mechanisms, some within and beyond patent law, to ensure their economic recovery and participation in the evolving 21st century knowledge economy.

Another possible cause of the observed effects may lie in ongoing governmental and intergovernmental efforts to facilitate greater cross-border legal harmonization engendering both regional and international harmonization of IP laws and policies. IP harmonization, in particular, is ostensibly being pursued, in part, to reduce cross-border transaction costs faced by the producers, creators and holders of IP rights and IP-rich technologies and creative works, as well as by the consumers and other parties that use them. In addition, it is being pursued, in part, to facilitate, at a higher more abstract level, greater global governance over cross-border economic transactions and relationships entailing the licensing, transfer or sharing of such IP rights and assets. These efforts have been long and arduous, especially in light of the distinct and often disparate national legal systems involved, which have produced different national constitutions that have created different behavioral incentives and transaction costs.[2] In this regard, it is helpful to consider the similarities and differences between the preventive justice-based Napoleonic civil law system of Continental Europe and its many former colonies located in Africa, Latin America and Asia, and the contentious justice-based Anglo-American common law system of North America, the United Kingdom and Oceania which posits private property rights and the role of government differently.[3] Arguably, the slow pace of harmonization reflects ongoing competition between these two

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[1] *See* Ladas and Perry, LLP, *A Brief History of the Patent Law of the United States* (2009), available at: http://www.ladas.com/Patents/USPatentHistory.html.

[2] *See* Svetozar Pejovich and Enrico Colombatto, *The Rule of Law and the Economic Functions of the Constitution*, Chap. 6, at p. 100, *in Law, Informal Rules and Economic Performance: The Case for Common Law*, Edward Elgar Pub (August 30, 2008) (permission for citation obtained), Editorial Review on Amazon.com website, at: http://www.amazon.com/Law-Informal-Rules-Economic-Performance/dp/1845428730/ref=sr_1_1?ie=UTF8&s=books&qid=1226081580&sr=1-1; Svetozar (Steve) Pejovich, *On Liberalism, Capitalism, The Rule of Law, and the Rule of Men*, Discussion Paper prepared for CRCE Conference on the Rule of Law in the Market Economy Slovenia (October 2-4, 2008), at pp. 2-4; Svetozar (Steve) Pejovich, *Capitalism and the Rule of Law: The Case for Common Law*, prepared for discussion at Workshop in Philosophy, Politics and Economics at George Mason University (Oct. 9, 2007), available at: http://econfaculty.gmu.edu/pboettke/workshop/archives/fall07/Pejovich.pdf.

[3] *See* Lawrence A. Kogan, *The Creeping 'Authenticity' of Europe's Intrusive Civil Law System*, Institute for Trade, Standards and Sustainable Development (2008), available at:

legal systems and the economic frameworks anchoring them (Keynesian economics versus neo-economic liberalism, respectively) to establish global standards and secure the 'commanding heights.'[4]

A third possible cause to which the observed effects can be attributed may actually be political in nature. Since the end of the Cold War the United Nations (including its many agencies, treaty secretariats, offices and instrumentalities), assisted by an evolving European Union and its Member States and by developing country UN member nations (especially emerging "BRICS" nations Brazil, Russia, India, China and South Africa), has gradually broadened its initial operating mandate and field of operations such that its foci now extend far beyond the Security Council (dedicated to the preservation of international peace and security). The UN secretariat, with member nation financial, logistical and administrative support, has created myriad new agencies and secretariats and expanded the scope and mandate of others. It has also immersed itself in the international economic, social and cultural affairs of all nations on universal human, economic, environmental, health, social and cultural rights grounds for the purpose of achieving a new global sustainable development paradigm. As a result, non-Security Council-related UN 'soft law'[5] initiatives now impact the economic life of every nation, including, the United States.[6] The matters addressed are quite numerous and include an emphasis on intellectual property, innovation, technology transfer and knowledge dissemination, commercial licensing, antitrust and unfair competition law issues. As these presentation materials clearly show, the multiple UN bodies that have performed extensive evaluations of the scope, exercise and enforcement of private patents and copyrights and their impact on the "public interest" have concluded that the current use of these intangible assets is hopelessly in conflict with universal human, economic, environmental, health, social and cultural rights and that, consequently, the attendant private and public interests must be 'appropriately', 'fairly' and 'delicately' rebalanced. In other words, to achieve sustainable development goals there must be more cross-border research and development collaboration,[7] interoperability,

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http://nebula.wsimg.com/bcb1adacf17baedeeb2d200cafc85b20?AccessKeyId=39A2DC689E4CA87C906D&disposition=0; http://www.notaries.org.uk/eu_authentic_acts/eu_authentic_acts.html.

[4] *See* Charlemagne, *Brussels rules OK: How the European Union is becoming the world's chief regulator*, The Economist (Sept. 20, 2007), available at: http://www.economist.com/node/9832900; Tobias Buck, *Standard bearer*, Financial Times (July 10, 2007), available at: http://www.ft.com/cms/s/0/6e721ba2-2e7d-11dc-821c-0000779fd2ac.html#axzz2qJACCTMU; Brandon Mitchener, *Rules, Regulations of Global Economy Are Increasingly Being Set in Brussels*, WALL ST. J. (Apr. 23, 2002), available at: http://online.wsj.com/news/articles/SB1019521240262845360.

[5] *See, e.g.*, Andrew T. Guzman and Timothy L. Meyer, *International Soft Law*, 2 Journal of Legal Analysis 171-225 (2010), available at: http://works.bepress.com/cgi/viewcontent.cgi?article=1040&context=andrew_guzman.

[6] Arguably, the UN and such member nations have pursued these efforts largely as a counterweight to US economic and political hegemony in the former Bretton Woods institutions (the General Agreement on Tariffs and Trade (GATT), which evolved into the World Trade Organization (WTO); the International Bank for Reconstruction and Development (IBRD), which is part of today's broader World Bank Group; and the International Monetary Fund) - each of which, since the beginning of this millennium, has evolved and incorporated within its organizational mandate global development goals and objectives.

[7] During 2003, for example, "John Barton, Professor of Law at Stanford University and Chair of the U.K. Commission in Intellectual Property Rights…proposed a treaty to preserve the global scientific and technology commons. He argue[d] that science and technology require a commons of data, ideas, and insight, and that all scientists will benefit from having access to the work of their predecessors. Such a commons should be global. Existing restrictions to creating a commons – such as licensing regulations that favor nationals and the global trend to expand the scope of IP protection to include basic ideas, procedures, methodologies, and research tools – need to be overcome. This requires an international treaty to create a global scientific and technology commons. This treaty could include a commitment ensuring that the benefits of publicly funded

information and data exchanges, open access and benefit sharing, open and transparent technology standardization and related finance and investment that ensure meaningful transfers of developed country environmental technologies, health technologies and information and communication technologies (ICTs) at less than fair market value prices.

A fourth possible cause of the observed effects may derive from the political and social philosophy underlying the alternative and fundamentally different development paradigm of sustainable development toward which the world is now proceeding. Sustainable development seeks to meet the needs and aspirations of the present without compromising the ability to meet those of the future. Environmental protection, poverty eradication and social justice and equity are each inherent in sustainable development in a precarious, often, offsetting balance. To achieve sustainable development, there must be international cooperation between developed and developing countries consisting of research and development collaboration, information sharing, technology transfer and diffusion, and financial investment (i.e., knowledge and wealth transfers). Sustainable development advocates argue that these communal and communitarian activities will ensure the collective widespread utilization of advanced health, information and communication and environmentally sound technologies capable of protecting and preserving the global environment, eradicating global poverty, reversing under-development, improving education, restoring social justice (each a human right), and providing a higher quality of life to both present and future generations. However, these advocates also state that achieving sustainable development will require major changes in the current domestic and international laws and policies of every nation. Many of these are premised, especially those of the United States, on Enlightenment-era intellectual reason, empirical science, free market economics and personal liberty and individualism, which has given rise to globalization. Thus, current patterns of production and consumption arising from globalization and resulting in tangible property ownership must be transformed; and the exercise of exclusive private rights held in created intellectual property assets underlying scientific, technical and technological discoveries, innovations and creative works economically exploited in the course of globalization, must be circumscribed whenever such deemed 'global public goods'[8] are necessary to serve the greater public interest. This means that, where

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research are made available to all and not just to nationals of a few wealthy countries." *See* Ellen F.M. 't Hoen, *The Responsibility of Research Universities to Promote Access to Essential Medicines*, 3 Yale Journal of Health Policy, Law, and Ethics 293, 299-300 (2003), available at: http://digitalcommons.law.yale.edu/cgi/viewcontent.cgi?article=1068&context=yjhple (referencing John H. Barton, *Preserving the Global Scientific and Technological Commons*, Address at the International Centre for Trade and Sustainable Development, U.N. Conference on Trade and Development Policy Dialogue on a Proposal for an International Science and Technology Treaty (April 11, 2003), available at: http://www.un.org/esa/sustdev/natlinfo/indicators/idsd/pdf/documents/dialogue_treaty_international_ICT.pdf). Professor Barton's proposal has long been considered in the context of healthcare, by the World Health Organization and its membership. *See, e.g.*, Rebecca Hersher, Pharma backs latest attempt at a global health R&D treaty, 18 *Nature Medicine* 838 (2012), available online (June 6, 2012), available at: http://www.nature.com/nm/journal/v18/n6/full/nm0612-838a.html.

[8] According to intellectual property law professors Reichman and Maskus, "[g]lobal public goods might usefully be defined as those goods (including policies and infrastructure) that are systematically underprovided by private market forces anf for which such under-provision has important international externality effects. The concept that a good is 'public' stems from a combination of non-rivalry in consumption and nonexcludability in use. An item is nonrival if its use by one actor does not restrict the ability of another actor to benefit from it as well. A good is nonexcludable to the extent that unauthorized parties ('free riders') cannot be prevented from using it. Classic examples include national defense, environmental protection, and investments in new technical information…Many critical public goods have become increasingly global in their effects and

governments determine that such exercise of exclusive private rights to the use, transfer and/or enforcement of patents, copyrights, trade secrets or trademarks[9] conflict with or otherwise contravene human rights or threaten the achievement of any aspect of sustainable development at the expense of the global community, such rights must be diminished or sacrificed. Consequently, to the extent that sustainable development represents a rejection and replacement of Enlightenment-era values[10] with which it is arguably opposed, it can be said to be "already postmodern".[11] In other words, the

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supply needs…This situation is well illustrated by the emerging global system of IP protection. By long tradition, IPRs were constituted as a national policy prerogative, with relatively little attention paid to coordinating standards across countries. However, wide variations in national regulations can have significant international static and dynamic externalities." *See* Keith E. Maskus and Jerome H. Reichman, *International Public Goods and Transfer of Technology Under a Globalized Intellectual Property Regime*, Cambridge University Press (2005) at pp. 8-9, available at: http://books.google.com/books?id=6SGRt2CZNyYC&pg=PA8&lpg=PA8&dq=intellectual+property+%2B+nonrival+public+goods&source=bl&ots=r82BQgwCU0&sig=-qrHw4HBvF_QXP9d6sRLV9y_YLk&hl=en&sa=X&ei=n4bWUrD6CZW_sQTci4DYAg&ved=0CFcQ6AEwBw#v=onepage&q=intellectual%20property%20%2B%20nonrival%20public%20goods&f=false.

[9] Due to the limitations of space and time, this presentation does not address emerging governmental restrictions imposed on the use of trademarks to promote and market what have come to be known as 'unhealthy lifestyle' products (including tobacco, alcohol, processed foods and baby formula) deemed harmful to public health and nutrition. For an overall discussion of such restrictions *See* Lawrence A. Kogan, *Trade/Investment Issues Surrounding Health-Based Regulatory Impairment of 'Unhealthy Lifestyle' Product IP (TMs, Packaging and Promotion/Advertising)*, presented at the Joint Session of the Intellectual Property, Cross-Border Investment and International Trade Committees, Inter-Pacific Bar Association Annual Conference/Meeting (Seoul, Korea, April 20, 2013), available at: http://www.koganlawgroup.com/uploads/4-20-13_-_LA_Kogan_-_IPBA_-Seoul_2013_--Trade-Investment_Issues_Surrounding_Health-Based_Regulation_of___Unhealt.pdf. For an in-depth discussion of the international trade implications of trademark-use impairing infant formula marketing rules in Hong Kong and the Philippines, *See* Lawrence A. Kogan, *Hong Kong's Draft Infant Formula & Complementary Foods Marketing Code Violates WTO Law* (Part 3 of 3), LexisNexis Emerging Issues 7049 (2013), available at: http://www.koganlawgroup.com/uploads/Hong_Kong_s_Draft_Infant_Formula___Complementary_Foods_Marketing_Code_Violates_WTO_Law__Part_3_of_3_.pdf; Lawrence A. Kogan, *The Philippines Breastmilk Substitute/Supplement Marketing Framework Violates WTO Law* (Part 2 of 2), LexisNexis Emerging Issues 7067 (2013), available at: http://www.koganlawgroup.com/uploads/The_Philippines_Breastmilk_Substitute-Supplement__BMS__Framework_Violates_the_WTO_TRIPS_Agreement__Part_2_of_2_.pdf.

[10] "Postmodernism rejects the reason and individualism that the entire Enlightenment world depends upon. And so it ends up attacking all of the consequences of the Enlightenment philosophy, from capitalism and liberal forms of government to science and technology...Postmodernism's essentials are the opposite of modernism's." *See* Stephen Hicks, *Explaining Postmodernism: Skepticism and Socialism from Rousseau to Focault*, (Scholarly Publishing © 2004), at p. 14, available at: http://nebula.wsimg.com/8d5e98664570b762885a531748dcb57a?AccessKeyId=39A2DC689E4CA87C906D&disposition=0&alloworigin=1. "A founder of post-modernism, Foucault denies that there is universal rationality, and suggests that any knowledge, including scientific knowledge, reflects specific interests and serves as an instrument for domination. 'The theme that underlies all Foucault's work is the relationship between power and knowledge, and how the former is used to control and define the latter. What authorities claim as 'scientific knowledge' are really just means of social control.'" *See* Philip Stokes, *Philosophy: 100 Essential Thinkers* (London: Arcturus, 2004), at p. 157 (discussing the theories of Michel Foucault). *See also* Michel Foucault, *The Birth of Biopolitics: Lectures at the Collège de France, 1978–1979*, Translated by Graham Burchell, (London: Palgrave Macmillan, 2008), *referenced in* Lucas Bergkamp and Lawrence Kogan, *Trade, the Precautionary Principle, and Post-Modern Regulatory Process: Regulatory Convergence in the Transatlantic Trade and Investment Partnership*, 4 European Journal of Risk Regulation 493, 499 at fn# 57, available at: http://www.koganlawgroup.com/uploads/2013_Trade__Precaution_and_Post-Modern_Regulatory_Process_EJRR-c.pdf.

[11] "The phrase 'sustainable development' links the metanarrative of 'environmentalism' and 'economic development' in ongoing dynamic tension...'Sustainable development' is an intentional oxymoron, a paradox. It is a self-contained deconstruction in which one term endlessly undoes the other...'Sustainable development' incorporates the metaphor of 'trace' by making opposite concepts explicit and inseparable. Thus, it becomes impossible to conceptualize either 'development' or

emergence and evolution of postmodern international sustainable development law[12] is likely a key putative cause of the growing restrictions imposed by governments (individually and collectively under the auspices of multilateral and regional intergovernmental organizations) on IP rights, assets and uses around the world.[13]

'sustainability' without considering the other. 'Sustainable development' is already postmodern." *See* Barbara Stark, *Sustainable Development and Postmodern International Law: Greener Globalization?*, 27 Wm. & Mary Envtl. L. & Pol'y Rev. 137, 154 (2002), http://scholarship.law.wm.edu/wmelpr/vol27/iss1/5.

[12] "The] following] three observations correspond to three concepts widely viewed as characteristically postmodern. First, the absence of a big picture corresponds to Jean-Francois Lyotard's definition of postmodernism as 'incredulity toward metanarratives.' Second, the mad proliferation of projects reflects what geographer David Harvey describes as 'the most startling fact about postmodernism…its total acceptance of…emphemerality, fragmentation, discontinuity, and the chaotic.' Third, the contrast between the United States' key role in globalization, and its marginal role in the WSSD [World Summit on Sustainable Development] process, exemplifies critic Frederic Jameson's description of postmodernism as 'the cultural logic of late capitalism.' These three distinct but related concepts provide a working definition of postmodern international law ('PIL') and show how PIL can be used to define, albeit contingently, and to encourage greener globalization." *Id*., at p. 142.

[13] "Empirical evidence on the role of IP protection in promoting innovation and growth in general remains limited and inconclusive. Conflicting views also persist on the impacts of IPRs in the development prospects. Some point out that, in a modern economy, the minimum standards laid down in TRIPS will bring benefits to developing countries by creating the incentive structure necessary for knowledge generation and diffusion, technology transfer and private investment flows. *Others stress that intellectual property, especially some of its elements, such as the patenting regime, will adversely affect the pursuit of sustainable development strategies by raising the prices of essential drugs to levels that are too high for the poor to afford; limiting the availability of educational materials for developing country school and university students; legitimising the piracy of traditional knowledge; and undermining self-reliance of resource-poor farmers*" (emphasis added). *See* Ricardo Melendez-Ortiz and Rubens Ricupero, at *Foreword*, pp. i-ii, in Keith E. Maskus, *Encouraging International Technology Transfer*, UNCTAD-ICTSD Project on IPRs and Sustainable Development (May 2004), available at: http://ictsd.org/downloads/2008/07/b.pdf.

II. OBSERVED INCIDENTS OF CHANGE IN THE WORLD OF INTELLECTUAL PROPERTY

1. **Patents**

a. United States

- Supreme Court
  - Supreme Court Preserving "Tools of Scientific and Technological Work"
    - **Patentable Subject Matter** –
      - In ***Diamond v. Chakrabarty***,[14] the Supreme Court held that microorganisms produced by genetic engineering are not excluded from patent protection by 35 U.S.C. 101. The test it established for patentable subject matter in this area is whether the living matter is the result of human intervention.[15] Indeed, "[s]ince 1984, the U.S. Patent and Trademark Office has granted more than 40,000 patents tied to genetic material." [16]
      - The Supreme Court's interest in patentable subject matter resurfaced during 2004 in the case of ***Laboratory Corp. of America Holdings v. Metabolite Laboratories, Inc.***, to which certiorari was initially granted but later revoked (2006).[17] The Court ultimately concluded that the Federal Circuit had failed to previously address the patentable subject matter issue. According to at least one legal commentator, "[f]or the quarter century preceding *Laboratory Corporation*, the United States Patent and Trademark Office ("PTO"), the courts, and the patent bar, had—for the most part—taken it for granted that new advances in biotechnology were patentable subject matter...The Supreme Court's renewed interest in patentable subject matter threatened to revive…aging precedents [which although never clearly overruled, had seemed destined to be lost in antiquity, as more recent decisions from the Court of Appeals for the Federal Circuit consistently overruled prior judicial exclusions from patentable subject matter, thereby] disturbing the expectations of a patent-sensitive industry."[18]
      - In ***Bilski v. Kappos***,[19] the Supreme Court once again reached the merits of a patentable subject matter dispute in a case involving business method patents.

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[14] 447 U.S. 303 (1980)

[15] *See* United States Patent and Trademark Office, Patent Laws, Regulations, Policies & Procedures Manual of Patent Examining Procedure, Chapter 2100, *2105 Patentable Subject Matter — Living Subject Matter [R-9]*, available at: http://www.uspto.gov/web/offices/pac/mpep/s2105.html.

[16] *See* Richard Wolf, *Supreme Court Skeptical of Patent on Breast Cancer Gene*, USAToday (April 15, 2013), available at: http://www.usatoday.com/story/news/nation/2013/04/15/genes-patents-supreme-court-breast-cancer-ovarian/2084335/.

[17] See *Petition for a Writ of Certiorari, LabCorp*, (No. 04-607), 2004WL 2505526, *cert denied*, 548 U.S. 124; 126 S. Ct. 2921 (2006).

[18] *See* Rebecca Eisenberg, *Wisdom of the Ages or Dead-Hand Control? Patentable Subject Matter for Diagnostic Methods after in Re Bilski*, 3 Case Western Reserve Journal of Law, Technology & the Internet 1 (2012), at pp. 2-3, available at: http://law.case.edu/journals/JOLTI/Documents/Eisenberg%20-%20new.pdf.

[19] 561 U.S. ___, 130 S. Ct. 3218, 177 L. Ed. 2d 792 (2010).

- According to at least one legal commentator, "[**a]lthough the Justices were unanimous in concluding that the claims were <u>not</u> drawn to patentable subject matter, they differed in their reasoning**. Four Justices would have embraced a categorical exclusion for 'business methods' but five Justices rejected such an exclusion as inconsistent with the statutory text. **<u>All the Justices apparently agreed, however, that *Bilski's* claim fell within the Court's traditional exclusion of 'abstract ideas' from patentable subject matter</u>**. **The Justices also agreed that the Federal Circuit had repeatedly erred in its interpretation of the Supreme Court's precedents on patentable subject matter: first, by setting the bar too low under the 'useful, concrete and tangible' test from its 1998 decision in *State Street Bank & Trust Co. v. Signature Financial Group*; and second, by setting too rigid a rule in the 'machine-or-transformation test' as set forth in its 2008 en banc decision in *In re Bilski***. Meanwhile, the Supreme Court left it to the Federal Circuit to figure out the implications of *Bilski v. Kappos* for pending cases involving method claims from the biopharmaceutical industry."[20]
- This same commentator has concluded that **the Court's *Bilski* decision "has created a state of high uncertainty as to the rules of patentable subject matter**. By directing the lower courts to seek guidance from its own prior decisions without actually explaining the policies served by patentable subject matter doctrine, it demands formal adherence to the principle of *stare decisis* without following the discipline of common law reasoning." In particular, the commentator argues that these precedents fail to adequately distinguish between patentable subject matter limitations (e.g., unpatentability of natural phenomena and fundamental principles) and the doctrines of prior art and disclosure.[21]

- In ***Mayo Collaborative Services v. Prometheus Laboratories, Inc.***,[22] the disputed patent "claimed a method of optimizing therapeutic efficacy for treatment of an immune-mediated gastrointestinal disorder such as Crohn's disease and ulcerative colitis,"[23] by comparing a patient's levels of two drug metabolites with reference values specified in the patent. "The patent embod[ied] findings that [metabolite] concentrations in a patient's blood [exceeding certain reference values] indicate[d] that the dosage was likely too high for the patient, [while metabolite] concentrations in a patient's blood lower than [a certain reference value] level indicated that the dosage [wa]s likely too low to be effective."[24]
  - According to at one legal commentator, "The Supreme Court thought that the patent impermissibly claimed laws of nature, 'namely, relationships between concentrations of certain metabolites in the blood and the likelihood that a dosage

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[20] *See* Rebecca Eisenberg, *Wisdom of the Ages or Dead-Hand Control? Patentable Subject Matter for Diagnostic Methods after in Re Bilski*, 3 Case Western Reserve Journal of Law, Technology & the Internet 1 (2012), *supra* at pp. 3-5.
[21] *Id*., at pp. 64-65.
[22] 566 U.S. ___, 132 S. Ct. 1289 (2012).
[23] *See* Slip Op at p. 5.
[24] *Id*.

of a thiopurine drug will prove ineffective or cause harm.' Other steps in the process recited in the claim (such as administering a thiopurine drug to a patient or determining the patient's levels of drug metabolites) consisted of 'well-understood, routine, conventional activity previously engaged in by scientists in the field.' In the Court's view, those process steps did not add enough to the natural laws to classify the claim as a patent-eligible application of the natural laws rather than an impermissible 'patent upon the natural law itself'". Consequently, in her estimation, the decision "raises doubts about the eligibility of these diagnostic tools for patent protection and calls into question the validity of many previously issued patents…[It also casts a shadow over the] promise of personalized medicine [which] cannot be delivered without new precision diagnostic tools for tailoring treatment interventions to the needs of individual patients."[25]

- In ***Association for Molecular Pathology v. Myriad Genetics***,[26] the Supreme Court held as invalid respondent's diagnostic method patents, but upheld the validity of its therapeutic screening method patent.
  - "The "Court struck down patent claims on genomic DNA that ha[d] been merely 'isolated' from the body [i.e., removed and separated from its natural environment in the cell], [holding] that genomic DNA does not meet the threshold test of patentable subject matter under section 101. It upheld the subject matter status of cDNA, which it defined as 'synthetically created DNA…which contains the same protein-coding information found in a segment of natural DNA but omits portions within the DNA segment that do not code for proteins [introns].'"[27]
- ***Alice Corporation Pty. Ltd. v. CLS Bank International*** (Petition for Certiorari filed Sept. 4, 2013; granted Dec. 6, 2013)[28] (a patentable subject matter case involving computer software-implemented method of creating and exchanging financial instruments[29])
  - The Question Presented by the patent owner:
    - "Whether claims to computer-implemented inventions—including claims to systems and machines, processes, and items of manufacture—are directed to

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[25] *See* Rebecca S. Eisenberg, *Prometheus Rebound: Diagnostics, Nature, and Mathematical Algorithms*, 122 YALE L.J. ONLINE 341 (2013), http://yalelawjournal.org/2013/04/01/eisenberg.html.

[26] 569 U. S. ____ (2013).

[27] *See* John Conley, *Myriad, Finally: Supreme Court Surprises by not Surprising*, Genomics Law Report (June 18, 2013), available at: http://www.genomicslawreport.com/index.php/2013/06/18/myriad-finally-supreme-court-surprises-by-not-surprising/.

[28] *See* US Supreme Court, *Alice Corporation Pty. Ltd. v. CLS Bank International*, Docket No. 13-298, available at: http://www.scotusblog.com/case-files/cases/alice-corporation-pty-ltd-v-cls-bank-international/. *See also* Petition for Certiorari, available at: http://sblog.s3.amazonaws.com/wp-content/uploads/2013/11/AliceCorpPet.pdf.

[29] "Alice, which is half-owned by National Australia Bank Limited…applied for and obtained patents, four of which are at issue in this case…covering aspects of…the INVENTCO system. One aspect of the INVENTCO system, which is recited in the asserted claims, relates to a specific computer system and computerized process for the execution of a previously agreed-upon exchange, known as 'settlement.'" *See* Petition at pp. 6-7. "The asserted claims include system, computer-readable media, and method claims." *Id*., at p. 8.

patent-eligible subject matter within the meaning of 35 U.S.C. § 101 as interpreted by this Court?"[30]

- In a rehearing *en banc* "to address two questions relating to the patent eligibility of inventions that involve the use of computers: (1) 'What test should the court adopt to determine whether a computer-implemented invention is a patent ineligible 'abstract idea'; and when, if ever, does the presence of a computer in a claim lend patent eligibility to an otherwise ineligible abstract idea?' and (2) 'In assessing patent eligibility under 35 U.S.C. § 101 of a computer-implemented invention, should it matter whether the invention is claimed as a method, system, or storage medium ...?'…[the Federal Circuit Court of Appeals]…issued six separate opinions spanning more than 125 pages, none of which reflected an approach endorsed by a majority. The court split 5-5 with respect to Alice's claims to computer system inventions, leaving in place the district court's original summary judgment ruling holding them non-patentable. Alice's remaining claims were held non-patentable, although for different, and inconsistent, reasons."[31]

- ***WildTangent, Inc. v. Ultramercial, LLC*** (Petition for Certiorai filed Aug. 23, 2013; Brief of respondents Ultramercial, LLC, et al, filed Jan. 6, 2014)[32] (a patentable subject matter case involving a patent "claiming exclusivity on the basic economic concept of trading advertisement viewing for access to content—over the Internet."[33])
  - The Question Presented by the alleged infringer:
    - "When is a patent's reference to a computer, or computer-implemented service like the Internet, sufficient to make an unpatentable abstract concept patent eligible under 35 U.S.C. § 101?"[34]
  - "After the Federal Circuit initially held that the patent at issue was eligible under § 101, this Court granted WildTangent's petition for certiorari, vacated the judgment, and remanded for reconsideration in light of *Mayo* [*Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289 (2012)]. In *Mayo*, this Court unanimously directed the Federal Circuit to apply the § 101 inquiry with more rigor. On remand in this case, however, the Federal Circuit not only reached the same result as it did before *Mayo*, but did so in a decision that goes even further than its initial decision in dismantling § 101 as a meaningful screening device. Indeed, although he agreed with the bottom-line result, one Judge on the panel below took the unusual step of writing separately to explain his belief that the

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[30] *See* Petition at p. ii.
[31] *See* Petition at p. 2; *CLS Bank International v. Alice Corp. Pty. Ltd*., 717 F.3d 1269 (Fed. Cir. 2013).
[32] *See* US Supreme Court, *WildTangent, Inc. v. Ultramercial, LLC*, Docket No. 13-255, available at: http://www.scotusblog.com/case-files/cases/wildtangent-inc-v-ultramercial-llc/. *See also* Petition for Certiorari, available at: http://sblog.s3.amazonaws.com/wp-content/uploads/2013/11/WildTangent-Petition-for-Cert-and-App.pdf.
[33] *See* Petition at p. 6. "It lists eleven basic steps that relate to receiving the content, selecting an advertisement, and restricting access to the content based on advertisement viewing….Step three states that the content should be offered 'for sale at an Internet website.'…Claim 8, the only other independent claim, similarly requires listing products 'on an Internet website'…It is undisputed that the patent does not specify any computer programming." *Id*.
[34] *See* Petition at p. i.

> Federal Circuit 'should concisely and faithfully follow' *Mayo* rather than 'set[ting] forth [its] own independent views, however valid [it] considers them to be.'"[35]

- USPTO Initiatives

  - USPTO 'Peer-to-Patent' Pilot Program - During 2007, USPTO embraced a two-year pilot "Peer-to-Patent" program initiated by New York Law School. Former Red Hat General Counsel Mark Webbink led this initiative. The initial Peer-to-Patent program came to an end at the USPTO in June 2009, but has since expanded to other countries' patent offices.[36]
    - The program's objective was "to determine the extent to which the organized submission of documents together with comments by the public would be useful to examiners…[in] effective[ly] locat[ing] prior art that might not otherwise be located by the USPTO during the typical patent examination process."[37]
      - During October 2010, the USPTO decided to initiate a second Peer-to-Patent pilot program that was broader in scope, which was scheduled to expire on Sept. 30, 2011. "The USPTO is cooperating with Peer To Patent, organized by the New York Law School's Center for Patent Innovations, which will manage the **public aspects** of the pilot."[38]
  - USPTO 'Prior Art' Crowdsourcing Website - These two pilots have led to USPTO's launch of a third program - **a prior art public crowd-sourcing website**[39] - with the assistance of Google and StackExchange named Ask.com.[40]
    - USPTO represents that **this program implements 35 USC § 122 – Preissuance Submissions - of the America Invents Act, which in turns, "builds on the success of the P2P" programs.**[41] However, patent attorneys have expressed doubts about

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[35] *Id*., at pp. 2-3.

[36] *See* New York Law School, *Peer to Patent – About Peer to Patent*, at: http://peertopatent.org/ ; New York Law School, *USPTO and New York Law School Announce Extension and Expansion of Peer-to-Patent Pilot*, Press Release (July 16, 2008), available at: http://www.nyls.edu/news-and-events/uspto-and-new-york-law-school-announce-extension-and-expansion-of-peer-to-patent-pilot/.

[37] *See* United States Patent and Trademark Office, *Peer Review Pilot FY2011*, available at: http://www.uspto.gov/patents/init_events/peerpriorartpilotindex.jsp.

[38] *Id*; See also *Peer-to-Patent Begins Expanded Pilot*, PatentlyO (Oct. 19, 2010), available at: http://www.patentlyo.com/patent/2010/10/peer-to-patent-begins-expanded-pilot.html.

[39] See *USPTO Encourages Third Parties to Participate in Review of Pending Patent Applications*, USPTO Press Release 12-60 (Sept. 12, 2012), available at: http://www.uspto.gov/news/pr/2012/12-60.jsp.

[40] "AskPatents.com is formatted in a question/answer style in which citizen volunteers and other interested parties ask about patent applications (and patents) they think are suspicious. In turn, the community reviews the questions, proposes prior art solutions and votes up/down posted prior art to rate examples people find. The USPTO provides a system for submission of the prior art, while Google provides an algorithmic search utility to help uncover references. The site has several thousand registered users, with thousands of questions and answer already pending." *See* Jake Koering, *Technology: It Takes a Village*, InsideCounsel (June 7, 2013), available at: http://www.insidecounsel.com/2013/06/07/technology-it-takes-a-village.

[41] "*The Leahy-Smith America Invents Act sought to build on the success of P2P and other crowdsourcing prior art attempts by providing another, improved mechanism for the submission of prior art to the USPTO for pending applications*. The Preissuance Submissions Provision of the American Invents Act allows any third party to "submit for consideration and

"whether the general public has the sophistication to locate much that is relevant", and whether parties other than "people who have an ax to grind"[42] or "smaller companies that don't have the resources to [utilize]…the third-party submission system…[to] monitor[] their competitors' patent applications and search[] for prior art to send the USPTO", will use this website.[43] Yet, there are those who have praised the website for stopping weak patents applied for by large corporations which would have otherwise been vulnerable to challenge if granted.[44]

- USPTO Public Comments Crowdsourcing Website - In addition, the USPTO has also solicited public comments via **a crowdsourcing website** in an effort to revise its

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inclusion in the record of a patent application, any published patent application or other printed publication of potential relevance to the examination of the application" as long as the application has not been allowed and the submission is within six months of publishing or before a first rejection is issued, whichever is later. The provision provides a more robust mechanism for the submission of relevant prior art by the public than the previous third-party submission process. Previously, a public submission was barred from including "any explanation of the patents or publications, or any other information." Under the new procedure, however, a third party may submit with the prior art "a concise description of the asserted relevance of each submitted document." The new procedures went into place on Sept. 16, 2012" (emphasis added). *Id*. *See also* Ryan Davis, *Patent Reform Would Expand Peer-To-Patent: Kappos*, Law360 (March 25, 2011), available at: http://www.law360.com/articles/234696/patent-reform-would-expand-peer-to-patent-kappos ("In a speech at New York Law School in Manhattan, Kappos said he was pleased that the version of patent reform that passed the Senate by a vote of 95-5 on March 8 included language supporting the goals of the peer-to-patent program, which allows members of the public to discuss pending patent applications online and submit prior art. That language explicitly states that members of the public may submit prior art about any published patent application, setting the stage for the program, developed at New York Law School, to grow far beyond its two successful pilot programs, Kappos said. 'I fully plan to implement peer-to-patent into our infrastructure once the legislation gets passed,' he said. 'To me, it's a no-brainer.'" *Id*.

[42] *See, e.g.*, John F. Hornick, *Crowdsourcing Prior Art to Defeat 3D Printing Patent Applications*, Finnegan (May 17, 2013), available at: http://www.finnegan.com/resources/articles/articlesdetail.aspx?news=a9c5090a-630d-48c5-8137-330fb99a966f ("The U.S. Congress intended preissuance submissions to help the USPTO increase the efficiency of examination and the quality of issued patents. Congress did not, however, intend the use of this mechanism to interfere with patent examination. Nor did it intend preissuance submissions to allow for third party protest or preissuance opposition. Yet a segment of the 3D printing (3DP) community, known as Makers, is using preissuance submissions as a sword to oppose 3DP-related patent applications. Perhaps more importantly, they are leveraging the concept of crowdsourcing to do so, potentially creating problems for patent applicants everywhere…The 3DP community consists of essentially four segments: small and large scale, closed and open. Although the lines between them can be fuzzy, the large-scale segment is essentially the industrial segment, which relies on a closed platform, and therefore on intellectual property. Of equal—and some would say more—significance, is the small-scale segment, which consists of entrepreneurs, garage, basement, and school lab innovators, and kids, many of whom are dedicated to open availability of the technology. They are called 'Makers.' Makers are a growing and potentially powerful force, similar in some ways to PDP music file sharers, but more organized. They are a community and decide, collectively, whether and what intellectual property is appropriate in the 3DP world. Makers would keep 3DP open and unhindered by the constraints of intellectual property.") *Id*.

[43] *See* Ryan Davis, *USPTO Prior Art Crowdsourcing Site May Have Limited Reach*, Law360 (Sept. 20, 2012), available at: http://www.law360.com/articles/380106/uspto-prior-art-crowdsourcing-site-may-have-limited-reach.

[44] *See* Bruce S. Itchkawitz, Crowdsourcing: Inciting a Mob to Battle Patent Trolls, Orange County Business Journal, Vol. 36, No. 34 (Aug. 26-Sept. 1, 2013), available at: http://www.knobbe.com/pdf/2013-08-26_OCBJ%20article%20on%20crowdsourcing.pdf; Joel Spolsky, *Victory Lap for Ask Patents*, Joel on Software (July 22, 2013), available at: http://www.joelonsoftware.com/items/2013/07/22.html; Tim Worstall, Crowdsourcing – *The Fight Against Bad Software Patents*, Forbes (July 23, 2013) available at: http://www.forbes.com/sites/timworstall/2013/07/23/crowdsourcing-the-fight-against-bad-software-patents/.

Trademark Manual of Examining Procedure (TMEP)[45] and *Trademark Trial and Appeal Board Manual of Procedure* (TBMP),[46] and also to better understand the motivations for utilizing Requests for Continued Examination" ("RCEs"), which tend to increase the patent application backlog.[47]

- Congressional Initiatives

  - America Invents Act ("AIA")[48] (Substantially Reforms US Patent Law)
    - AIA Objectives - The enactment into law of the **AIA fundamentally reforms US patent law** in a number of ways that **bring it closer to the European ("international") model**. The AIA's objectives are to:
      - Facilitate greater international harmonization of patent law (and reduction of cross-border administrative and transaction costs);
      - Address concerns that inadequate disclosure by patent applicants of prior art prevented USPTO patent examiners from correctly evaluating whether patent eligibility standards (patentability criteria, namely, the existence of prior art) have been satisfied (and consequently resulting in the grant of too many overall weaker patents susceptible to legal challenge);
      - Address concerns that the surrounding legal uncertainties plus the growing backlog of patent applications at the USPTO have triggered increased litigation that has raised the cost of patent ownership for SMEs, and imposed severe administrative burdens on the US judicial system (which litigation is attributed, in many cases, to non-practicing entities ("NPEs").
    - AIA Reforms:
      - Filing Reforms
        - *Inter alia*, a transition from a First-to-Invent patent system to a system where priority is given to the first inventor to file a patent application, and the

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[45] See *Discuss Trademark Policy – Trademark Policy Collaboration*, The United States Patent and Trademark Office, available at: http://uspto-tmep.ideascale.com/; *TMEP IdeaScale Website Available*, The United States Patent and Trademark Office, available at: http://www.uspto.gov/trademarks/notices/Idea_Scale_1100_1700.jsp.

[46] See *Discuss TTAB Policy - TTAB Policy Coordination*, The United States Patent and Trademark Office, available at: http://uspto-tbmp.ideascale.com/.

[47] See *RCE Outreach*, The United States Patent and Trademark Office, available at: http://www.uspto.gov/patents/init_events/rce_outreach.jsp ("The USPTO is looking for feedback from the public to help us reduce our backlog of patent applications associated with a Request for Continued Examination (RCE). An RCE is a request by an applicant to reopen prosecution of the patent application after prosecution of the application is closed. There is currently a backlog of over 90,000 applications related to RCEs, and this backlog diverts our resources from examination of new applications."). *Id*; *See also* "Discuss the Request for Continued Examination Process", The United States Patent and Trademark Office, available at: http://uspto-outreach.ideascale.com/ ("The Office is now soliciting public feedback in an effort to better understand the full spectrum of factors that impact the decision to file an RCE. Responders to Ideascale can choose to address as many of these questions as desired."). *Id*.

[48] *See* Leahy-Smith America Invents Act, P.L. 112-29 (Sept. 16, 2011), available at: http://www.gpo.gov/fdsys/pkg/PLAW-112publ29/pdf/PLAW-112publ29.pdf.

inquiry is "whether a claimed invention in an earlier filed application was derived from the later filed application";[49]

- A prohibition against the patenting of human organisms[50];

- Examination reforms
  - Reforms 35 USC 102(a) so that there are only two forms of 'prior art' :
    - Pursuant to revised Section 102(a)(1), 'prior art' includes a claimed invention that was patented, described in a printed publication, or in public use, on sale, or otherwise available to the public [**anywhere in the world]** dated before the effective filing date of the claim in question.
    - Pursuant to revised Section 102(a)(2), 'prior art' also includes a claimed invention described in a U.S. patent or application that had: (1) been issued, published, or deemed to have been published; (2) at least one inventor different from the inventors of the claim in question; *and* (3) an effective filing date before that of the claim in question.
  - Reforms 35 USC 102(b)(1) to provide **two 'grace period' exceptions** to the 35 USC 102(a)(1) definition of 'prior art' (disclosures with prior public availability date), for disclosures made 1 year or less before the effective filing date of a claimed invention, IF:
    - 35 USC 102(b)(1)(A) - Made by the Inventor or Joint Inventor or obtained from the Inventor or Joint Inventor during such grace period; **or**
    - 35 USC 102(b)(1)(B) – Made by an Intervening Third Party during such grace period.
  - Reforms 35 USC 102(b)(2) to provide **three subject matter 'disclosure' exceptions** to the 35 USC 102(a)(2) definition of 'prior art' (US patent, US patent application, and PCT application with prior filing date), for disclosures, IF:
    - 35 USC 102(b)(2)(A) - Obtained from the Inventor or Joint Inventor;
    - 35 USC 102(b)(2)(B) – Previously publicly disclosed by the Inventor, or a Joint Inventor, or by an Intervening Third Party that obtained the subject matter disclosed from the Inventor or Joint Inventor; OR
    - 35 USC 102(b)(2)(C) – A commonly-owned disclosure (were owned by the same person or subject to an obligation of assignment to the same person).[51]

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[49] This provision will have a genuine impact on the prior art against which an invention is measured. A claimed invention's "effective filing date" (i.e., for the subject matter of a claim) is its earliest priority date, or its actual filing date if there is no priority claim to an earlier application. Pursuant to 35 U.S.C. §§119-121 or 365, a priority date can derive from corresponding applications filed in another country or parent applications filed in the US.

[50] *See* Section 33(a), Leahy-Smith America Invents Act. *See also* United States Patent and Trademark Office, *Claims Directed to or Encompassing a Human Organism*, Memorandum to Patent Examining Corps (Sept. 20, 2011), available at: http://www.uspto.gov/aia_implementation/human-organism-memo.pdf. According to the memo, this provision "codifies existing USPTO policy that human organisms are not patent-eligible subject matter." *Id.*

[51] *See* United States Patent and Trademark Office, *America Invents Act (AIA): First Inventor to File (FITF) – Redefining Prior Art* (March 2013), at p. 6, available at: http://www.uspto.gov/aia_implementation/fitf_introductory_video_2013mar.pdf. *See also* Robert E. Yoches, Esther H. Lim,

- Third Party Reforms
  - Creates new Pre-Grant patent review administrative procedure:
    - 35 USC 311(a)-(b) – Inter Partes Review
      - "Any person other than the patent owner may petition the USPTO for inter partes review of a patent requesting to cancel at least 1 claim as unpatentable **under Section 102 or 103 based on patent(s) or printed publication(s)**."[52]
      - However, pursuant to 35 USC 315(a)(1), an "inter partes review may not be instituted if, before the date on which the petition for such a review is filed, the petitioner or real party in interest filed a civil action challenging the validity of a claim of the patent."
  - **Creates new Post-Grant patent review administrative procedure**:
    - 35 USC 321(a) - Any person other than the patent owner may petition the USPTO for post-grant review of a patent, requesting, pursuant to 35 USC 321(b), "to cancel as unpatentable 1 or more claims of a patent **on any ground that could be raised under paragraph (2) or (3) of section 282(b) (relating to invalidity of the patent or any claim)**."
      - However, pursuant to 35 USC 321(c), a "petition for a post-grant review may only be filed not later than the date that is 9 months after the date of the grant of the patent."
    - 35 USC 324(a)-(b) – USPTO may grant a post-grant review only if:
      - "the Director determines that the information presented in the petition…[if] not rebutted, would demonstrate that it is more likely than not that at least 1 of the claims challenged in the petition is unpatentable"; OR
      - "the petition raises a novel or unsettled legal question that is important to other patents or patent applications."
- New Business Method Patent Opposition Procedure - Creates new transitional mechanism for Business Method Patent Opposition (relating primarily to financial services and products)
  - AIA Section 18(a)(1) – USPTO directed to promulgate regulations "establishing and implementing a transitional post-grant review proceeding [unlike the post-grant review procedure of 35 USC 321 – AIA Sec. 18(a)(1)(A)] for review of the validity of 'covered business method patents'."

Christopher S. Schultz, Linda J. Thayer, and Erika Harmon, *How Will Patent Reform Affect the Software and Internet Industries?*, The Computer & Internet Lawyer (Dec. 2011), available at: http://www.finnegan.com/resources/articles/articlesdetail.aspx?news=345b9502-13f7-4dbe-b40d-dcb671ff3c44; American Intellectual Property Law Association (AIPLA), *America Invents Act - Summary of the America Invents Act*, available at: http://www.aipla.org/advocacy/congress/aia/Pages/summary.aspx.

[52] *See* AIPLA, *America Invents Act - Summary of the America Invents Act*, supra.

- During August 2012, USPTO issued final regulations under 37 CFR Part 42 in implementation of Section 18.[53]

- However, "**a petition** for a transitional proceeding with respect to a covered business method patent [**may not be filed**] **unless** the person or the person's real party in interest or privy has been sued for infringement of the patent or has been charged with infringement under that patent." AIA Sec. 18(a)(1)(B).
- A petition must challenge the validity of 1 or more claims in a covered business method patent on a ground raised under 35 USC 102 or 103, as they existed prior to their AIA reforms, pursuant to the pre-AIA definition of 'prior art'. AIA Sec. 18(a)(1)(C)(i)-(ii).

- Innovation Act of 2013 – H.R. 3309[54] (Proposed/Expired)
  - Intended to Curb Abusive Litigation - Introduced on Oct. 23, 2013, passed House of Representatives on Dec. 5, 2013; forwarded to Senate for consideration.[55] Some commentators advise that the Innovation Act is intended "to curb abusive patent litigation" and, thus, address "[t]he perceived 'patent troll' problem."[56]
    - "The proposed bill includes a number of…disparate provisions that would have a substantial impact on patent enforcement, procurement, and ownership."[57] Some of the changes include:
      - Heightened Pleading Requirements
        - "1. A heightened pleading requirement for filing patent infringement claims…"[58]
      - Attorneys' Fees Awarded to Prevailing Party
        - "2. An assumption that attorney-fees will be awarded to a prevailing party…"[59]
      - Limited Discovery
        - "3. Discovery will be limited until after a ruling on claim construction…
      - Heightened Disclosure of Financial Interests
        - "4. **[T]he patentee in an infringement litigation must disclose anyone with a financial interest in either the patents at issue or the patentee**

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[53] *See* United States Patent and Trademark Office, *Transitional Program for Covered Business Method Patents—Definitions of Covered Business Method Patent and Technological Invention - Final Rule*, 77 FR 48734 (Aug. 14, 2012), available at: http://www.gpo.gov/fdsys/pkg/FR-2012-08-14/pdf/2012-17904.pdf.

[54] *See* United States House of Representatives 113TH CONGRESS 1ST SESSION, *H.R. 3309 - To amend title 35, United States Code, and the Leahy-Smith America Invents Act to make improvements and technical corrections, and for other purposes* (Oct. 23, 2013), available at: http://judiciary.house.gov/news/2013/10232013%20%20Innovation%20Act.pdf.

[55] See *H.R. 3309: Innovation Act*, available at: https://www.govtrack.us/congress/bills/113/hr3309.

[56] *See* Mengyi Wang, *Innovation Act of 2013 – Latest Effort to Disarm Patent Trolls*, Harvard Journal of Law and Technology JOLT Digest (Nov. 3, 2013), available at: http://jolt.law.harvard.edu/digest/patent/innovation-act-of-2013-latest-effort-to-disarm-patent-trolls.

[57] *See* Dennis Crouch, *New Patent Legislation: Innovation Act of 2013*, PatentlyO (Oct. 24, 2013), available at: http://www.patentlyo.com/patent/2013/10/new-patent-legislation-innovation-act-of-2013.html.

[58] *Id*.

[59] *Id*.

and must additionally disclose the 'ultimate parent entity' of the patentee…"[60]

- Direct Appeal to Federal Circuit Only
  - "7. No Civil Action to Challenge PTO…Patent applicants refused by the patentee would rather only have the option of appealing directly to the Federal Circuit…"[61]
- Scope of Covered Business Method Review Restricted
  - "8. [R]estrict[ion of] the scope of…Covered Business Method Patent Review…to only cover first-to-invent patents (rather than pre-AIA patents) as defined in Section 3(n)(1) of the AIA. The new law would also, inter alia, codify the USPTO's somewhat broad definition of 'financial product or service' described in the *Versata*[62] case."[63]

- U.S. Federal Trade Commission and Department of Justice Initiatives Concerning Patent-Essential Standards

  - FTC & DOJ USITC Section 337 Interventions
    - The FTC and DOJ have undertaken to ensure that industry members do not 'abuse' their exclusive patent rights to prevent **interoperability** between and among technologies **by refusing to license on reasonable ("FRAND"/"RAND") terms patents deemed essential to the deployment and use of technical standards incorporating said technologies (i.e., standard-essential patents ("SEPs")**. SMART Energy & Health GRID technologies[64], considering their frequent dependence on software, are among the more critical technologies susceptible to interoperability concerns.
      - During June and December 2012, for example, the FTC filed amicus briefs at the U.S. International Trade Commission expressing its preference concerning how the USITC should address refusal to license issues surrounding patent-essential standards – i.e., that the USITC not issue injunctions in favor of SEPs.[65]

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[60] *Id*.
[61] *Id*.
[62] For a brief discussion of this case, *See* Dennis Crouch, *Working out the Kinks in Post-Issuance Reviews: Versata v. SAP*, PatentlyO (Aug. 9, 2013), available at: http://www.patentlyo.com/patent/2013/08/working-out-the-kinks-in-post-issuance-reviews-versata-v-sap.html.
[63] *See* Dennis Crouch, *New Patent Legislation: Innovation Act of 2013*, PatentlyO, *supra*.
[64] *See* Lawrence A. Kogan, *How SMART are Standards that Sacrifice Intellectual Property Rights?*, Institute for Trade Standards and Sustainable Development, presented at the American National Standards Institute (ANSI) Intellectual Property Rights Policy Committee (IPRPC) (April 15, 2010), available at: http://nebula.wsimg.com/f29b30c2d7c5011d656a927279401de6?AccessKeyId=39A2DC689E4CA87C906D&disposition=0. *See also* Lawrence A. Kogan, *How SMART are Standards that Sacrifice Intellectual Property Rights? – Abstract*, available at: http://nebula.wsimg.com/a64769b56afc41407bbe037beedea102?AccessKeyId=39A2DC689E4CA87C906D&disposition=0.
[65] *See, e.g.*, United States Federal Trade Commission Press Release, *FTC Files Amicus Brief Explaining How Injunctions Related to Standard-Essential Patents Can Harm Competition, Innovation, and Consumers* (Dec. 5, 2012), available at: http://www.ftc.gov/news-events/press-releases/2012/12/ftc-files-amicus-brief-explaining-how-injunctions-related. *See also*

- During January 2013, **the Department of Justice, together with the USPTO, provided to the USITC a joint policy statement expressing a preference for the USITC to seriously consider the "public interest" when deciding cases involving refusals to license, especially in the case of SEPs**. In particular, it declared its general opposition to the issuance of injunctions and exclusion orders in Section 337[66] investigations.[67]

- White House USITC Section 337 Intervention to Ensure Against Issuance of Exclusion Orders That Sanction Refusals to License
  - Even the President has weighed in with the USTIC to express his disapproval, on "public interest" grounds, of its decision to issue an exclusion order in the case of *Certain Electronic Devices, Including Wireless Communication Devices, Portable Music And Data Processing Devices, And Tablet Computers*, Investigation No. 337-TA-794 ("the -794 investigation").[68]
    - "**In particular, the President's decision cited the January 8, 2013 joint Department of Justice/U.S. Patent and Trademark Office Policy Statement**.[69]According to USTR, that policy statement expressed substantial concerns, 'which I

United States Federal Trade Commission Press Release, *FTC Comment Before the United States International Trade Commission, Concerning Certain Gaming and Entertaining Consoles, Related Software, and Components Thereof* (June 2012), available at: http://www.ftc.gov/policy/policy-actions/advocacy-filings/2012/06/ftc-comment-united-states-international-trade; Practical Law, *The Federal Trade Commission Proposes Limiting Standard-Essential Patent Protections*, Thompson Reuter (June 28, 2012), available at: http://us.practicallaw.com/5-520-0992?q=&qp=&qo=&qe=#null (discussing how "[t]he Federal Trade Commission (FTC) recently proposed limiting the ways that holders of standard-essential patents (SEPs) can protect their rights in those patents. In a recent filing made with the International Trade Commission, the FTC advised against granting SEP holders injunctive relief against infringers because of the potential anticompetitve effects that might result, including higher consumer prices and reduced interoperability.") *Id. See also* Ken Yeung, *FTC Orders Google to Stop Excluding Competitors from Licensing Motorola's Standards Essential Patents*, TheNextWebBlog (Jan. 3, 2013), available at: http://thenextweb.com/google/2013/01/03/google-is-ordered-to-stop-excluding-competitors-from-using-motorolas-standards-essential-patents/#!r5ERy.

[66] *See* Section 337 of the Tariff Act of 1930, 19 U.S.C.§ 1337. "Section 337 investigations" are conducted pursuant to 19 U.S.C. § 1337 and the Administrative Procedure Act. They include trial proceedings before administrative law judges and review by the Commission. *See* United States International Trade Commission, *Intellectual Property Infringement and Other Unfair Acts*, available at: http://www.usitc.gov/intellectual_property/.

[67] *See, e.g.*, United States Department of Justice and United States Patent & Trademark Office, *Policy Statement on Remedies for Standards-Essential Patents Subject to Voluntary F/RAND Commitments* (Jan. 8, 2013), available at: http://www.uspto.gov/about/offices/ogc/Final_DOJ-PTO_Policy_Statement_on_FRAND_SEPs_1-8-13.pdf (declaring to the United States International Trade Commission "concern about the potential impact of exclusion orders on 'competitive conditions in the United States' and 'United States consumers' in some cases involving F/RAND-encumbered patents that are essential to a standard, and the conditions under which they may be denied", "recommend[ing] caution in granting injunctions or exclusion orders based on infringement of voluntarily F/RAND-encumbered patents essential to a standard", and expressing its "belie[f] that that, depending on the facts of individual cases, the public interest may preclude the issuance of an exclusion order in cases where the infringer is acting within the scope of the patent holder's F/RAND commitment and is able, and has not refused, to license on F/RAND terms."). *Id*., at pp. 8-9.

[68] *See* King and Spalding Client Alert, *President Disapproves ITC Exclusion Order In -794 Investigation On Public Interest Grounds*, International Trade and Litigation Practice Groups (Aug. 19, 2013), at p. 1, available at: http://www.kslaw.com/imageserver/KSPublic/library/publication/ca081913.pdf. In the estimation of this article's authors, "[t]his is the first such Presidential disapproval of an ITC exclusion order since 1987 and heralds a new era for examining the public interest impact of ITC exclusion orders. It could lead to significant changes in Section 337 practice." *Id*.

[69] *Id*., at p. 2.

strongly share, about the potential harms that can result from owners of standards-essential patents (SEPs)…engaging in 'patent hold-up'…"[70]

- White House Biologics Intervention to Ensure Reduction of Data Exclusivity Period Granted by Congress for Biological Reference Products
  - The President publicly released a line-by-line review of his 2012 budget during mid-February 2011. **The line-by-line budget review contained a proposal to <u>reduce from 12-years to 7-years the exclusivity period</u> granted by Congress to reference biologic products pursuant to the Biologics Price, Competition and Innovation Act ("BPCIA")** which the President ultimately signed into law. The administration's proposal was **<u>based on a 2009 Federal Trade Commission study</u>** which had concluded that a "twelve-year exclusivity [was] unnecessary to promote innovation by brand biologic drug manufacturers and [could] potentially harm consumers…"'[71] In addition, the President's line-by-line review sought to "prohibit…innovator brand biologic manufacturers from receiving additional exclusivity by 'evergreening' their products."[72] "These elements of the President's budget proposal, which were consistent with the White House's earlier position on such issues prior to the BPCIA's enactment,[73] estimated that USD 2.34 billion of national healthcare cost-savings could be achieved during 2012–2021 by '[modify[ing the] length of exclusivity to facilitate faster development of generic biologics.'"[74]

b. <u>European Union</u>

- European Council and European Parliament

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[70] *Id*.

[71] *See* "Fiscal Year 2012, Terminations, Reductions, and Savings, Budget of the U.S. Government", Office of Management and Budget, Executive Office of the President, *Reduction: Health Care (Pharmaceutical Proposals)*, Department of Health and Human Services, 119, http://www.whitehouse.gov/sites/default/files/omb/budget/fy2012/assets/trs.pdf. "According to the Federal Trade Commission, 12-year exclusivity is unnecessary to promote innovation by brand biologic drug manufacturers and can potentially harm consumers by directing scarce research and development funding toward developing low-risk clinical data for drug products with proven mechanisms of action rather than toward new products to address unmet medical needs." *See* Federal Trade Commission, *Emerging Health Care Issues: Follow-on Biologic Drug Competition*, p.27 (June 2009), available at: http://www.ftc.gov/reports/emerging-health-care-issues-follow-biologic-drug-competition-federal-trade-commission-report.

[72] *See* "Fiscal Year 2012, Terminations, Reductions, and Savings, Budget of the U.S. Government", Office of Management and Budget, Executive Office of the President, *Reduction: Health Care (Pharmaceutical Proposals)*, supra, at p. 119.

[73] ''White House officials, in a letter [dated Jun. 25, 2009] to Representative Henry Waxman, said seven years strikes the appropriate balance between innovation and competition by providing for seven years of exclusivity.'' *See* Lisa Richwine, *White House: 7 Years Enough to Shield Biotech Drugs*, Reuters (Jun. 25, 2009), www.reuters.com/article/2009/06/25/us-obama-generics-idUSTRE55O6ZZ20090625.

[74] *See* "Fiscal Year 2012, Terminations, Reductions, and Savings, Budget of the U.S. Government", *supra*, 119, cited in Lawrence A. Kogan, *The U.S. Biologics Price Competition and Innovation Act of 2009 Triggers Public Debates, Regulatory/Policy Risks, and International Trade Concerns*, Global Trade & Customs Journal (Vol. 6, Nos. 11-12) (2011), at p. 528, available at: http://nebula.wsimg.com/505e73c2112fb8efe82e7a0b5da41a1f?AccessKeyId=39A2DC689E4CA87C906D&disposition=0&alloworigin=1.

- On May 17, 2006, the European Council adopted a regulation[75] "allowing compulsory licensing of patented medicines for export to 'countries in need' without sufficient capacity to produce them. **Compulsory licensing means that a government allows companies to produce copies of the patented product or process without the consent of the patent owner**."[76]

- On November 29, 2007, the European Parliament adopted a resolution relating to trade and climate change[77] that *inter alia*:

  - "9. **Stresse[d] the need for strong cooperation between the UN Environment Programme, the UN Framework Convention on Climate Change and the WTO**, and ask[ed] the [EU] Commission to develop an initiative to support this aim;
  - [A]sk[ed] for swift progress to be made in updating the WTO's definition of environmental goods and services, particularly in the current Doha Round negotiations, but **recommend[ed]**, as a starting point, a specific link to climate change, in order to reach agreement on **the removal of tariff and non-tariff barriers to 'green' goods and services that prevent or slow the dissemination of low carbon technologies**;
  - …[**R]ecommend[ed] launching a study on possible amendments to the WTO Agreement on Trade Related Aspects of Intellectual Property Rights [TRIPS] in order to allow for the compulsory licensing of environmentally necessary technologies**, within the framework of clear and stringent rules for the protection of intellectual property, and the strict monitoring of their implementation worldwide;…"[78]

- On 11 December 2012, the European Parliament voted in favor of "the EU Council's compromise proposals for two **draft EU regulations on a unitary patent for Europe**. The first draft regulation concerns unitary patent protection,[79] and the second sets out the translation arrangements for such protection[80]…The regulations…apply from 1 January 2014

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[75] *See* REGULATION (EC) No 816/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 17 May 2006 on compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems, O.J. L 157/1 (6/9/06), available at: http://eur-lex.europa.eu/LexUriServ/site/en/oj/2006/l_157/l_15720060609en00010007.pdf.

[76] *See* Euractiv.com, *EU accepts compulsory licensing of pharma patents for 'countries in need'* (May 28, 2012), available at: http://www.euractiv.com/health/eu-accepts-compulsory-licensing-news-216538; *See also* European Commission Press Release, *Commission welcomes changes to EU law to allow export of patented medicine to countries in need*, IP/06/550 (4/28/06), available at: http://europa.eu/rapid/press-release_IP-06-550_en.htm?locale=en.

[77] *See* European Parliament resolution of 29 November 2007 on trade and climate change (2007/2003(INI)), available at: http://www.europarl.europa.eu/sides/getDoc.do?Type=TA&Reference=P6-TA-2007-0576&language=EN.

[78] *Id.*, at par. 9.

[79] *See* REGULATION (EU) No 1257/2012 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 17 December 2012 implementing enhanced cooperation in the area of the creation of unitary patent protection, O.J. L 361/1 (12/31/12), available at: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2012:361:0001:0008:EN:PDF.

[80] *See* COUNCIL REGULATION (EU) No 1260/2012 of 17 December 2012 implementing enhanced cooperation in the area of the creation of unitary patent protection with regard to the applicable translation arrangements, O.J. L 361/89 (12/31/12), available at: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2012:361:0089:0092:EN:PDF.

or the date of entry into force of the Agreement on a Unified Patent Court, whichever is the later."[81]

- 25 EU Member states agreed to cooperate under the auspices of the EPO which will "deliver and administer unitary patents."[82] Croatia, Italy, Poland and Spain will not be participating.
- The UPC Agreement will enter into force on the latter of:
  - "the first day of the 4th month after the deposit of the 13th instrument of ratification or accession (whereby France, Germany and the United Kingdom must be included among these 13 states)";[83] or
  - "the first day of the 4th month after the date of entry into force of the amendments to Regulation (EC) 1215/2012 (*Regulation (EU) No 1215/2012 of the European Parliament and of the Council of 20.12.2012 on jurisdiction and the recognition and enforcement of judgments in civil and commercial matters* (OJEU L351/1 of 20.12.2010[84]), including any subsequent amendments) concerning its relationship with this Agreement."[85]
    - As of August 7, 2013, only Austria had both signed and ratified the UPC Agreement.[86]

- European Commission

  - Proposed Rules to Protect Against Trade Secret Theft
    - On November 28, 2013, the European Commission announced that it had "proposed new rules on the protection of undisclosed know-how and business information (trade secrets) against their unlawful acquisition, use and disclosure. The draft directive introduces a common definition of trade secrets, as well as means through which victims of trade secret misappropriation can obtain redress."[87]

  - Speech Affirming Anti-competition (Interoperability) Policy Towards Refusals to License Standard-Essential Patents, Patent Pools and Non-assertion Entities

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[81] *See* European Patent Office, *Unitary Patent* (Dec. 11, 2012), available at: http://www.epo.org/law-practice/unitary/unitary-patent.html. "The two regulations entered into force on 20 January 2013. They will apply from 1 January 2014 or from the entry into force of the Agreement on a Unified Patent Court, whichever is the later date." See European Patent Office, *Unitary Patent - Frequently Asked Questions*, available at: http://www.epo.org/law-practice/unitary/faq.html.

[82] *See* European Patent Office, *European Patent Office Welcomes Historic Agreement on Unitary Patent* (Dec. 11, 2012), available at: http://www.epo.org/news-issues/press/releases/archive/2012/20121211.html. "The unitary patent will provide legal protection for inventors in 25 EU member states through one single administrative step." *Id*.

[83] *See* European Patent Office, *Unitary Patent - Frequently Asked Questions*, supra.

[84] *See* REGULATION (EU) No 1215/2012 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 12 December 2012 on jurisdiction and the recognition and enforcement of judgments in civil and commercial matters, O.J. L 351/1 (12/20/12), available at: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2012:351:0001:0032:en:PDF.

[85] *Id*.

[86] *See* European Commission, The Single EU Market, *Unitary patent – ratification progress*, available at: http://ec.europa.eu/internal_market/indprop/patent/ratification/index_en.htm. See also

[87] *See* European Commission Press Release, *Commission proposes rules to help protect against the theft of confidential business information*, IP/13/1176 (11/28/13), available at: http://europa.eu/rapid/press-release_IP-13-1176_en.htm.

- In a December 2013 speech delivered at an IP Summit in Paris, Joaquín Almunia, the EU Commission Vice President responsible for EU competition policy, made several statements that could be considered as potentially threatening to the exercise of patent rights and the private right to contract, the right to association, and the right to choose one's own business model, all within the context of patents and standards. For example, he stated that IP "abuse…sometimes…takes the form of a refusal to license…**Refusing to licence a patent or other IP rights can lead to such negative impacts on competition that it is justified to oblige the holders to license out their IPs.**"[88]
- He also stated that "[i]n addition to our decisions, we have also given guidance on standardisation processes in our 2010 antitrust guidelines on co-operation agreements, which devote a whole section to them. These **Horizontal Guidelines set out the criteria under which the Commission will not take issue with standard-setting agreements**. These criteria include clear rules on disclosure and FRAND commitments…To the extent possible, industries should avoid creating opportunities for abuse by individual companies. And the best way to do it is building good safeguards when establishing standard-setting organisations and deciding on their procedures."[89]
- In addition, he stated the Commission's preference regarding technology transfer agreement terms, as reflected in forthcoming guidance documents. "More guidance is given in the antitrust rules on licensing agreements for the transfer of technology –which will be renewed next year. These rules are designed to give incentives to innovation but also to prevent that these agreements are misused to partition markets or foreclose new technologies. For example, **while the rules give a safe harbour to exclusive licensing, they do not allow restrictions on the use of the licensee's own competing technology or research**."[90]
- Furthermore, he stated the Commission's preference for patent pools as reflected in forthcoming guidance documents. "Patent pools can give companies easier access to necessary inputs, such as standard essential patents, and ideally provide them with a one-stop-shop at a cheaper price. However, there are still too few of them out there. To encourage their creation, we are planning to introduce more guidance on our future assessment of **patent pools. In short, the new rules will set out the 'safe harbour' principles under which such pools will raise no competition concerns**. This will give a push to pro-competitive pools and help companies navigate through 'patent thickets' which – as you know – can grow very dense in some sectors these days."[91]

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[88] *See* European Commission Press Release, *Intellectual Property and Competition Policy*, SPEECH/13/1042 (12/9/13), available at: http://europa.eu/rapid/press-release_SPEECH-13-1042_en.htm. "I will recall here the landmark cases involving Magill in the 1990's on TV listings, IMS Health in the pharmaceutical sector, and subsequently Microsoft. In all these cases, the European Courts have upheld our decisions establishing that refusing to license an IPR by a dominant company may constitute an abuse of dominant position. But the Courts have also made it clear that refusing to licence can be an infringement of competition law only in 'exceptional circumstances'; that is, when a company needs access to the IPR to enter the market and effective competition would be eliminated if the license were not granted. And this jurisprudence draws a clear boundary for our enforcement work." *Id*.

[89] *Id*.

[90] *Id*.

[91] *Id*.

- Moreover, he stated that, **with respect "to the strategic use of standard-essential patents i[n] the standard-setting context...I believe that injunctions should not be available when there is a willing licensee**. Ideally, this principle should be implemented by the standard-setting organisations themselves. But since that is not happening, I am willing to provide clarity to the market through competition enforcement."[92]
- Finally, he stated that he understands that patent assertion entities (patent trolls) "whose only commercial activity consists in licensing and enforcing patents…are a growing concern… **According to some studies, 40% to 60% of all patent lawsuits in the US are initiated by patent trolls** – including prominent ones targeting retailers and small businesses. This has prompted our colleagues at the Federal Trade Commission to look more closely into the issue and better understand the impact of these organisations on innovation and competition. For a variety of reasons, patent trolls have been less active in Europe than in the US. However, this could change in the future. You can [be] rest assured that we are watching this space very carefully. **DG competition will hold patent trolls to the same standards as any other patent holder.**" [93]
- EU Commissioner Almunia's comments did not arise in a vacuum. There had been significant debate within the EU, and particularly, the UK, during the past decade regarding the patents and standards issues discussed above. That debate was inspired by a significant lobbying effort undertaken by nongovernmental entities operating in the Free and Open Source Software ("FOSS") community and certain members of industry seeking to develop a software-as-a-service ("SaaS", and ultimately, a 'cloud')-based business model in order to counter the patent royalty-based business model of large U.S. software developers. Said effort helped to ensure that **"interoperability" is viewed as an important "public interest"** in the context of patents (as well as copyrights) which cannot be compromised by the 'abusive' exercise of patent rights, especially in the case of "patent essential standards" relating to environmentally-sensitive and medical device technologies.[94]

c. <u>BRICS and Developing Countries</u>

- BRICS and Developing Countries Grant Compulsory Licenses
  - Between 2003 and 2012, various developing and emerging economies issued compulsory licenses on "public interest" grounds to secure transfer of developed country high technologies at concession-rate prices, and for the purpose of participating in the burgeoning 21st century knowledge economy.[95] Compulsory licenses were issued by the following countries:

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[92] *Id*.
[93] *Id*.
[94] *See* Lawrence A. Kogan, *Commercial High Technology Innovations Face Uncertain Future Amid Emerging 'BRICs' Compulsory Licensing and IT Interoperability Frameworks*, 13 San Diego Intl. L.J. 201, 249-275 (2012), available at: http://nebula.wsimg.com/86aca0fc652b3b02522fc133f00a7fda?AccessKeyId=39A2DC689E4CA87C906D&disposition=0&alloworigin=1.
[95] *See* Lawrence A. Kogan, *Rediscovering the Value of Intellectual Property Rights: How Brazil's Recognition and Protection of Foreign IPRs Can Stimulate Domestic Innovation and Generate Economic Growth*, 8 INT'L J. ECON.

- Brazil (2007)[96]; Ecuador (2010, 2012); India (2012); Indonesia (2004, 2012); Malaysia (2003); Thailand (2007, 2008);[97] Eritrea (2005); Ghana (2005); Mozambique (2004); Zambia (2004); Zimbabwe (2002).[98]

- In March 2012, India granted its first compulsory license for Bayer Corporation's anti-cancer drug Sorafenib marketed under the brand name Nexavar. The compulsory license "permit[ed] Natco [Pharma Ltd.] to produce and sell a generic version of Nexavar. Bayer appealed against the Controller [of Patent]'s decision to the Intellectual Property Appellate Board (IPAB). The Controller's decision was upheld by IPAB and an order was passed to that effect on 4 March, 2013. The compulsory license had been granted on the following grounds: (a) Bayer had failed to fulfill 'reasonable requirements' of the public with regard to the patented invention; (b) Nexavar was not available to the general public at a 'reasonably affordable' price; and (c) Bayer had 'not worked' the patented invention in the territory of India"[99] (and instead had only imported it).[100]
  - "…The Controller's ruling set an important precedent in India, which is bound to have far-reaching consequences for the Indian pharmaceutical industry…The method of analysis [employed to assess]…the costs and benefits to the different stakeholders associated with the decision…borrowed elements from the methodology employed by the Organization for Economic Co-operation and Development (OECD) Regulatory Impact Analysis (RIA) to assess the impact of a policy. According to OECD (2008), "RIA is a process of systematically identifying and assessing the expected effects of regulatory policies, using a consistent analytical method, such as benefit/cost analysis".[101] Indeed, it has since been "reported that additional drugs may be subject to CLs imminently and that the decisions related to these CLs are being improperly driven by an interest in growing the pharmaceutical market in India."[102]

DEVELOPMENT, no. 1–2 (Southern Public Administration Education Foundation (2006), available at: http://www.spaef.com/article/970/Rediscovering-the-Value-of-Intellectual-Property-Rights:-How-Brazil's-Recognition-and-Protection-of-Foreign-IPRs-Can-Stimulate-Domestic-Innovation-and-Generate-Economic-Growth.

[96] *See* Lawrence A. Kogan, *Brazil's IP Opportunism Threatens U.S. Private Property Rights*, 38 U. MIAMI INTER-AM. L. REV. 1, 1–139 (2006), available at: http://nebula.wsimg.com/3c989656884f47ca704003be9a8a95ae?AccessKeyId=39A2DC689E4CA87C906D&disposition=0&alloworigin=1.

[97] *See* United Nations Department of Economic and Social Affairs, *MDG Gap Task Force Report 2013: The Global Partnership for Development: The Challenge We Face* (2013), at Table 1, p. 67, available at: http://www.un.org/en/development/desa/publications/mdg-gap-task-force-report-2013.html.

[98] *See* Savita Gautam and Meghna Dasgupta, *Compulsory Licensing: India's Maiden Experience*, ARTNeT Working Paper Series, No. 137 (Bangkok, Nov. 2013), United Nations Economic and Social Commission for Asia and the Pacific (ESCAP) at Table 1, available at: http://www.unescap.org/tid/artnet/pub/wp13713.pdf.

[99] *Id*., at p. 9.

[100] "The argument that Bayer had not made adequate efforts to exploit its patent in the three-year period was also backed by the fact that Bayer had not begun importing the drug until 2008 and had continued to do so only in small quantities in 2009 and 2010." *Id*., at p. 10.

[101] *Id*., at p. 12.

[102] *See* Congressman Erik Paulsen, *Paulsen Leads Bipartisan Letter Pressing for Action on India's Intellectual Property Violations*, Congress of the United States, press release (June 18, 2013), available at: http://paulsen.house.gov/press-releases/paulsen-leads-bipartisan-letter-pressing-for-action-on-indias-intellectual-property-violations/

- India Revokes Granted Pharmaceutical Patents

  - In 2012, "India revoked patents granted to Pfizer Inc's cancer drug Sutent, Roche Holding AG's **hepatitis C drug** Pegasys, and Merck & Co's **asthma treatment aerosol suspension formulation**. All were revoked on grounds that included lack of innovation."[103]

  - In August 2013, India "revoked a patent granted to GlaxoSmithKline Plc for **breast cancer drug** Tykerb, a decision that follow[ed] a landmark India court ruling **disallowing patents for incremental innovations** that was a blow to global pharmaceutical firms. However, the Intellectual Property Appellate Board (IPAB) upheld a patent granted on the original compound, or active pharmaceutical ingredient, lapatinib, citing innovative merit."[104] The landmark case referred to above involved the April 2013 rejection by "India's Supreme Court…[of] a patent for Novartis AG's **cancer drug** Glivec, [on the grounds that] it was an amended version of a known molecule called imatinib, setting the precedent for more such cases in the country."[105]

  - In December 2013, it was reported that, "[t]he turf war between Big Pharma and generic companies, which was largely restricted to exorbitantly priced drugs for cancer and HIV, is now spilling over to **chronic and lifestyle problems**. In yet another instance of a drug MNC losing monopoly, the Chennai Patent Office, [in response to] an opposition filed by Ranbaxy, has revoked Pfizer's patent on a **drug used in urinary incontinence**, which is expected to bring down its price substantially." [106]
    - The Patent Office reasoned that "the invention claimed in the revoked patent was found to be 'prior claimed' by another patent of Pfizer on the same drug. The invention claimed in the revoked patent was also found to be obvious, and not involving any technical advancement compared to existing knowledge, legal sources say. Simply put, the invention claimed in the patent is same to the formulation on which Pfizer has monopoly rights, weakening the basic premise of the first patent."[107]

- South Africa Replicates India's 'Denial of Easy Drug Patents' Strategy

  - During April 2013, it was reported that, "South Africa plans to revamp its intellectual property laws to make it **more difficult for pharma companies to win protection for new versions of older drugs**. The move comes soon after India's top court…denied Novartis…a

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[103] *See* Kaustubh Kulkarni, *India Revokes GSK Cancer Drug Patent in Latest Big Pharma Blow*, Reuters (Aug. 2, 2013), available at: http://in.reuters.com/article/2013/08/02/india-gsk-idINDEE97103720130802.
[104] *Id*.
[105] *Id*. *See also* Tracy Staton, *As Novartis Loses Glivec Bid, India's War on Pharma Patents Threatens to Spread*, FiercePharma (April 1, 2013), available at: http://www.fiercepharma.com/story/novartis-loses-glivec-bid-indias-war-pharma-patents-threatens-spread/2013-04-01?utm_medium=nl&utm_source=internal.
[106] *See* Rupali Mukherjee, *Patent War Spills Over to Non-cancer Drugs*, The Times of India (Dec. 19, 2013), available at: http://timesofindia.indiatimes.com/business/india-business/Patent-war-spills-over-to-non-cancer-drugs/articleshow/27610813.cms.
[107] *Id*.

patent on Glivec, a leukemia treatment…[and]…backed strict requirements for drug patents."[108] Arguably, such move was precipitated, in part, by NGO public health activist groups, such as "Médecins Sans Frontières (MSF), [which had]…been urging South Africa to follow India's lead in reforming patent laws. The country has a sizable population of HIV-positive patients who would benefit from low-cost treatments. A top government official told Reuters that the changes would speed cheap generics to market and keep drugmakers from milking their older products for profits."[109] According to South Africa "Department of Trade and Industry's MacDonald Netshitenzhe…'We have a policy position that says 'Let us have a strong system that does not grant easy patents'…Because if you grant easy patents, a weak patent, there will be people that take it a little bit forward and claim an extension on the original patent.'"[110] "…**MSF officials suggested that emerging markets such as Brazil and China use compulsory licenses to bypass pharma patents. Public health groups were already urging Greece to do the same**…"[111]

- South Africa's proposal, which "would allow for greater production of low-cost generics",[112] has prompted objections from pharmaceutical industry members, and the development of a now leaked proposal to form a coalition called 'Forward South Africa'. Said coalition "would be directed from Washington and work toward delaying and, ultimately, modifying the draft policy. The coalition would try to emphasize a connection between wealth and health – strong intellectual property rules can bolster the economy. At the same time, the proposal also suggests pushing back against non-governmental organizations by arguing that the central health issue in South Africa is poor infrastructure, and not drug pricing or a subsequent lack of access to medicines."[113] The leaked industry coalition proposal triggered a harsh response from "South African Health Minister Aaron Motsoaledi, who accused multi-national drug makers of conspiring against the country. 'This document can sentence many South Africans to death. That is no exaggeration. This is a plan for genocide…'"[114]

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[108] *See* Tracy Staton, *South Africa Follows India's Lead with Proposed Drug-patent Reforms*, FiercePharma (April 23, 2013), available at: http://www.fiercepharma.com/story/south-africa-follows-indias-lead-proposed-drug-patent-reforms/2013-04-23?utm_medium=nl&utm_source=internal.

[109] *Id*.

[110] *Id*.

[111] *Id*.

[112] *See* Ed Silverman, *As Pharma Eyes Patent Changes In South Africa, A Government Minister Cries 'Genocide'*, Forbes (1/18/14), available at: http://www.forbes.com/sites/edsilverman/2014/01/18/as-pharma-eyes-patent-changes-in-south-africa-a-government-minister-cries-genocide/.

[113] *Id*. *See also* Public Affairs Engagement, *A Proposal Prepared for PhRMA and IPASA: Campaign to Prevent Damage to Innovation from the Proposed Draft National IP Policy in South Africa (Jan.-Feb. 2014)*, available at: http://cdn.mg.co.za/content/documents/2014/01/16/skmbt36314011511040.pdf; Email from Michael Azrak, Merck Managing Director for Southern and East Africa to Multiple Pharmaceutical Industry Recipients (Jan. 10, 2014), available at: http://keionline.org/sites/default/files/merck-email.pdf, *discussed in* James Love, *New Leaked Merck Missive Reveals Deep Drug, Medical Device Company Opposition to South African Patent Reforms*, Knowledge Ecology International (Jan. 20, 2014), available at: http://keionline.org/node/1908.

[114] *See* Ed Silverman, *As Pharma Eyes Patent Changes In South Africa, A Government Minister Cries 'Genocide'*, Forbes *supra*. *See also* Philipp de Wet, *How the Big 'Pharma' Plot Died an Early Death*, Mail & Guardian (1/18/14), available at: http://mg.co.za/article/2014-01-18-how-the-big-pharma-plot-died-an-early-death ("discussing how the Innovative

- China Revises Implementing Protocols for 2003 Compulsory Licensing Law

  - During March 2012, China's State Intellectual Property Office (SIPO) approved revisions of the Measures for Compulsory Licensing of Patent Implementation (2003), which went into full force and effect on May 1, 2012. "The Measures for Compulsory Licensing of Patent Implementation was promulgated in 2003. In the revision this time, the SIPO integrated the version in 2003 and the Measures for Compulsory License on Patent Implementation concerning Public Health Problems promulgated in 2005 and formed a draft for new measures. The SIPO publicized the draft for opinions in October 2011."[115] "…Based on the Measures, **when emergent or unusual situations occur in the country or public interest is considered, competent authorities of the State Council can advise the SIPO to give compulsory licensing to the designated qualified entities** in accordance with the provisions of Article 49 of the Patent Law."[116] "…According to the revised measures, in the fields involving the public interest such as medicine, compulsory licensing may bring more affordable medicine and benefit more people…For the purpose of public health, under Article 50 of the Patent Law, qualified entities can request for compulsory licensing to manufacture patented drugs and export them to the following countries or regions: **the least developed countries or regions, and the developed or developing members that express their expectation to import such medicine through informing World Trade Organization (WTO) in accordance with relevant international treaty**."[117]

- China Declares Pharma Patent Invalid on Novelty Grounds

  - During 2013, following the 2012 revision of its compulsory licensing law, China's State Intellectual Property Office (SIPO) was reported to have "yanked…Gilead Sciences'…patent for Viread, saying it lack[ed] novelty."[118] At least one health expert "sees it as another move by China to gain negotiating power over drug prices in the face of a burgeoning healthcare budget…**The country has a growing HIV/AIDS population**

Pharmaceutical Association South Africa (Ipasa), which represents companies including Merck, Sanofi, Pfizer, Roche and Novartis, had seriously considered the coalition strategy proposal prepared by Public Affairs Engagement on behalf of PhRMA until the South African *Mail & Guardian* published details of the plan on January 17); Linda Daniels, *Concerns Erupt Over Leaked Pharma Lobbying Plan Against IP Policy In South Africa*, Intellectual Property Watch (Jan. 22, 2014), available at: http://www.ip-watch.org/2014/01/22/concerns-erupt-over-leaked-pharma-lobbying-plan-against-ip-policy-in-south-africa/?utm_source=weekly&utm_medium=email&utm_campaign=alerts.

[115] *See* People's Republic of China State Intellectual Property Office, *Newly Revised Measures for Compulsory Licensing of Patent Implementation to Come into Force*, Press Release – Intellectual Property Protection in China (March 21, 2012), available at: http://www.chinaipr.gov.cn/newsarticle/news/government/201203/1285090_1.html.

[116] *Id*.

[117] *Id*. *See also* Tracy Staton, *China Now Carries a Big Compulsory-licensing Stick*, FiercePharma (June 11, 2012), available at: http://www.fiercepharma.com/story/china-now-carries-big-compulsory-licensing-stick/2012-06-11?utm_medium=nl&utm_source=internal.

[118] *See* Eric Palmer, *China Revokes Patent on Gilead's Viread: Move Comes Days After Indian Authorities Yanked Some Patents for Roche's Herceptin*, Fierce Pharma (Aug. 7, 2013), available at: http://www.fiercepharma.com/story/china-revokes-patent-gileads-viread/2013-08-07?utm_medium=nl&utm_source=internal.

> **and as many as 30 million people with chronic hepatitis B**...'The big trend is that they want pharma companies to be more flexible on pricing. **They will likely be able to use this decision to negotiate lower prices on more drugs**.'…The revocation came on a challenge from Chinese API maker Aurisco. **Because China invalidated the patent instead of using its compulsory licensing law, any drugmaker will be able to produce tenofovir**."[119]

- BRICS Nations Adopt ICT Interoperability Frameworks Requiring Nonproprietary or Royalty-Free Patent Licensing Between 2005-2010

  - Between 2005 and 2010, BRICS nations adopted legislative frameworks, at the insistence of Free and Open Source Software ("FOSS") advocates and certain industry members employing a software-as-a-service ("SaaS") business model to regulate private FRAND/RAND licensing of information and communication technologies (ICTs) to preserve systems interoperability in the realm of government procurement for the benefit of the "public interest". These nations include:
    - Brazil (2005); Russia (2010); India (2010); China (2009); South Africa (2007).[120]

  - Apparently, these countries learned a great deal from the EU and UK ICT interoperability debates surrounding patents and standards.[121]

2. **Copyrights**

   a. United States

- US Department of Commerce

  - Internet Policy Task Force Launched

    - During April 2009, the US Department of Commerce launched a department-wide Internet Policy Task Force to identify leading public policy and operational issues impacting the U.S. private sector's ability to realize the potential for economic growth and job creation through the Internet.[122]

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[119] *Id*.

[120] *See* Lawrence A. Kogan, *Commercial High Technology Innovations Face Uncertain Future Amid Emerging 'BRICs' Compulsory Licensing and IT Interoperability Frameworks*, 13 San Diego Intl. L.J. 201, *supra* at pp. 275-290.

[121] *Id.*, at pp. 265-275. *See also* Institute for Trade, Standards and Sustainable Development, *Supplement to ITSSD Comments Concerning the WIPO Report on Standards and Patents (SCP/13/2) Paragraph 44* (March 2009), available at: http://www.wipo.int/export/sites/www/scp/en/meetings/session_14/studies/itssd_supplement.pdf.

[122] *See* United States Department of Commerce, *Commerce Secretary Locke Announces Public Review of Privacy Policy and Innovation in the Internet Economy, Launches Internet Policy Task Force*, Press Release (April 21, 2009), available at: http://www.commerce.gov/print/news/press-releases/2010/04/21/commerce-secretary-locke-announces-public-review-privacy-policy-and-i. "The Task Force is comprised of staff members from the National Telecommunications and Information Administration (NTIA), the International Trade Administration (ITA), the National Institute of Standards and

- Internet Policy Task Force Releases 'Green Paper' on Copyright Reform

  - In July 2013, the DOC Internet Policy Task Force released a "green paper" that examines the relationship between the availability and protection of online copyrighted works and innovation in the Internet economy.[123]
    - The objective of the **green paper** was "to assess whether ***the*** current ***balance of rights, exceptions and responsibilities*** – crafted, for the most part, **before the rapid advances in computing and networking** of the past two decades – is still working for creators, rights holders, service providers, and consumers".[124]
    - "From its inception, copyright law has ***balanced rights and exceptions*** in the service of promoting the creative arts. As the law is updated to accommodate technological change, this relationship requires ongoing adjustment. This does not mean, of course, that every change in rights must give rise to a corresponding change in exceptions, or *vice versa*. It is also important to acknowledge that while ***an appropriate balance*** remains the goal, there can never be such a thing as a perfect equilibrium in a complex, dynamic system, and the process of calibration will never be complete. **Since the mid-1990s, the rights and exceptions in U.S. and international copyright law have been amended several times to respond to digital technologies**".[125]

- DOC Seeks Public Comment on 'Green Paper'

Technology (NIST) and the Patent and Trademark Office (PTO)…In addition to privacy and innovation, the Internet Policy Task Force will examine cyber security, online copyright protection and international barriers to moving data around the globe, and the ability of entrepreneurs, and small- and medium-sized businesses to expand their operations via the Internet." *Id*.

[123] *See* The Department of Commerce Internet Policy Task Force, *Copyright Policy, Creativity, and Innovation in the Digital Economy* (July 2013), available at: http://www.uspto.gov/news/publications/copyrightgreenpaper.pdf.

[124] *Id*., at p. iii. "The government can promote progress as a convener of the many stakeholder groups – including creators, industry, and consumers – that share an interest in maintaining *an appropriate balance* within the copyright system" (emphasis added). *Id*., at pp. iii-iv. "Some would argue that copyright protection and the free flow of information are inextricably at odds—that copyright enforcement will diminish the innovative information-disseminating power of the Internet, or that policies promoting the free flow of information will lead to the downfall of copyright. Such a pessimistic view is unwarranted. The ultimate goal is to find, as then-Secretary of Commerce Gary Locke explained, "the sweet spot on Internet policy – one that ensures the Internet remains an engine of creativity and innovation; and a place where we do a better job protecting against piracy of copyrighted works." *Effective and balanced copyright protection* need not be antithetical to the free flow of information, nor need encouraging the free flow of information undermine copyright" (emphasis added). *Id*., at p.1. "The Task Force's recommendations fall into three broad categories and can be summarized as follows: 1) ***Updating the balance of rights and exceptions***" (emphasis added). *Id*., at p. 3. "Section II outlines efforts *to maintain an appropriate balance in copyright law*, as rights and exceptions continue to be updated in response to technological change" (emphasis added). *Id*., at p. 4. "Copyright law grants exclusive rights to authors in order to encourage the production of creative works, to the benefit of society as a whole. *These exclusive rights are balanced by a range of limitations and exceptions* that permit some uses of copyrighted works without the need for authorization" (emphasis added). *Id*., at p. 5.

[125] *Id*., at pp. 9-10.

- During October-December 2013, DOC continued to seek[126] public comment[127] on this document,[128] particularly, with respect to the application of the 'first-sale- doctrine to digital media and delivery systems.[129]

- US Copyright Office[130]

  - **Copyright Director Speech Outlines Proposed Areas for Copyright Reform** - During March 2013, US Copyright Office Director Maria Pallente publicly revealed in a Columbia University speech her ambition to secure sweeping changes to US copyright law which many tech and entertainment lawyers and executives doubt can be achieved. Arguably, these proposed changes are, in part, responses to public and industry backlash to two controversial Congressional bills - PIPA and SOPA.

    - **Digital Millennium Copyright Act Update Targeted** - "Pallante said the time [was] right for 'Congress to once again think big,' and create 'the next great copyright act.' As she outlined the areas of the law she believes need to be fixed, **she focused on the**

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[126] *See* United States Department of Commerce Patent and Trademark Office and National Telecommunications and Information Administration, *Request for Comments on Department of Commerce Green Paper, Copyright Policy, Creativity, and Innovation in the Digital Economy* (Docket No. 130927852–3852–01), 78 FR 61337 (Oct. 3, 2013), available at: http://www.ntia.doc.gov/files/ntia/publications/ntia_pto_rfc_10032013.pdf; http://www.ntia.doc.gov/federal-register-notice/2013/request-comments-department-commerce-green-paper-copyright-policy-creat. *See also* United States Department of Commerce Patent and Trademark Office and National Telecommunications and Information Administration, *Request for Comments on Department of Commerce Green Paper, Copyright Policy, Creativity, and Innovation in the Digital Economy* (Docket No. 130927852–3852–01), 78 FR 66337 (Nov. 5, 2013), available at: http://www.ntia.doc.gov/files/ntia/publications/copyright_green_paper_public_meeting.pdf.

[127] *See* United States Department of Commerce National Telecommunications and Information Administration, *Comments Received on Department of Commerce Green Paper* (11/13/2013), available at: http://www.ntia.doc.gov/federal-register-notice/2013/comments-received-department-commerce-green-paper-11132013.

[128] *See* United States Department of Commerce Patent and Trademark Office and National Telecommunications and Information Administration, *Extension of Comment Period for Public Comments on Department of Commerce Green Paper, Copyright Policy, Creativity, and Innovation in the Digital Economy* (Docket No. 130927852–3852–01), 78 FR 78341 (Dec. 26, 2013), available at: http://www.ntia.doc.gov/files/ntia/publications/online_copyright_commment_extension_notice.pdf.

[129] *See* The Department of Commerce Internet Policy Task Force, *Copyright Policy, Creativity, and Innovation in the Digital Economy* (July 2013), supra at p. 37 ("The USPTO, in collaboration with the Copyright Office, will solicit public comments and hold a series of roundtables regarding the relevance and scope of the first sale doctrine in the digital age.") *Id*. *Cf*. Corynne McSherry, *2013 in Review: The Next Great Copyright Act?* Electronic Frontier Foundation (Dec. 26, 2013), available at: https://www.eff.org/deeplinks/2013/12/next-great-copyright-act ("It would be great to see Congress restore some sanity to our rules on copyright penalties, so that innovators don't have to risk crushing liability if they guess wrong about whether their new service or technology infringes copyright. We'd also love to Congress clarify that the first sale doctrine applies equally to digital goods – 'you bought it, you own it' should be the rule, not the exception, whether the thing purchased is a CD or an mp3. And while they are at it, our legislators should repeal the anti-circumvention law that has caused no end of collateral damage, with little corresponding benefit.") *Id*.

[130] The Copyright Office is a service unit of the Library of Congress, which is an agency of the legislative branch of the U.S. government. *See* United States Library of Congress, *About the Library*, available at: http://www.loc.gov/about/index.html; *United States Copyright Office: A Brief Introduction and History*, available at: http://www.copyright.gov/circs/circ1a.html.

Digital Millennium Copyright Act.[131] The DMCA,[132] created to deal with copyright issues on the internet, is much maligned in both Silicon Valley and Hollywood. Many in tech and in entertainment believe the law should favor them more and the other less."[133]

- "Pallante…**thinks there should be tougher penalties for illegal streaming**. She said creating and distributing reproductions can be prosecuted as a felony but streaming pirated work is only a misdemeanor.
- Pallante argues that web radio and traditional broadcasters should pay the same royalty rates. **She would encourage volunteer antipiracy efforts by web sites and pointed to Google as a company doing it right** — a strong position when many in the media industry single out the search giant as a prime offender.
- Pallante said **the Copyright Office is studying the possibility of enabling rights owners to take people who infringe their work to a 'small-claims tribunal,' which her office might administer**."[134]

- US Congress

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[131] See *Digital Millennium Copyright Act*, Pub. L. No. 105-304, 112 Stat. 2860 (Oct. 28, 1998), codified at 17 U.S.C. 512, 1201-05, 1301-22; 28 U.S.C. 4001, available at: http://www.gpo.gov/fdsys/pkg/PLAW-105publ304/pdf/PLAW-105publ304.pdf.

[132] The DMCA implements the WIPO Internet Treaties. Although it "did not lead to the introduction of new limitations in the U.S Copyright Act…it did provide Congress with the opportunity to modify the limitations on ephemeral recordings by broadcasting organisations and on public libraries and archives. Apart from these two modifications, no other limitation was considered necessary, because the fair use doctrine was deemed sufficiently flexible to accommodate the needs of users and rights owners as a consequence of any new technological development." *See* Lucie Guibault, *The Nature and Scope of Limitations and Exceptions to Copyright and Neigbouring Rights With Regard to General Interest Missions for the Transmission of Knowledge: Prospects for Their Adaption to the Digital Environment*, prepared for the United Nations Educational, Scientific and Cultural Organization, e-Copyright Bulletin (Oct.-Dec. 2003), at p. 20, available at: http://www.unesco.org/new/fileadmin/MULTIMEDIA/HQ/CLT/CLT/pdf/Copyright-eBulletin-Oct_2003.pdf.

[133] *See* Greg Sandoval, *The Head of the Copyright Office Says the Law is Broken — But Can She Fix It In Time?*, TheVerge.com (March 20, 2013), available at: http://www.theverge.com/2013/3/20/4126936/copyright-register-today-will-embark-on-mission-to-overhaul-us. "One of the biggest hurdles facing any copyright rewrite is that legal scholars say significant changes to copyright rules typically occur during calm periods, when the major stakeholders aren't at odds. At the intersection of copyright and the web, the environment is more akin to a legal cage match, and copyright rules are increasingly affecting the lives of everyday Americans: media conglomerates have filed dozens of lawsuits against internet services for allegedly pirating their materials, sweeping ordinary users into the mix. Some sites have been sued out of existence, like TorrentSpy, Zediva, and Napster. Major record companies filed suit against their customers for illegal file sharing. Piracy has allegedly halved revenue for recorded music — and while critics decry the industry's self-serving "copyright math," those numbers still carry weight with policymakers. But consumers and activists are beginning to push back, as well: last year, thousands took to the streets of New York to protest the anti-piracy legislation Stop Online Piracy Act, better known as SOPA. A controversy erupted last month after the Copyright Office decided unlocking mobile phones was no longer expressly permitted…An overhaul of US copyright law has historically required a Herculean effort: the last sweeping rewrite began in the late 1950s and wasn't passed until 1976. *Most of the tech and entertainment lawyers and executives interviewed by The Verge are skeptical Pallante can bring about any significant change — while many on both sides are clamoring for an update of the DMCA, many of the interested parties fear that they could end up with an even unfriendlier law*. 'Nobody wants to open it up,' said one artist's manager, who asked to remain anonymous. 'They're afraid it's not going to move forward in their favor.' Rick Carnes, president of the Songwriters Guild of America, said the DMCA is undoubtedly broken, but some copyright owners won't want to risk losing what ability they still have to protect their work…(emphasis added)." *Id*

[134] *Id*.

- **Senate and House Judiciary Committees Introduce PIPA and SOPA Copyright Enforcement Bills in 2011 Which Trigger Public and Industry Backlash and Later Die in Committee**
  - In May 2011, the Senate Judiciary Committee introduced the Protect Intellectual Property Act (PIPA) (PIPA-S.968 112th Cong., May 12, 2011)[135] and, in October 2011, the House Judiciary Committee introduced counterpart legislation – the Stop Online Privacy Act (SOPA-H.R. 3261 112th Cong., Oct. 26, 2011). Generally speaking, the objective of these bills was to provide "government and copyright holders [with new criminal enforcement] tools to stop Americans [from] reaching illegal material."[136] These bills triggered public backlash from digital rights groups, such as the Electronic Frontier Foundation and Public Knowledge, and from technology companies offering internet services (internet service providers), such as Wikipedia, Google, Facebook and Twitter.[137] "Companies argue[d] that the bills would impose heavy regulatory costs, harm innovation, and give the government too much power to shut down Web sites accused of copyright violations even if they are later found to be innocent of the charges…The twin bills were drafted to target foreign Web sites that illegally post copyrighted material from the United States. But these Web firms argue that the onus of blocking out pirated material rests on U.S. companies — search engines, aggregators and forums — who worry they'll have to take on the role of policing every link on their Web sites…In the controversy over [SOPA]…a rift ha[d] emerged between two camps of small business owners: Web entrepreneurs whose businesses rely on traffic from links to content they did not create and the independent artists and others who produce the material and want to be paid for it."[138]
    - "These bills have pitted the entertainment industry against the technology industry. 'Hollywood' has a legitimate interest in protecting its intellectual property. Not only are profits at stake but so are jobs. Thousands of Americans make their living by dreaming up content and selling it to the world and piracy does in fact take money out of their pockets. Silicon Valley has invested billions in creating companies that freely distribute information. While Google and every other Silicon Valley company must

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[135] See *S. 968 (112th): Preventing Real Online Threats to Economic Creativity and Theft of Intellectual Property Act of 2011*, Gov.track.us, available at: https://www.govtrack.us/congress/bills/112/s968.

[136] *See* BBC News-Technology, Americans Face Piracy Website Blocking, (May 13, 2011), available at: http://www.bbc.co.uk/news/technology-13387795. "'The Protect IP Act targets the most egregious actors, and is an important first step to putting a stop to online piracy and sale of counterfeit goods,' said Senator Patrick Leahy in a statement released as the bill began its progress through the US legislature. 'Both law enforcement and rights holders are currently limited in the remedies available to combat websites dedicated to offering infringing content and products,' said Senator Leahy, one of 10 politicians backing the proposal…The Protect IP bill gives government and copyright holders tools to stop Americans reaching illegal material. Digital rights groups said they were "dismayed" by the proposals and feared the effect the final law would have on the internet." *Id.*

[137] *Id*; *See also* The Washington Post-Business, *SOPA and PIPA Bills Lose Support on Capitol Hill as Google, Wikipedia and Others Stage Protests*, (Jan. 8, 2012), available at: http://www.washingtonpost.com/business/economy/sopa-and-pipa-bills-lose-support-on-capitol-hill-as-google-wikipedia-and-others-stage-protests/2012/01/18/gIQAwIs38P_story.html.

[138] *See* The Washington Post-Business, *SOPA and PIPA Bills Lose Support on Capitol Hill as Google, Wikipedia and Others Stage Protests*, supra.

respect copyrights, they thrive on helping people find what they want. If, suddenly, every web site that had links to other sites had to worry that they could be in violation of the law by linking to a 'banned' site, it could put undo pressure on these companies. There is also worry that SOPA and PIPA could be abused and lead to censorship for purposes other than intellectual property protection."[139]

- **House Judiciary Committee Hearings to Review Copyright Law Announced** - On April 24, 2013, "House Judiciary Committee Chairman Bob Goodlatte (R-Va.) announced that the Judiciary Committee will conduct a comprehensive review of U.S. copyright law over the coming months" in response to new technologies and business models.[140]
  - **Three Public Hearings Convened** - Thus far, three public hearings, in July,[141] August,[142] and November,[143] have been convened by the House Judiciary Committee's Subcommittee on Courts, Intellectual Property, and the Internet, with several more promised in 2014.

b. <u>European Union</u>

- The European Council and European Parliament

  - **European Council Directive 91/250/EEC of 14 May 1991 on the legal protection of computer programs** extends copyright protection to original intellectual creations of computer software programs as literary works. However, ideas and principles underlying its interfaces are not so protected.[144]

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[139] *See* Larry Magid, *What Are SOPA and PIPA and Why All the Fuss?*, Forbes (1/18/12), available at: http://www.forbes.com/sites/larrymagid/2012/01/18/what-are-sopa-and-pipa-and-why-all-the-fuss/.

[140] See *Chairman Goodlatte Announces Comprehensive Review of Copyright Law*, United States House of Representatives Committee on the Judiciary, Press Release (April 24, 2013), available at: http://judiciary.house.gov/news/2013/04242013_2.html. "I am announcing today that the House Judiciary Committee will hold a comprehensive series of hearings on U.S. copyright law in the months ahead. The goal of these hearings will be to determine whether the laws are still working in the digital age. I welcome all interested parties to submit their views and concerns to the Committee. I also look forward to working with the Register and the Copyright Office that has served Congress well since its creation over 110 years ago. There is much work to be done." *Id*.

[141] *See* House of Representatives Committee on the Judiciary, Subcommittee on Courts, Intellectual Property, and the Internet, *Hearing on Innovation in America: The Role of Copyrights*, 113th Cong. (July 25, 2013), available at: http://judiciary.house.gov/hearings/113th/hear_07252013.html.

[142] *See* House of Representatives Committee on the Judiciary, Subcommittee on Courts, Intellectual Property, and the Internet, *Hearing on Innovation in America: The Role of Technology*, 113th Cong. (Aug. 1, 2013), available at: http://judiciary.house.gov/hearings/113th/hear_08012013.html.

[143] *See* House of Representatives Committee on the Judiciary, Subcommittee on Courts, Intellectual Property, and the Internet, *Hearing on The Rise of Innovative Business Models: Content Delivery Methods in the Digital Age*, 113th Cong. (Nov. 19, 2013), available at: http://judiciary.house.gov/hearings/113th/hear_11192013.html.

[144] See *Council Directive 91/250/EEC of 14 May 1991 on the legal protection of computer programs*, O.J. L 122, 17/05/1991, at Articles 1(1)-1(3), available at: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31991L0250:EN:HTML.

- Legal advocates for 'openness' have concluded that the Directive "was intended to promote reuses of interfaces essential to interoperability".[145] Their interpretation relies on Recitals 10-12 of the Directive.[146] They also conclude that "this policy also underlies a provision of the Software Directive that forbids decompilation of computer program code except insofar as it is 'indispensable to obtain the information necessary to achieve the interoperability of an independently created computer program with other programs".[147]
- In general, **Council Directive 91/250/EEC provides that copyright holders may require authorization of "the permanent or temporary reproduction of a computer program** by any means and in any form, in part or in whole", **and "the translation, adaptation, arrangement and any other alteration of a computer program** and the reproduction of the results thereof".[148]
- **However, the Directive provides for the following exceptions**:
  - No authorization by the rightholder shall be required where temporary reproduction or translation, adaptation, arrangement and any other alteration "are **necessary for the use of the computer program by the lawful acquirer** in accordance with its intended purpose, including for error correction."[149]
    - The rightholder may not prevent a person having a right to use the computer program from making a back-up copy for such use.[150]
  - No authorization by the rightholder shall be required of **a person having a right to use the computer program "to observe, study or test the functioning of the program** in order to determine the ideas and principles which underlie any element

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[145] *See* Pamela Samuelson, *The Past, Present and Future of Software Copyright Interoperability Rules in the European Union and United States*, 34 European Intellectual Property Review 229 (2012) at p. 232, available at: http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2170550&download=yes. See also Pamela Samuelson, Thomas C. Vinje and William R. Cornish, *Does Copyright Protection Under the EU Software Directive Extend to Computer Program Behaviour, Languages and Interfaces?*, 34(1) European Intellectual Property Review 158 (2012), available at: http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1974890&download=yes ("In defining the scope of copyright protection for computer programs for the EU, the drafters of the Directive sought to strike ***a careful balance*** between, on the one hand, providing appropriate copyright protection to computer programs in order to stimulate investments in new software development, and, on the other hand, enabling second comers to engage in independent development of software capable of fully interoperating with other programs. As the recent *Microsoft* antitrust case demonstrated, if competitors cannot produce software that is interoperable with industry-leading computer programs, consumers will be deprived of innovative competing and/or complementary products" (boldfaced emphasis added). *Id*., at pp. 158-159.

[146] Recital 10 provides that "Whereas the function of a computer program is to communicate and work together with other components of a computer system and with users and, for this purpose, a logical and, where appropriate, physical interconnection and interaction is required to permit all elements of software and hardware to work with other software and hardware and with users in all the ways in which they are intended to function". Recital 11 provides that, "Whereas the parts of the program which provide for such interconnection and interaction between elements of software and hardware are generally known as 'interfaces`". Recital 12 provides that, "Whereas this functional interconnection and interaction is generally known as 'interoperability'; whereas such interoperability can be defined as the ability to exchange information and mutually to use the information which has been exchanged". *See* Council Directive 91/250/EEC, *supra* at Recitals 10-12.

[147] *See* Pamela Samuelson, *The Past, Present and Future of Software Copyright Interoperability Rules in the European Union and United States*, 34 European Intellectual Property Review 229 (2012), *supra* at p. 232.

[148] Id., at Articles 4(a)-(b).

[149] *Id*., at Article 5(1).

[150] *Id*., at Article 5(2).

of the program if he does so while performing any of the acts of loading, displaying, running, transmitting or storing the program."[151]

- No authorization by the rightholder shall be required "where reproduction of the code and translation of its form…**are indispensable to obtain the information necessary to achieve the interoperability of an independently created computer program with other programs**".[152] **However**:
  - Such acts of reproduction and translation must be "performed by the licensee or by another person having a right to use a copy of a program, or on their behalf by a person authorized to do so";[153]
  - "[T]he information necessary to achieve interoperability has not previously been readily available to [such] persons";[154] AND
  - Such acts of reproduction and translation "are confined to the parts of the original program which are necessary to achieve interoperability."[155]

- On February 16, 2012, the EU Parliament unanimously approved a Resolution expressing a European mandate to negotiate a binding treaty at the World Intellectual Property Organisation (WIPO) to improve access to books for blind people.[156]

- European Commission

  - "In 2010, in its **Digital Agenda for Europe**,[157] the Commission endeavoured to **open up access to content** as part of its strategy to achieve a vibrant Digital Single Market and identified a number of actions in the field of copyright."[158] It concluded that, in order maintain the trust of right-holders and users and facilitate cross-border licensing, the governance and transparency of collective rights management needs to improve and adapt to technological progress…[there was a need for "innovative business models, through which

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[151] *Id*., at Article 5(3).
[152] *Id*., at Article 6(1).
[153] *Id*., at Article 6(1)(a).
[154] *Id*., at Article 6(1)(b).
[155] *Id*., at Article 6(1)(c).
[156] See *European Parliament resolution of 16 February 2012 on Petition 0924/2011 by Dan Pescod (British), on behalf of the European Blind Union (EBU)/Royal National Institute of Blind People (RNIB), on access by blind people to books and other printed products*, (P7_TA(2012)0059) - Blind persons' access to books, available at: http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//NONSGML+TA+P7-TA-2012-0059+0+DOC+PDF+V0//EN; http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//TEXT+TA+P7-TA-2012-0059+0+DOC+XML+V0//EN.
[157] "The objective of this Agenda is to chart a course to maximise the social and economic potential of ICT, most notably the internet, a vital medium of economic and societal activity: for doing business, working, playing, communicating and expressing ourselves freely." *See* COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE COUNCIL, THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE AND THE COMMITTEE OF THE REGIONS, A Digital Agenda for Europe, COM(2010) 245 final/2 (8/26/10), at p. 3, available at: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=com:2010:0245:fin:en:pdf.
[158] *See* European Commission, COMMUNICATION FROM THE COMMISSION *On content in the Digital Single Market*, COM(2012) 789 final (12/18/12), at p. 2, available at: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2012:0789:FIN:EN:PDF.

content would be accessed and paid for in many different ways that **achieve *a fair balance* between right-holders' revenues and the general public's access to content and knowledge**."[159]

- In 2011, the EU Commission released its **Intellectual Property Strategy, *A Single Market for Intellectual Property Rights***.[160] The strategy proposed, among other approaches for establishing a legal framework for the collective management of copyright, the creation of a European Copyright Code that would facilitate a far-reaching overhaul of copyright at European level. Such a Code "could encompass a comprehensive codification of the present body of EU copyright directives in order to harmonise and consolidate the entitlements provided by copyright and related rights at EU level...[and]…**examine whether the current exceptions and limitations to copyright granted under the 2001/29/EC Directive**[161] **need to be updated or harmonised at the EU level**. A Code could therefore help to clarify the relationship between the various exclusive rights enjoyed by rights holders and the scope of the exceptions and limitations to those rights."[162]

- **Orphan Works Directive Adopted** - On October 4, 2012, the EU Commission announced that the EU Council had adopted a Directive on orphan works,[163] which was subsequently enacted into law on October 25, 2012.[164] The directive enables cultural institutions ["publicly accessible libraries, educational establishments and museums, as well as by archives, film or audio heritage institutions and public-service broadcasting organisations, established in the Member States"] to digitize works or phonographs[165] without the required authorisation of the rightholder(s), if "none of the rightholders in that work or phonogram is identified or,

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[159] See *A Digital Agenda for Europe*, COM(2010) 245 final/2, supra at p. 8.

[160] *See* COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE COUNCIL, THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE AND THE COMMITTEE OF THE REGIONS, *A Single Market for Intellectual Property Rights Boosting creativity and innovation to provide economic growth, high quality jobs and first class products and services in Europe*, COM(2011) 287 final (5/24/11), available at: http://ec.europa.eu/internal_market/copyright/docs/ipr_strategy/COM_2011_287_en.pdf.

[161] *See* DIRECTIVE 2001/29/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 22 May 2001 on the harmonisation of certain aspects of copyright and related rights in the information society, O.J. L 167/10 (6/22/01), available at: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2001:167:0010:0019:EN:PDF. "The objectives of the Directive on the harmonisation of certain aspects of copyright and related rights in the information society (2001/29/EC) [were] to adapt legislation on copyright and related rights to reflect technological developments and to transpose into Community law the main international obligations arising from the two treaties on copyright and related rights adopted within the framework of the World Intellectual Property Organisation (WIPO) in December 1996." *See* European Commission, *Copyright in the Information Society - Directives and Communications: Directive 2001/29/EC*, available at: http://ec.europa.eu/internal_market/copyright/copyright-infso/index_en.htm.

[162] COM(2011) 287 final, *supra* at Sec. 3.3.1., p. 11.

[163] *See* European Commission, Press Release - *Commissioner Barnier welcomes final adoption of the Orphan Works Directive by the Council*, MEMO/12/744 (10/4/12), available at: http://europa.eu/rapid/press-release_MEMO-12-744_en.htm?locale=en.

[164] See *Directive 2012/28/EU of the European Parliament and of the Council of 25 October 2012 on certain permitted uses of orphan works*, O.J. L 299/5 (Oct. 25, 2012), available at: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2012:299:0005:0012:EN:PDF.

[165] *Id*., at Article 1.

even if one or more of them is identified, none is located despite a diligent search for the rightholders having been carried out and recorded",[166] in accordance with prescribed conditions/procedures.[167]

- On December 5, 2013, the EU Commission launched a **public consultation to review the continued viability of the EU copyright directive**[168] in the current era of digitization,[169] as part of its ongoing efforts to review and modernise EU copyright rules.[170] The consultation seeks stakeholder comments on and will address, among other issues, "limitations and exceptions to copyright in the digital age",[171] and will be undertaken "with a view to a decision in 2014 whether to table the resulting legislative reform proposals."[172] The consultation period is scheduled to close on February 5, 2014.[173]

c. United Kingdom

- UK Public Consultation on Copyright Reform and Policy Response

  - **UK Public Consultation** - From December 2011 to March 2012, the UK conducted a public consultation[174] in review of its national copyright laws with the purpose of "adapt[ing] its

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[166] *Id*., at Article 2.
[167] *See also* European Commission Press Release, *Orphan works – Frequently asked questions*, MEMO/12/743 (10/4/12), available at: http://europa.eu/rapid/press-release_MEMO-12-743_en.htm?locale=en.
[168] *See* Directive 2001/29/EC of the European Parliament and of the Council of 22 May 2001 on the harmonisation of certain aspects of copyright and related rights in the information society, O.J. L 167 (6/22/01), available at: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32001L0029:EN:HTML.
[169] *See* European Commission Press Release, *Copyright –Commission launches public consultation*, IP/13/1213 (12/5/13), available at: http://europa.eu/rapid/press-release_IP-13-1213_en.htm.
[170] *See* European Commission Press Release, *Commission agrees way forward for modernising copyright in the digital economy*, MEMO/12/950 (12/5/12), available at: http://europa.eu/rapid/press-release_MEMO-12-950_en.htm?locale=en. "…[T]he Commission is carrying out in-depth legal and economic analysis as regards the scope and functioning of copyright and related rights associated with internet transmissions in the Single Market, *including whether the current exceptions and limitations to copyright granted under the Directive 2001/29/EC* on the harmonisation of certain aspects of copyright and related rights in the information society need to be updated or further harmonised at EU level" (emphasis added). *See* European Commission, *Proposal for a DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on collective management of copyright and related rights and multi-territorial licensing of rights in musical works for online uses in the internal market*, COM(2012) 372 final (July 11, 2012) at p. 4, available at: http://ec.europa.eu/internal_market/copyright/docs/management/com-2012-3722_en.pdf.
[171] *See* European Commission Press Release, *Copyright –Commission launches public consultation*, IP/13/1213 (12/5/13), available at: http://europa.eu/rapid/press-release_IP-13-1213_en.htm. *See also* European Commission, *Public Consultation on the review of the EU copyright rules*, at Section III – Limitations and Exceptions in the Single Market, pp. 16-30, available at: http://ec.europa.eu/internal_market/consultations/2013/copyright-rules/docs/consultation-document_en.pdf.
[172] *See* European Commission, COMMUNICATION FROM THE COMMISSION *On content in the Digital Single Market*, COM(2012) 789 final (12/18/12), supra at p. 5.
[173] *See* European Commission – the Single EU Market, *Public Consultation on the review of the EU copyright rules* (2013), available at: http://ec.europa.eu/internal_market/consultations/2013/copyright-rules/index_en.htm.
[174] *See* Government of the United Kingdom Intellectual Property Office, *Consultation on proposals to change the UK's copyright system* (Dec. 14, 2011), available at: http://www.ipo.gov.uk/pro-policy/consult/consult-live/consult-2011-copyright.htm.

strong but rigid framework for copyright into one that is modern, robust and flexible."[175] In December 2012, the UK Government issued its final policy response to the many comments it received. In implementation of said response, the UK Intellectual Property Office released, during June-July 2013, a series of **draft reforms (i.e., copyright exceptions) to the Copyright, Designs and Patents Act 1988**.[176]

- **Proposed UK Reforms (Exceptions & Limitations) Following Consultation** - "After considering the responses to the consultation from a wide range of stakeholders and individuals the Government considers that **permitting people to make wider use of copyright works, but with suitable safeguards for rights holders, can make those works more valuable for everyone**. The Government **aims to find a *balance* between the interests of rights holders, creators, consumers and users** by introducing through Parliament a revised framework of boundaries for copyright and related rights **in the digital age**."[177] "**The Government intends [to] amend the number and scope of permitted acts in the following ways**:
  - 1. Private Copying - **People will be permitted to copy content they have bought onto any medium or device that they own, strictly for their own personal use** (such as transferring their music collection from CD to iPod)."[178]
    - *See* Draft Exception, new Section 28B of the Copyright, Designs and Patents Act 1988 (2013).[179]
  - "…2. Education - **Government will provide a fair basis for future licensing by modernising the current educational exceptions**. Changes will make it easier to use interactive whiteboards and similar technology in classrooms, provide access to copyright works over secure networks to support the growing demand for distance learning, and allow use of all media in teaching and education. **Only limited use of works will be allowed without a licence**, so educational institutions will continue to require licences for general reprographic copying."[180]

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[175] *See* Government of the United Kingdom Intellectual Property Office, *Modernising Copyright: A modern, robust and flexible framework Government response to consultation on copyright exceptions and clarifying copyright law*, Intellectual Property Office (Dec. 20, 2012), at p. 2, available at: http://www.ipo.gov.uk/response-2011-copyright-final.pdf.

[176] *See* Government of the United Kingdom Intellectual Property Office, *Technical review of draft legislation on copyright exceptions* (2013), available at: http://www.ipo.gov.uk/types/hargreaves/hargreaves-copyright/hargreaves-copyright-techreview.htm. The UK IPO also initiated other draft reforms of UK copyright legislation with respect to orphan works, collecting societies – digital rights management, and collective licensing schemes. *See* Government of the United Kingdom Intellectual Property Office, *Implementing the Hargreaves review – Progress to date*, available at: http://www.ipo.gov.uk/types/hargreaves.htm.

[177] *See* Government of the United Kingdom Intellectual Property Office, *Modernising Copyright: A modern, robust and flexible framework Government response to consultation on copyright exceptions and clarifying copyright law*, *supra* at pp. 2-3.

[178] *Id.*, p. 4.

[179] *See* Government of the United Kingdom Intellectual Property Office, *Private Copying* (2013), available at: http://www.ipo.gov.uk/techreview-private-copying.pdf.

[180] *See* Government of the United Kingdom Intellectual Property Office, *Modernising Copyright: A modern, robust and flexible framework Government response to consultation on copyright exceptions and clarifying copyright law*, *supra* at p. 4.

- *See* Draft Amendments to Sections 32, 35 and 36 of the Copyright, Designs and Patents Act 1988 (2013)[181]

- "…5. Research and private study - **The Government will allow sound recordings, films and broadcasts to be copied for non-commercial research and private study purposes, without permission from the copyright holder**. **This includes both user copying and library copying**…**Educational institutions, libraries, archives and museums will also be permitted to offer access to the same types of copyright works on their premises** by electronic means at dedicated terminals."[182]
  - *See* Draft Amendments to Section 29 of the Copyright, Designs and Patents Act 1988 ("the Copyright Act") (2013)[183]
- "…6. Data analytics for non-commercial research - **Non-commercial researchers will be allowed to use computers to study published research results and other data without copyright law interfering**. **Where researchers have lawful access to copyright works**, for example through a subscription to a scientific journal or having copies of papers published under a Creative Commons licence, **they will be allowed to make copies of those works to the extent necessary for their computer analysis**."[184]
  - *See* Draft Exception, new Section 29A of the Copyright, Designs and Patents Act 1988 (2013).[185]
- "…7. Access for people with disabilities - **Government will allow people with disabilities the right to obtain copyright works in an accessible form**, if there is not a suitable one on the market already. **This will apply to all types of disability that prevent someone from accessing a copyright work, and to all types of copyright work**."[186]
  - *See* Draft Exceptions, new Sections 31A and 31B of the Copyright, Designs and Patents Act 1988 (2013).[187]
- "8. Archiving and preservation - **Museums, galleries, libraries and archives will be allowed to preserve any type of copyright work that is in their permanent collection and cannot readily be replaced**."[188]

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[181] *See* Government of the United Kingdom Intellectual Property Office, *Education* (2013), available at: http://www.ipo.gov.uk/techreview-education.pdf.

[182] *See* Government of the United Kingdom Intellectual Property Office, *Modernising Copyright: A modern, robust and flexible framework Government response to consultation on copyright exceptions and clarifying copyright law*, *supra* at p. 5.

[183] *See* Government of the United Kingdom Intellectual Property Office, *Research, Libraries and Archives* (2013), available at: http://www.ipo.gov.uk/techreview-research-library.pdf.

[184] *See* Government of the United Kingdom Intellectual Property Office, *Modernising Copyright: A modern, robust and flexible framework Government response to consultation on copyright exceptions and clarifying copyright law*, *supra* at p. 5.

[185] *See* Government of the United Kingdom Intellectual Property Office, *Data analysis for non-commercial research* (2013), available at: http://www.ipo.gov.uk/techreview-data-analysis.pdf.

[186] *See* Government of the United Kingdom Intellectual Property Office, *Modernising Copyright: A modern, robust and flexible framework Government response to consultation on copyright exceptions and clarifying copyright law*, *supra* at p. 5.

[187] *See* Government of the United Kingdom Intellectual Property Office, *Disability exceptions* (2013), available at: http://www.ipo.gov.uk/techreview-disability-exceptions.pdf.

[188] *See* Government of the United Kingdom Intellectual Property Office, *Modernising Copyright: A modern, robust and flexible framework Government response to consultation on copyright exceptions and clarifying copyright law*, *supra* at p. 5.

- *See* Draft Amendments to Sections 37 to 40 and 43, and Draft Exceptions new Sections 43A and 43B of the Copyright, Designs and Patents Act 1988 (2013).[189]

3. **Plurilateral Trade Agreements Bearing 'Controversial' Copyright & Patent Provisions Triggering Public Debates**

- Anti-Counterfeiting Trade Agreement ("ACTA") (Negotiated 2007-2011)[190]

  - ACTA's objective was to strengthen the international framework for combatting counterfeit patented and trademarked goods, and pirated copyrighted works. It also focused on providing industry and government with law enforcement tools for detecting and prosecuting IP violations.[191]

  - ACTA, thus far, has been signed by 31 national and regional governments, including the U.S., 22 EU Member States, the EU, and Japan. Japan is the only country to have signed AND ratified ACTA. ACTA will enter into force only following its ratification by 6 governments.

  - ACTA fell subject to extreme criticism and protest by NGO activist groups, such as the Electronic Frontier Foundation and Public Knowledge, and by academicians in the US, Canada and Europe. Such criticism and protest was triggered partly, because of the lack of public transparency surrounding its negotiation, and partly because of the draft ACTA negotiating texts leaked by Wikileaks which revealed what many perceived as objectionable and ***imbalanced*** IP provisions.
    - For example, according to protesters in Europe, "[t]he leaked documents also suggested that the EU wanted to establish power (PDF) for judges 'to issue pre-litigation seizure orders and injunctions against Internet intermediaries whose services are being used by a third party to infringe IP rights.' **The 'internet termination obligations were thought to remove any discretion that Congress gave internet service providers through the Digital Millennium Copyright Act (DMCA).**'"[192]
    - "[T]he impact of ACTA on Canadian copyright law would be noticeable; the proposed treaty would import into Canadian copyright law notions that are not in harmony with its purpose, provisions, and/or judicial interpretation… ACTA's claimed purpose as a treaty

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[189] *See* Government of the United Kingdom Intellectual Property Office, *Research, Libraries and Archives* supra.

[190] *See* Government of Japan, Ministry of Foreign Affairs, *Final Text of the Anti-Counterfeiting Trade Agreement (ACTA)*, available at: http://www.mofa.go.jp/policy/economy/i_property/pdfs/acta1105_en.pdf.

[191] "The goal of the ACTA negotiations is to provide an international framework that improves the enforcement of intellectual property right (IPR) laws…to create improved international standards as to how to act against large-scale infringements of IPR. This goal is pursued through three primary components of ACTA: (i) international cooperation; (ii) enforcement practices; and (iii) legal framework for enforcement of IPRs." *See* European Commission, *The Anti-Counterfeiting Trade Agreement (ACTA) Fact Sheet* (Nov. 2008), at p. 1, available at: http://trade.ec.europa.eu/doclib/docs/2008/october/tradoc_140836.11.08.pdf.

[192] *See* Hannah Minkevitch, *The Anti-Counterfeiting Trade Agreement*, Berkeley Tech. L.J. Bolt (November 4, 2010), available at: http://btlj.org/2010/11/04/the-anti-counterfeiting-trade-agreement/.

against piracy and counterfeiting is surrounded by **the suspicion that ACTA is merely a new battle to win the long going war over more absolute control of intellectual property**. In this battle, battle, industrial countries aim to achieve two goals: ratcheting up international intellectual property protection and enforcement and, at the same time, opposing any user-oriented force."[193]

- The EU Commission signed the ACTA in 2012, despite the European Parliament's prior March 2010 Resolution (P7_TA(2010)0058)[194] expressing doubts and suspicions regarding it.
  - The EU Parliament's Rapporteur to the ACTA negotiations, French MEP Kader Arif was so concerned about ACTA's criminal IP enforcement measures that he resigned in protest during February 2012. According to the Rapporteur, ACTA's criminal IP enforcement provisions would undermine EU IPR limitations and personal data protections, impede innovation and competition, and restrict the free flow of information, and thereby, burden legitimate trade.
    - The Rapporteur was concerned that ACTA could be interpreted to treat generic drugs as 'counterfeit' drugs, thus cutting access to life-saving drugs. In addition, he was concerned that ACTA would restrict internet freedom, insofar as it could potentially be interpreted "so that someone crossing a border who has a single song or film on their computer could face criminal charges."[195] "A patent holder can stop the shipment of drugs to a developing country, seize the cargo and order destruction of the goods…It limits the flexibilities in the TRIPS Agreement to support developing countries in need of generic drugs…Internet freedoms could also be under threat. The chapter on the internet reintroduces the concept of liability of internet providers that could make ISPs, who provide internet access liable for users' illicit file-sharing. There could [also] be more intrusive checks at borders to fight counterfeiting."[196] He recommended that the Parliament outright reject ACTA because the Parliament "could not guarantee adequate protection for citizens' rights under ACTA."[197]
- During February 2012, the EU Commission, in a speech delivered by Trade Commissioner Karel De Gucht, announced that it would submit a request to the European Court of Justice (ECJ) to assess whether the ACTA violated "the EU's fundamental

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[193] *See* Elizabeth Judge and Saleh Al-Sharieh, *The Impact of the Anti-Counterfeiting Trade Agreement (ACTA) on Canadian Copyright Law*, PIJIP Research Paper Series. Paper 13 (2010), at pp. 1, 6-7, available at: http://digitalcommons.wcl.american.edu/research/13/.

[194] *See* European Parliament resolution of 10 March 2010 on the transparency and state of play of the ACTA negotiations, P7_TA(2010)0058, available at: http://www.europarl.europa.eu/sides/getDoc.do?type=TA&language=EN&reference=P7-TA-2010-0058.

[195] *See* Charles Arthur, *Acta Goes Too Far, Says MEP*, The Guardian, *supra*.

[196] *Id*.

[197] *See* Charles Arthur, *Acta Goes Too Far, Says MEP*, The Guardian (Feb. 1, 2012), available at: http://www.theguardian.com/technology/2012/feb/01/acta-goes-too-far-kader-arif.

human rights and freedoms, such as freedom of expression and information or data protection and the right to property in the case of intellectual property."[198]

- During April 2012, Arif's replacement, new EU Parliament ACTA Rapporteur, David Martin (Socialists & Democrats (S&D) MEP (UK)), thereafter crafted a draft resolution recommending that "the European Parliament decline[] to give consent to ACTA."[199]
  - "Intellectual property (IP) is the raw material of the Union. Your rapporteur believes Europe cannot compete in the global economy without adequate protection for European fashion, car parts, films and music. Global coordination of IP protection is vital to developing a knowledge-based European Union and protecting and creating jobs throughout the Union. Within this knowledge-based economy, the way we share information is changing rapidly **and the *balance* between the protection of intellectual property rights and fundamental freedoms is evolving**. International agreements dealing with any aspect of criminal sanctions, online activity or intellectual property must clearly define the scope of the agreement and the protection of individual liberties, in order to avoid unintended interpretations of the agreement."[200]
- In July 2012, the EU Parliament overwhelmingly voted, 478 to 39, to reject ACTA.[201] In December 2012, the EU Commission withdrew its request for review by the ECJ.[202]

- In the U.S., during March 2012, Democratic members of Congress (Sen. Ron Wyden (D-OR)[203] and the U.S. State Department's Legal, Advisor Harold Hongju Koh,[204] had advised

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[198] *See* European Commission Press Release, *Statement by Commissioner Karel De Gucht on ACTA (Anti-Counterfeiting Trade Agreement)*, MEMO/12/128 (2/22/12), available at: http://europa.eu/rapid/press-release_MEMO-12-128_en.htm.

[199] *See* European Parliament Committee on International Trade, *DRAFT RECOMMENDATION on the draft Council decision on the conclusion of the Anti-Counterfeiting Trade Agreement between the European Union and its Member States, Australia, Canada, Japan, the Republic of Korea, the United Mexican States, the Kingdom of Morocco, New Zealand, the Republic of Singapore, the Swiss Confederation and the United States of America* (12195/2011 – C7-0027/2012 – 2011/0167(NLE)), (April 12, 2012), available at: http://www.europarl.europa.eu/sides/getDoc.do?type=COMPARL&reference=PE-486.174&format=PDF&language=EN&secondRef=02.

[200] *Id*. *See also* Glyn Moody, *ACTA Rapporteur's Recommendations: Reject Treaty, But Ask European Commission To Come Up With Replacement*, TechDirt (April 17, 2012), available at: http://www.techdirt.com/articles/20120417/03325918518/acta-rapporteurs-recommendations-reject-treaty-ask-european-commission-to-come-up-with-replacement.shtml.

[201] *See* David Meyer, *ACTA Rejected by Europe, Leaving Copyright Treaty Near Dead*, ZDNet (July 4, 2012), available at: http://www.zdnet.com/acta-rejected-by-europe-leaving-copyright-treaty-near-dead-7000000255/; Don Melvin, *EU Parliament Rejects ACTA Anti-piracy Treaty*, Bloomberg BusinessWeek (July 4, 2012), available at: http://www.businessweek.com/ap/2012-07-04/eu-parliament-holds-key-vote-on-anti-piracy-treaty.

[202] *See* European Commission Secretariat General, *MINUTES of the 2028th meeting of the Commission held in Brussels on Wednesday 19 December*, 2012PV(2012) 2028 final (Jan. 15, 2013), at par. 6.3, available at: http://ec.europa.eu/transparency/regdoc/rep/10061/2012/EN/10061-2012-2028-EN-F1-1.Pdf. *See also* David Meyer, *ACTA Gets Final Stake Through Heart As EC Drops Court Referral*, ZDNet (Dec. 20, 2012), available at: http://www.zdnet.com/acta-gets-final-stake-through-heart-as-ec-drops-court-referral-7000009070/.

[203] *See* Nate Anderson, *Sen. Wyden Demands Vote on American Copyright, Patent Treaties*, Ars Technica (March 20, 2012), available at: http://arstechnica.com/tech-policy/2012/03/sen-wyden-demands-vote-on-american-copyright-patent-treaties/

the White House that ACTA was a congressional executive agreement that could not be ratified without congressional consent.

- ACTA had also been perceived in the media as "an attempt to push the [U.S. Digital Millennium Copyright Act] DMCA onto the rest of the world, and especially the developing world. It was an attempt by the rich Western nations to keep a tight grip on and a narrow definition of what constituted IP and counterfeiting."[205]
- Notwithstanding that "ACTA may have been watered down and the US government's attempt to export DMCA rules to the rest of the world may have been a failure[, and] SOPA and PIPA may have guttered out in congress for the time being[,]…[the Trans-Pacific Partnership Agreement] TPP represents the latest present danger to internet freedom, and ACTA may still allow governments to adopt more restrictive IP rules."[206]
  - According to one NGO activist, "[p]erhaps the fact that ACTA was a stand-alone IP agreement worked to our advantage. The TPP, on the other hand, is a trade agreement that covers a diverse range of issues including textiles, telecommunications, agriculture, etc. **It is easy for our concerns about *unbalanced* intellectual property provisions** to get lost among other priorities as countries trade concessions in one chapter for stronger IP rules."[207]

- The Trans-Pacific Partnership Agreement ("TPP") (Still under negotiation)

("Sen. Ron Wyden (D-OR) is a long-time opponent of the secretly negotiated Anti-Counterfeiting Trade Agreement (ACTA). Today he introduced an amendment to a Senate 'jobs bill' that would force ACTA to come before Congress for approval. A second amendment would make the US Trade Representative, which negotiates US trade deals, drop the veil of secrecy around its copyright and patent negotiations. USTR currently insists the president can ratify ACTA without the usual Senate sign-off on treaties. The current legal thinking seems to be that Congress delegated this authority to the executive branch by passing 2008's PRO-IP Act, which contained a general call to cut down on counterfeiting, etc. That legal approach is contested; Wyden's amendment simply overrules it.") *Id*.

[204] *See* Letter from the United States Department of State Legal Adviser to The Honorable Ron Wyden (March 6, 2012), available at: http://infojustice.org/wp-content/uploads/2012/03/84365507-State-Department-Response-to-Wyden-on-ACTA.pdf (indicating that "Congress ha[d] passed legislation explicitly calling for the Executive Branch to work with other countries to enhance enforcement of intellectual property rights. For example, the Prioritizing Resources and Organization for Intellectual Property Act of 2008, Pub. L. 110-403, codified at 15 U.S.C. 8113(a) [PIPA], calls for the Executive Branch to develop and implement a plan aimed at 'eliminating international counterfeiting and infringement networks' and to 'work[] with other countries to establish international standards and policies for the effective protection and enforcement of intellectual property rights.' The ACTA helps to answer that legislative call.") *Id*. *See also* Sean Flynn, *Wyden Amendment Needed to Challenge Dubious ACTA Justification*, Infojustice.org (March 20, 2012), available at: http://infojustice.org/archives/9072.

[205] *See* Erik Kain, *Final Draft Of ACTA Watered Down, TPP Still Dangerous On IP Rules*, Forbes (1/28/12), available at: http://www.forbes.com/sites/erikkain/2012/01/28/final-draft-of-acta-watered-down-tpp-still-dangerous-on-ip-rules/. "Nate Anderson of *Ars Technica* writes: 'US Trade Representative Ron Kirk, whose office negotiated the US side of the deal, issued astatement this morning about the 'tremendous progress in the fight against counterfeiting and piracy,' but the real story here is the tremendous climbdown by US negotiators, who have largely failed in their attempts to push the Digital Millenium Copyright Act (DMCA) onto the rest of the world.'" *Id*.

[206] *Id*.

[207] *See* Rashmi Rangnath, *What We Won In ACTA*, Public Knowledge Policy Blog (Oct. 3, 2011), available at: http://www.publicknowledge.org/blog/what-we-won-acta.

- The TPP was previously an Asia-Pacific regional trade agreement being negotiated among nine nations – Australia, Brunei, Chile, Malaysia, New Zealand, Peru, Singapore, the United States, and Vietnam.[208] It is currently being negotiated by twelve countries – with Canada, Mexico and Japan as recent additions.
  - TPP Parties have bilateral and regional Free Trade Agreements ("FTAs") in effect with other TPP negotiating partners, and are in the process of negotiating FTAs with other TPP Parties.[209]
  - Furthermore, current TPP Parties include 4/10 members of the Association of Southeast Asian Nations ("ASEAN") – Brunei Darussalam, Malaysia, Singapore, and Vietnam.[210] And, ALL current TPP Parties are members of the 21-country Asia-Pacific Economic Cooperation ("APEC").[211]
- The IP chapter of the TPP has been quite controversial given its adherence to the USTR's previously expressed trade negotiating objectives incorporated into the last US trade promotion authority legislation passed by Congress. P.L. 107-210 (The Trade Act of 2002)[212] covered the five-year period spanning 2002-2007. These objectives included seeking:
  - Accelerated implementation of the WTO TRIPS Agreement's enforcement provisions;[213]
  - Strong enforcement of IP rights, including through accessible, expeditious and effective civil, administrative and criminal enforcement mechanisms;[214]
  - Assurance that trade negotiations "reflect a standard of protection similar to that found in U.S. law",[215] which objectives have since largely tracked the terms of the US-Korea FTA, which many governments and activists now refer to as "TRIPS-plus" standards;[216]
  - Application of existing IPR protection to digital media;[217]

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[208] *See* Trans-Pacific Partnership Agreement, as entered into force on Nov. 8, 2006, www.sice.oas.org/Trade/CHL_Asia_e/mainAgreemt_e.pdf; Trans-Pacific Partnership, Office of the United States Trade Representative, Executive Office of the President of the United States, www.ustr.gov/tpp; *Trans-Pacific Strategic Economic Partnership Agreement (P4), Chile-Brunei Darussalam-New Zealand-Singapore*, Foreign Trade Information System, Organization of American States, available at: www.sice.oas.org/TPD/CHL_Asia/CHL_Asia_e.ASP.

[209] *See* Ian F. Fergusson, William H. Cooper, Remy Jurenas, and Brock R. Williams, *The Trans-Pacific Partnership Negotiations and Issues For Congress*, Congressional Research Service Report R42694 (Aug. 21, 2013), at Figure 2, available at: http://www.fas.org/sgp/crs/row/R42694.pdf.

[210] See Association of Southeast Asian Nations, *ASEAN Member States*, available at: http://www.asean.org/asean/asean-member-states.

[211] See Asia-Pacific Economic Cooperation, About APEC-Member Economies, available at: http://www.apec.org/about-us/about-apec/member-economies.aspx.

[212] See Public Law 107-210, *An Act to extend the Andean Trade Preference Act, to grant additional trade benefits under that Act, and for other purposes ("Trade Act of 2002")*, § 2102, 116 Stat. 933, 995–996 (codified at 19 U.S.C. § 3802) available at: http://www.gpo.gov/fdsys/pkg/PLAW-107publ210/html/PLAW-107publ210.htm.

[213] Sec. 2102(b)(4)(A)(i)(I).

[214] Sec. 2102(b)(4)(A)(v).

[215] This negotiating objective, alone, has triggered protestations from legal academics and nongovernmental activist groups. See e.g., Sean M. Flynn, Brook Baker, Margot Kaminski and Jimmy Koo, *The U.S. Proposal for an Intellectual Property Chapter in the Trans-Pacific Partnership Agreement*, 28 AM. U. INT'L L. REV. 105, 106-107, available at: http://digitalcommons.wcl.american.edu/cgi/viewcontent.cgi?article=1775&context=auilr

[216] P.L. 107-201, Sec. 2102(b)(4)(A)(i)(II).

- Strong protection for new and emerging technologies and new methods of transmitting and distributing IP-embodying products;[218] and
- Respect for the Declaration on the TRIPS Agreement and Public Health.[219]

- Given the lack of transparency surrounding TPP negotiations since the U.S. formally joined them in 2008, several NGO activist groups have obtained, critiqued and posted on the web leaked copies of TPP Party negotiating texts. Such leaked texts, including those of the Government of New Zealand (Dec. 4, 2010[220]) and the USTR (February 2011[221]) and September 2011[222]), have thus far reflected USTR's TRIPS+ objectives, which have triggered government (e.g., Vietnam[223]) and civil society stakeholder objections that have slowed down TPP negotiations.
  - The leaked TPP IP Chapter negotiating texts reveal that the TPP largely follows the terms of the Korea-U.S. Free Trade Agreement ("KORUS"),[224] the provisions of the Anti-Counterfeiting Trade Agreement (ACTA)[225] not yet in force, and the US Digital Millennium Copyright Act (DMCA).[226]
  - Certain legal/academic commentators have alleged that, if successful, **U.S. efforts to establish a TRIP+ TPP framework would impose *an unbalanced view of IP rights* throughout the Asia region** which would adversely affect competing industries in other TPP Parties, the "public interest", both in the U.S. and such TPP Parties, and would also **severely impair access to health, information and technology in developing countries**.
    - "**Our ultimate conclusion is that the U.S. proposal, if adopted, would upset the current international framework *balancing the interests of rights holders and the public*.** It would heighten standards of protection for rights holders well beyond that which the best available evidence or inclusive democratic processes support.[fn] **It contains *insufficient balancing provisions* for users,**

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[217] Sec 2012(b)(4)(A)(iv).
[218] Sec. 2102(b)(4)(A)(ii).
[219] Sec. 2102(b)(4)(C).
[220] See New Zealand, *Proposed Text for an Intellectual Property Chapter* http://infojustice.org/download/tpp/tpp-texts/New%20Zealand%20Proposal%20for%20Intellectual%20Property%20Chapter,%20February%202011.pdf.
[221] See United States, *Proposed Text for an Intellectual Property Chapter* at: http://infojustice.org/download/tpp/tpp-texts/tpp%20IP%20chapter%20feb%20leak.pdf.
[222] See United States, *Proposed Text on IP and Medicines*, at: http://infojustice.org/download/tpp/tpp-texts/U.S.%20Proposed%20Text%20on%20IP%20and%20Medicines,%20dated%20September%202011,%20leaked%20October%202011.pdf.
[223] *See* Hoang Phi, *Intellectual property a hindrance in TPP negotiations*, Saigon Times (Sept. 11, 2013), available at: http://english.thesaigontimes.vn/Home/business/other/30978/Intellectual-property-a-hindrance-in-TPP-negotiations.html.
[224] *See* Office of the United States Trade Representative, *Korea-U.S. Free Trade Agreement*, at: http://www.ustr.gov/sites/default/files/uploads/agreements/fta/korus/asset_upload_file273_12717.pdf.
[225] See Government of Japan, *Final Text of the Anti-Counterfeiting Trade Agreement* (May 2011), available at: http://www.mofa.go.jp/policy/economy/i_property/pdfs/acta1105_en.pdf; Government of Japan, *Joint Press Statement of the Anti-Counterfeiting Trade Agreement Negotiating Parties*, Press Release (Oct. 2011), available at: http://www.mofa.go.jp/policy/economy/i_property/pdfs/acta1110.pdf.
[226] See Public Law 105–30, *Digital Millennium Copyright Act*, available at: http://www.copyright.gov/legislation/pl105-304.pdf.

consumers, and the public interest.[fn] The provisions would be particularly harmful for developing countries, where the risks and effects of exclusionary pricing by intellectual property monopolists are often most acute.[fn] **The general thrust of the proposal conflicts with the 'development agenda' being debated in WIPO, which has a much stronger focus on the harmonization of limitations and flexibilities in international intellectual property law**. The proposal **also conflicts with the overwhelming trend in multilateral institutions toward protection of TRIPS flexibilities for developing countries to promote access to affordable medications.**[fn] The proposal would make these changes in the context of a new and powerful dispute resolution system that would greatly expand the standing, venue, and causes of action that could be used to challenge domestic policies, including through actions by corporations directly against states.[fn]"[227]

- "Since Wikileaks made the intellectual property (IP) chapter public, multiple organizations have provided extensive and detailed critiques. According to these analyses, **the text demonstrates U.S. preference for increasing protections on existing copyrights and patents over *balanced* policies that promote global innovation, creativity and political freedom**. The disclosures especially suggest the inordinate influence of the motion picture and pharmaceutical industries."[228]
  - "**Further analysis of the IP chapter shows that it violates international consensus on several important issues**.
    - First, the U.S. is pushing provisions that **conflict with the World Intellectual Property Organization's Development Agenda**, which requires that development concerns be a formal part of global IP policy."[229]
    - "Second, the chapter also **takes a controversial approach to the World Trade Organization's (WTO) Doha Declaration on the Trade Related Aspects of Intellectual Property Rights (TRIPS) and Public Health**. TRIPS sets the standards for intellectual property protection in the world today, which are binding on all members of WTO. The Doha Declaration affirms that TRIPS signatories should interpret and implement TRIPS in a manner supportive of their own rights to protect public health and, in particular, to promote access to medicines for all. **Although the IP chapter makes explicit reference to the Doha Declaration, the IP chapter is designed to narrow its scope**, thereby limiting access to medicines and restricting what governments can do to protect public health."[230]

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[227] *See* Sean M. Flynn, Brook Baker, Margot Kaminski and Jimmy Koo, *The U.S. Proposal for an Intellectual Property Chapter in the Trans-Pacific Partnership Agreement*, 28 AM. U. INT'L L. REV. 105, 119-120, available at: http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2185402&download=yes.

[228] *See* Caroline Rossini, *US Push on Intellectual Property Conflicts With International Norms*, Al Jazeera America (Dec. 1, 2013), available at: http://america.aljazeera.com/opinions/2013/12/tpp-intellectualpropertywikileaks.html.

[229] *Id*.

[230] *Id*.

- "Third, U.S. proposals also **contradict the current policy discussions on access to medicines and on research & development at the World Health Organization and the UN Convention on Biological Diversity**."[231]
- "Fourth, the TPP chapter also **jeopardizes the flexibilities guaranteed under fair use doctrine by pushing for strict enforcement of copyrights online**."[232]

- The secrecy of TPP negotiations and the TRIPS+ nature of the TPP's substantive IP provisions have also triggered the ire of the US Congress, which has perceived the TPP as "undermin[ing] Internet freedom and consumer protections in the U.S. and abroad".[233]
  - For example, the TPP has prompted a backlash from 151 Democratic members of Congress[234] and growing bi-partisan opposition to granting the President 'Fast-Track' Trade Promotion Authority.[235]
  - Despite such opposition, bi-partisan Senate and House bills providing the President with such authority (Congressional Trade Priorities Act (S. 1900, H.R. 3830)) were recently drafted (in January 2014) and at least one hearing has been since held to discuss it.[236]

- The Transatlantic Trade and Investment Partnership Agreement ("TTIP") (under negotiation with the European Union and subject to criticism for nontransparency[237])

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[231] *Id*.
[232] *Id*.
[233] *See* Zach Carter, *Trans-Pacific Partnership Talks Stir House Bipartisan Opposition*, Huffington Post (Nov. 14, 2013), available at: http://www.huffingtonpost.com/2013/11/12/trans-pacific-partnership-house_n_4263174.html.
[234] See Congresswoman Rosa DeLauro, *DeLauro, Miller Lead 151 House Dems Telling President They Do Not Support Outdated Fast Track For Trans-Pacific Partnership Agreement*, Press Release (Nov. 12, 2013), available at: http://delauro.house.gov/index.php?option=com_content&view=article&id=1455:delauro-miller-lead-151-house-dems-telling-president-they-will-not-support-outdated-fast-track-for-trans-pacific-partnership&catid=2&Itemid=21.
[235] *See* Letter From Congressman Walter B. Jones to President Barack Obama (Nov. 12, 2013), available at: http://jones.house.gov/sites/jones.house.gov/files/11.12.13%20Fast%20Track%20Letter.pdf (accompanied by 21 republican signatures); Letter From Congressman Mike Thompson to President Barack Obama (Nov. 8, 2013), available at: http://www.larson.house.gov/images/11-8-13_TPA_Letter.pdf (accompanied by 11democratic signatures).
[236] *See* Derrick Cain, *Lawmakers Press for Fast-track Trade Promotion Authority*, AgriPulse (Jan. 21, 2014), available at: http://www.agri-pulse.com/Lawmakers-press-for-fast-track-trade-promotion-authority-01202014.asp. *Cf.* Amie Parnes, Obama: Give Me Fast Track Trade, The Hill (Jan. 21, 2014), available at: http://thehill.com/homenews/administration/195858-white-house-works-to-convince-dems-to-give-obama-fast-track-on-trade ("Legislation introduced last week to give Obama trade promotion authority was sponsored by House Ways and Means Committee Chairman Dave Camp (R-Mich.) and Senate Finance Committee Chairman Max Baucus (D-Mont.), as well as Sen. Orrin Hatch (R-Utah), the ranking member on Finance. No House Democrats are co-sponsoring the bill, however, and Rep. Sandy Levin (D-Mich.), the Ways and Means Committee ranking member, and Rep. Charles Rangel (D-N.Y.), the panel's former chairman, have both criticized it. They said the legislation doesn't give enough leverage and power to Congress during trade negotiations.") *Id*. *See also* Scott Flaherty, *Fast-Track Trade Bill Faces Pushback From Progressives*, Law360 (Jan. 17, 2014), available at: http://www.law360.com/articles/502240/fast-track-trade-bill-faces-pushback-from-progressives.
[237] "As with the TPP, the IP Chapter in the EU-US TTIP is likely to raise the most challenging of the trade issues to be resolved. Excessive secrecy cannot assist generating public support and momentum in favour of its ultimate adoption. Secrecy is a flaw in the process and, as with ACTA, can only increase the prospects of misinterpretation and alarmist concerns about the scope and applicability of the IP protection and enforcement provisions contained in the draft TTIP

- According to the European Union:

  - "In the debate around the Transatlantic Trade and Investment Partnership (TTIP), some commentators have tried to suggest that there is a conspiracy to use the negotiations to bring back parts of the Anti-Counterfeiting Trade Agreement (ACTA). Some have even claimed that TTIP will be a 'super-ACTA', aimed at attacking your online freedoms. These claims are – very simply – false."[238]
  - "More than a third (35%) of European jobs rely on intellectual property rights (IPR) such as patents, trademarks and design rights according to a new pan-European study, which the EU executive will use to boost policymaking. According to the analysis – produced jointly by the Munich-based European Patent Office and the Office for the Harmonization of the Internal Market based in Alicante, Spain – 39% of all European economic activity, worth €4.7 trillion, arises annually from IPR."[239]

- According to the Internet Society:

  - "[I]nstead of debating on whether intellectual property provisions should be included in the TTIP, **let's focus on this: how to ensure that intellectual property discussions in the TTIP do not impose unnecessary burdens on copyright law, the Internet or its users**. **The intellectual property chapter in the TTIP could provide a valuable perspective if approached in a way that seeks to strike a *balance* between the competing interests of all actors, includes limitations and exceptions that can allow the free flow of information and preserves the current role of intermediaries**. I think we could all agree, judging also from past legislative attempts, that copyright provisions are more practical when they are proportional and respect fundamental rights, including the right to speak freely and to create, encourage and disseminate information and content in the Internet. The same rationale of proportionality should be preserved in the context of data protection and privacy."[240]

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agreement. Conversely, greater transparency and wider access to negotiating texts has the ability to improve the quality of debate and contribute to the legitimacy of the TTIP negotiating process to great effect. If negotiators are to learn the lessons of ACTA's demise in the EU and the problems already being experienced by TPP negotiators elsewhere, openness and transparency should be the key strategy for the TTIP as EU and US negotiators prepare to begin the hard work of not only drafting text for the IP Chapter but also doing so in a way that convinces stakeholders and the public at large that the TTIP is an endeavour worthy of widespread support." *See* Duncan Matthews, *Negotiating the IP Chapter of an EU-US Transatlantic Trade and Investment Partnership: Let's Not Repeat Past Mistakes*, 44 International Review of Intellectual Property and Competition Law 491, 493 (Aug. 2013), available at: http://www.tsg.ecupl.edu.cn/xkjb/gsw/38.pdf; http://www.ip.mpg.de/files/pdf2/IIC-Vol.44No.5-2013.pdf.

[238] *See* European Commission, *How much does the TTIP have in common with ACTA?*, Fact Sheet (July 2013), available at: http://trade.ec.europa.eu/doclib/docs/2013/july/tradoc_151673.pdf.

[239] See Euractiv.com, *Study: 35% of EU Jobs Depend on Intellectual Property Rights*, (Oct. 1, 2013; updated Nov. 5, 2013), available at: http://www.euractiv.com/infosociety/eu-launches-new-intellectual-pro-news-530784.

[240] *See* Konstantinos Komaitis, *Reflections on the Transatlantic Trade and Investment Partnership (TTIP)*, Internet Society (June 3, 2013), available at: http://www.internetsociety.org/blog/2013/06/reflections-transatlantic-trade-and-investment-partnership-ttip.

- "**One of the ways the negotiating nations could approach the intellectual property chapter** – especially when deliberating on issues of proportionality, balance and scope – **would be to do so under the approach that has guided Internet open standards to date not too distant from the ones copyright is built on**, that could help shape and put the discussions into a more concrete perspective. These principles are the idea that the Internet has evolved technically in accordance with a set of specific principles embodied in the practices of the organizations that have developed the Internet-related technologies – the Internet Engineering Task Force (IETF), the World Wide Consortium (W3C), the IEEE. This open standards approach has allowed the organic evolution of the Internet and its transformation into an economic and social tool."[241]
- "Specifically, I am referring to the 'Open Stand' modern paradigm for open standards, which includes the principles of a) cooperation; b) adherence to due process, broad consensus, transparency, balance and openness principles; c) collective empowerment; d) **availability**; and, e) voluntary adoption."[242]
  - "**4. Availability** Standards specifications are made accessible to all for implementation and deployment. Affirming standards organizations have defined procedures to develop specifications that can be implemented under fair terms. **Given market diversity, fair terms may vary from royalty-free to fair, reasonable, and non-discriminatory terms (FRAND)**."[243]

- According to one activist tech media journalist, an EU Commission trade negotiator has leaked to EU MEP (Sweden) Erik Josefsson (an adviser on internet policies for the Greens/EFA Group in the European Parliament and an active campaigner against software patents),[244] elements of the transatlantic IP negotiating strategy which allegedly contradict EU Commission public statements:[245]

  - "Because we learn from a stunning report of a little-publicized meeting between corporate lobbyists and the **EU's negotiator on intellectual monopolies, Pedro Velasco Martins**, that putting many of the worst features of ACTA into TAFTA/TTIP is precisely what the European Commission has planned. Here's the background:"[246]

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[241] *Id*.

[242] *Id*. *See also* Konstantinos Komaitis, *Intellectual Property and the Value of an Open Internet*, DISCO (Disruptive Competition Project) (July 16, 2013), available at: http://www.project-disco.org/intellectual-property/071613-intellectual-property-and-the-value-of-an-open-internet/.

[243] *See* Open Stand, *Principles*, available at: http://open-stand.org/principles/.

[244] See *Erik Josefsson – Advisor on Internet Policies*, The Greens/European Free Alliance in the European Parliament, available at: http://www.greens-efa.eu/36-details/josefsson-erik-138.html; Wikipedia, *Erik Josefsson (activist)*, available at: http://en.wikipedia.org/wiki/Erik_Josefsson_(activist)#cite_note-4.

[245] *See* Erik Josefsson, *TTIP: Commission Intends to Place Secret, Corporate "Christmas list" of IPRs in Trade Treaty*, The Greens/EFA Internet Core Group (Dec. 19, 2013), available at: http://icg.greens-efa.org/pipermail/hub/2013-December/000083.html; *December 2013 Archives by subject*, Greens/EFA Internet Core Group, available at: http://icg.greens-efa.eu/pipermail/hub/2013-December/subject.html.

[246] *See* Glyn Moody, *European Commission Admits It Plans To Put 'Corporate Christmas List' Of IP Demands Into TAFTA/TTIP*, TechDirt (Dec. 19, 2013), available at: http://www.techdirt.com/articles/20131219/05544825628/actas-back-european-commission-reveals-plans-to-put-corporate-christmas-list-ip-demands-into-taftattip.shtml.

- "'Taking place at the American Chamber of Commerce offices in Brussels, the purpose of the two hour exchange was to strategize between businesses and the Commission in order to make sure that the maximum level of new IP restrictions will be written into the treaty…Controversially, the supposedly neutral Commission negotiator and the OHIM representative not only defined themselves as allies with the businesses lobbyists. They went far beyond this and started to instruct the representatives in detail on how they should campaign to 'educate' the public in order to maximise their outcome in terms of industry monopoly rights…'"[247]
- "'**Commission negotiator Velasco Martins revealed the existence of a secret list of corporate demands for new intellectual property rights in the transatlantic treaty**. Previously -- towards the public and the Parliament -- the Commission has created the impression that intellectual property rights will be downplayed. The only IP right mentioned has been geographical indications, a minor issue which few are concerned about. **In reality, the Commission now revealed that they have received "quite a Christmas list of items" on IP from corporate lobbyists and that…covers almost every major intellectual property right**. **On patents**, industry had shown 'quite an interest' especially on the **procedures around the granting of new patents**. **On copyrights the industry wants to have the 'same level of protection' in the US and EU**; in reality this always means harmonization up which results in more restrictions for the general public. **On plant variety rights** the pharma sector has lobbied for **'higher levels' of protection**. **On trademarks** the corporate lobbyists had made **classification-related requests** to the Commission. Additionally there had been a lot of interest in **trade secrets**.'"[248]
- "'**According to the negotiator, the most repeated request on the Christmas list was in "enforcement**". Concerning this, companies had made requests to "improve and formalize" as well as for the authorities to "make statements". **The Commission negotiator said that although joint 'enforcement statements' do not constitute "classical trade agreement language" -- a euphemism for things that do not belong in trade agreements -- the Commission still looks forward to "working in this area".'** That seems to go against explicit promises made earlier by the European Commission: 'Since the beginning of the TTIP negotiating process, it is very clear that the eventual agreement on intellectual property rights will not include elements that were controversial in the context of ACTA. For example, the ACTA provisions on IPR enforcement in the digital environment (ACTA articles 27.2 to 27.4) will not be part of the negotiations. Neither will ACTA's provisions on criminal sanctions.'"[249]

[247] *Id.*
[248] *Id.*
[249] *Id.*

III. APPARENT CAUSES OF CHANGE IN THE WORLD OF INTELLECTUAL PROPERTY[250]

1. **Patents**

a. Initiatives of the United Nations Secretariat, Agencies, Offices, and Instrumentalities

i. United Nations General Assembly[251]

- World Commission on Environment and Development[252] Report, *Our Common Future* (Aug. 1987):
  - "**The concept of sustainable development provides a framework for the integration of environment policies and development strategies** - the term 'development' being used here in its broadest sense. The word is often taken to refer to the processes of economic and social change in the Third World. But **the integration of environment and development is required in all countries, rich and poor. The pursuit of sustainable development requires changes in the domestic and international policies of every nation**."[253]
    - "**Sustainable development seeks to meet the needs and aspirations of the present without compromising the ability to meet those of the future**. Far from requiring the cessation of economic growth, it recognizes that **the problems of poverty and underdevelopment cannot be solved unless we have a new era of growth in which developing countries play a large role and reap large benefits**."[254]

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[250] The following discussion largely contains excerpts from key postmodern sustainable development and human rights initiatives.

[251] "The General Assembly (GA) is the main deliberative, policymaking and representative organ of the UN. Decisions on important questions, such as those on peace and security, admission of new members and budgetary matters, require a two-thirds majority. Decisions on other questions are by simple majority. Each country has one vote." See General Assembly of the United Nations, *About the General Assembly*, available at: http://www.un.org/en/ga/about/index.shtml.

[252] "The World Commission on Environment and Development was created as a consequence of General Assembly resolution 38/161 adopted at the 38th Session of the United Nations in the fall of 1983. That resolution called upon the Secretary General to appoint the Chairman and Vice Chairman of the Commission rind in turn directed them to jointly appoint the remaining members, at least half of whom were to be selected from the developing world…The Commission's Mandate [obliges it] to urgently: 1. to re-examine the critical issues of environment and development and to formulate innovative, concrete, and realistic action proposals to deal with them; 2. to strengthen international cooperation on environment and development and to assess and propose new forms of cooperation that can break out of existing patterns and influence policies and events in the direction of needed change; and 3. to raise the level of understanding and commitment to action on the part of individuals, voluntary organizations, businesses, institutes, and governments." See *Our Common Future*, (*Annex 2: The Commission and its Work*, General Assembly Document A/42/427 - Development and International Co-operation: Environment), United Nations General Assembly 42nd Sess. (Aug. 4, 1987), available at: http://www.un-documents.net/ocf-a2.htm.

[253] See *Our Common Future, Chapter 1: A Threatened Future*, Summary of *Our Common Future: Report of the World Commission on Environment and Development*, (Annex 1 to General Assembly Document A/42/427), supra - Development and International Co-operation: Environment), United Nations General Assembly 42nd Sess. (Aug. 4, 1987), at par. 48, available at: http://www.un-documents.net/ocf-01.htm.

[254] *Id*., at par. 49.

- "Economic growth always brings risk of environmental damage, as it puts increased pressure on environmental resources. But **policy makers guided by the concept of sustainable development will necessarily work to assure that growing economies remain firmly attached to their ecological roots and that these roots are protected and nurtured so that they may support growth over the long term. Environmental protection is thus inherent in the concept of sustainable development, as is a focus on the sources of environmental problems rather than the symptoms**."[255]

- United Nations Conference on Environment and Development (UNCED) ("Earth Summit" 1992), convened pursuant to General Assembly Resolution A/44/228 (Dec. 1989).[256]

  - Per Resolution A/44/228, the General Assembly:

    - "Reaffirm[ed] the need to strengthen international cooperation, particularly between developed and developing countries, in research and development and the utilization of environmentally sound technologies";[257]
    - "Decide[d] that [this] conference, in addressing environmental issues in the developmental context, should have the following objectives:"[258]
      - "To examine **strategies for national and international action** with a view to arriving at specific agreements and commitments by Governments for defined activities to deal with major environmental issues in order **to restore the global ecological *balance*** and to prevent further deterioration of the environment, taking into account the fact that the largest part of the current emission of pollutants into the environment, including toxic and hazardous wastes, originates in developed countries, and therefore recognizing that those countries have the main responsibility for combating such pollution;"[259]
      - "…To consider various funding mechanisms, including voluntary ones, and to examine the possibility of a special international fund and other innovative approaches, with a view to **ensuring, on a favourable basis, the most effective and expeditious transfer of environmentally sound technologies to developing countries**;"[260]
      - "To examine, with a view to making recommendations on effective modalities for **favourable access to, and transfer of, environmentally sound technologies, in particular to the developing countries, including on concessional and preferential terms**, and on modalities for supporting all countries in their efforts to create and develop their endogenous technological capacities in the field of scientific

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[255] *Id*., at par. 50
[256] *See* United Nations General Assembly Resolution A/RES/44/228 (12/22/89), at par. 1, available at: http://www.un.org/documents/ga/res/44/ares44-228.htm.
[257] *Id*., at par. 14.
[258] *Id*., at par. 15.
[259] *Id*., at par. 15(f).
[260] *Id*., at par. 15(l).

research and development, as well as in the acquisition of relevant information, and, in this context, to explore the concept of **assured access for developing countries to environmentally sound technologies, in its relation to proprietary rights**, with a view to developing effective responses to the needs of developing countries in this area;"[261]

- The *Rio Declaration on Environment and Development* (1992)[262] called for the following:
  - "**Human beings are** at the centre of concerns for sustainable development. They are **entitled to a healthy and productive life in harmony with nature**."[263]
  - "In order to achieve sustainable development, **environmental protection** shall constitute an integral part of the development process and cannot be considered in isolation from it."[264]
  - "**All States and all people shall cooperate in the essential task of eradicating poverty as an indispensable requirement for sustainable development**, in order to decrease the disparities in standards of living and better meet the needs of the majority of the people of the world."[265]
  - "**The special situation and needs of developing countries, particularly the least developed and those most environmentally vulnerable, shall be given special priority**. International actions in the field of environment and development should also address the interests and needs of all countries."[266]
  - "To achieve sustainable development and a higher quality of life for all people, **States should reduce and eliminate unsustainable patterns of production and consumption** and promote appropriate demographic policies."[267]
  - "**States should cooperate to strengthen endogenous capacity-building for sustainable development by** improving scientific understanding through exchanges of scientific and technological knowledge, and by **enhancing the development, adaptation, diffusion and transfer of technologies, including new and innovative technologies**."[268]

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[261] *Id*., at par. 15(m).
[262] See *Rio Declaration on Environment and Development*, United Nations Environment Programme ("UNEP"), Principle 1, UNEP website, available at: http://www.unep.org/Documents.Multilingual/Default.asp?documentid=78&articleid=1163.
[263] See *Rio Declaration on Environment and Development*, United Nations Environment Programme ("UNEP"), Principle 1, UNEP website, available at: http://www.unep.org/Documents.Multilingual/Default.asp?documentid=78&articleid=1163.
[264] *Id*., at Principle 4.
[265] *Id*., at Principle 5.
[266] *Id*., at Principle 6.
[267] *Id*., at Principle 8.
[268] *Id*., at Principle 9.

- *Agenda 21* – A Comprehensive Plan of Action to Achieve Sustainable Development, adopted at RIO UNCED:[269]

  - "This global partnership must build on the premises of General Assembly resolution 44/228 of 22 December 1989, which was adopted when the nations of the world called for the United Nations Conference on Environment and Development, and on the acceptance of **the need to take a *balanced* and integrated approach to environment and development questions**."[270]

  - "The developmental and environmental objectives of Agenda 21 will require a **substantial flow of new and additional financial resources to developing countries**, in order to cover the incremental costs for the actions they have to undertake to deal with global environmental problems and to accelerate sustainable development…"[271]

  - **Agenda 21 Implementation to Focus on "Economies in Transition"** - "In the implementation of the relevant programme areas identified in Agenda 21, special attention should be given to the particular circumstances facing the economies in transition…"[272]

    - "The programme areas that constitute Agenda 21 are described in terms of the basis for action, objectives, activities and means of implementation. **Agenda 21 is a dynamic programme. It will be carried out by the various actors according to the different situations, capacities and priorities of countries and regions in full respect of all the principles contained in the Rio Declaration on Environment and Development**. It could evolve over time in the light of changing needs and circumstances. This process marks the beginning of a new global partnership for sustainable development."[273]
    - Par. 4.2 – "Since the issue of changing consumption patterns is very broad, it is addressed in several parts of Agenda 21, notably those dealing with energy, transportation and wastes, and in the **chapters on** economic instruments and **the transfer of technology**."[274]
    - Par. 4.17(c) – "In the years ahead, Governments, working with appropriate organizations, should strive to meet the following broad objectives:.. c. To reinforce both values that encourage sustainable production and consumption patterns and policies that **encourage the transfer of environmentally sound technologies to developing countries**."[275]

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[269] *See* United Nations Sustainable Development, *Agenda 21*, United Nations Conference on Environment & Development, Rio de Janerio, Brazil (June 3-14, 1992), available at: http://sustainabledevelopment.un.org/content/documents/Agenda21.pdf. See also *Agenda 21*, Organization for Economic Cooperation and Development ("OECD"), Glossary of Statistical Terms, available at: http://stats.oecd.org/glossary/detail.asp?ID=62.
[270] *Id*., at Chap. 1, par. 1.2.
[271] *Id*., at Chap. 1, par. 1.4.
[272] *Id*., at Chap. 1, par. 1.5.
[273] *Id*., at Chap. 1, par. 1.6.
[274] *Id*., at Chap. 4, par. 4.2.
[275] *Id*. at Chap. 4, par. 4.17(c).

- Par. 6.1 – "**Health and development are intimately interconnected. Both insufficient development leading to poverty and inappropriate development resulting in overconsumption, coupled with an expanding world population, can result in severe environmental health problems in both developing and developed nations**. Action items under Agenda 21 must address the primary health needs of the world's population, since they are integral to the achievement of the goals of sustainable development and primary environmental care…"[276]
- Par. 6.7 – "New approaches to planning and managing **health care systems** and facilities should be tested, and research on ways of integrating appropriate technologies into health infrastructures supported. **The development of scientifically sound health technology should enhance adaptability to local needs and maintainability by community resources, including the maintenance and repair of equipment used in health care. Programmes to facilitate the transfer and sharing of information and expertise should be developed**, including communication methods and educational materials".[277]
- Par. 6.41 – "Nationally determined action programmes, with international assistance, support and coordination, where necessary, in this area should include:
  - a. Urban air pollution: i. **Develop appropriate pollution control technology** on the basis of risk assessment and epidemiological research for the introduction of environmentally sound production processes and suitable safe mass transport;"[278]
  - "…b. Indoor air pollution: i. Support research and develop programmes for applying prevention and control methods to reducing indoor air pollution, including the provision of economic incentives for the **installation of appropriate technology**;"[279]
  - "…c. Water pollution: i. **Develop appropriate water pollution control technologies** on the basis of health risk assessment;"[280]
  - "…e. Solid waste: i. **Develop appropriate solid waste disposal technologies** on the basis of health risk assessment;"[281]
  - "…i. Industry and energy production:… iv. **Promote the introduction of environmentally sound technologies within the industry and energy sectors**;"[282]
  - "j. Monitoring and assessment: **Establish, as appropriate, adequate environmental monitoring capacities** for the surveillance of environmental quality and the health status of populations;"[283]
  - "k. Injury monitoring and reduction: i. Support, as appropriate, the **development of systems to monitor** the incidence and cause of injury to allow well-targeted intervention/prevention strategies;…"[284]

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[276] *Id*., at Chap. 6, par. 6.1.
[277] *Id*., at Chap. 6, par. 6.7.
[278] *Id*., at Chap. 6, par. 6.41(a)(i).
[279] *Id*., at Chap. 6, par. 6.41(b)(i).
[280] *Id*., at Chap. 6, par. 6.41(c)(i).
[281] *Id*., at Chap. 6, par. 6.41(e)(i).
[282] *Id*., at Chap. 6, par. 6.4.1(i)(iv).
[283] *Id*., at Chap. 6, par. 6.41(j).
[284] *Id*., at Chap. 6, par. 6.41(k)(i).

- "l. Research promotion and methodology development: i. Support the **development of new methods for the quantitative assessment of health benefits and cost** associated with different pollution control strategies; ii. Develop and carry out **interdisciplinary research on the combined health effects of exposure to multiple environmental hazards**, including epidemiological investigations of long-term exposures to low levels of pollutants and the use of biological markers capable of estimating human exposures, adverse effects and susceptibility to environmental agents."[285]

- Par. 6.44 – "…In the activities listed in paragraph 6.41 (a) to (m) above**,** developing country efforts should be facilitated by **access to and *transfer of technology, know-how and information*, from the repositories of such knowledge and technologies, in conformity with chapter 34**."[286]

- **The following Agenda 21 Chapters refer to the exchange, dissemination, and/or transfer of scientific, technical and other information, data, knowledge, methods, techniques and technologies in furtherance of sustainable development, free of charge or at concession-rate prices**:

  - Chap. 7, pars. 7.39, 7.51(a)(iii), 7.70(d), 7.72; fn#7(e) - (re: promotion of sustainable human settlements);
  - Chap. 8, par. 8.33(c) – (re: integration of environment & development in decision-making);
  - Chap. 9, pars. 9.12(c)-(d), 9.15(b), 9.18(c), 9.24(a) – (re: protection of the atmosphere);
  - Chap. 10, par. 10.17 - (re: planning & management of land resources);
  - Chap. 11, pars. 11.5, 11.17, 11.24, 11.38 – (re: combating deforestation);
  - Chap. 12, par. 12.61 – (re: combating desertification);
  - Chap. 13, par. 13.6(b) – (re: managing sustainable mountain development);
  - Chap. 14, pars. 14.9(e), 14.22(a), 14.26(b), (14.59(a), 14.81, 14.89, 14.93, 14.98 – (re: promotion of sustainable agriculture & rural development);
  - Chap. 15, pars. 15.4(h), 15.7(c)-(d) – (re: conservation of biological diversity);
  - Chap. 16, pars. 16.6(d), 16.7(c), 16.18, 16.19, 16.25, 16.30, 16.38 – (re: environmentally sound management of biotechnology);
  - Chap. 17, pars. 17.2, 17.13, 17.35(d), 17.37, 17.37(f), 17.92(a)-(b), 17.110 – (re: protection of the marine environment);
  - Chap. 18, pars. 18.14, 18.30, 18.79, 18.80(f) – (re: protection of quality/supply and management of freshwater resources)
  - Chap. 19, par. 19.63(b) – (re: environmentally sound management of toxic chemicals & trafficking);
  - Chap. 20, par. 20.13(e), 20.19(a) and (f), 20.31(e) – (re: management of hazardous wastes & trafficking);

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[285] *Id*., at Chap. 6, par. 6.41(l)(i)-(ii).
[286] *Id*., at Chap. 6, par. 6.44.

- Chap. 21, pars. 21.12(a), 21.14(f), 21.23(a)-(c), 21.35(c), 21.46(d) – (re: environmentally sound management of solid wastes & sewage);
- Chap. 22, par. 22.4(c) – (re: safe & environmentally sound management of radioactive waste);
- Chap. 29, par. 29.5 – (re: strengthening the role of workers & trade unions);
- Chap. 30, par. 30.2 – (re: strengthening the role of business & industry);
- Chap. 31, par. 31.4(e) – (re: scientific & technology community);
- Chap. 33, pars. 33.1, 33.15 – (re: financial resources & mechanisms);

- **Chap. 34 – Transfer of Environmentally Sound Technology, Cooperation & Capacity-Building**:

  - Par. 34.3 – "[W]hen discussing transfer of [environmentally sound] technologies, the human resource development and **local capacity-building aspects of technology choices**, including gender-relevant aspects, should also be addressed."[287]
  - Par. 34.4 – "**There is a need for favourable access to and transfer of environmentally sound technologies**, **in particular to developing countries**, through supportive measures that promote technology cooperation and that **should enable transfer of necessary technological know-how as well as building up of economic, technical, and managerial capabilities** for the efficient use and further development of transferred technology…"[288]
  - Par. 34.5 – "The activities proposed in this chapter aim at **improving conditions and processes on information, access to and transfer of technology (including the state-of-the-art technology and related knowhow), in particular to developing countries**, as well as on capacity-building and cooperative arrangements and partnerships in the field of technology, in order to promote sustainable development."[289]
  - Par. 34.7 – "**The availability of scientific and technological information and access to and transfer of environmentally sound technology are essential requirements for sustainable development**."[290]
  - Par. 34.8 – "**The primary goal of improved access to technology information is to enable informed choices, leading to access to and transfer of such technologies** and the strengthening of countries' own technological capabilities."[291]
  - Par. 34.9 – "A large body of useful technological knowledge lies in the **public domain**…[or] are not covered by patents…**Developing countries would also need to have access to the know-how and expertise required for the effective utilization of the aforesaid technologies**."[292]

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[287] *Id*., at Chap. 34, par. 34.3.
[288] *Id*., at par. 34.4.
[289] *Id*., at par. 34.5.
[290] *Id*., at par. 34.7.
[291] *Id*., at par. 34.8.
[292] *Id*., at par. 34.9.

- Par. 34.10 – "**Consideration must be given to the role of patent protection and intellectual property rights along with an examination of their impact on the access to and transfer of environmentally sound technology, in particular to developing countries**, as well as to further exploring efficiently the concept of **assured access for developing countries to environmentally sound technology in its relation to proprietary rights** with a view to developing effective responses to the needs of developing countries in this area."[293]
- Par. 34.11 – "…At the same time that concepts and modalities for assured access to environmentally sound technologies, including state-of-the-art technologies, in particular by developing countries, continue[] to be explored, **enhanced access to environmentally sound technologies should be promoted, facilitated and financed as appropriate**, **while providing fair incentives to innovators** that promote research and development of new environmentally sound technologies."[294]
- Par. 34.14(b) – "The following objectives are proposed…(b) **To promote, facilitate, and finance, as appropriate, the access to and the transfer of environmentally sound technologies and corresponding know-how, in particular to developing countries, on favourable terms, including on concessional and preferential terms**, ***as mutually agreed***, **taking into account the need to protect intellectual property rights as well as the special needs of developing countries** for the implementation of Agenda 21".[295]
- Par. 34.15 – "Existing national, subregional, regional and international **information systems should be developed and linked through regional clearing-houses** covering broad-based sectors of the economy such as agriculture, industry and energy. **Such a network might, inter alia, include national, subregional and regional patent offices** that are equipped to produce reports on state-of-the-art technology. **The clearing-house networks would disseminate information on available technologies, their sources, their environmental risks, and the broad terms under which they may be acquired**…"[296]
- Par. 34.18(a) and (d) – "Governments and international organizations should **promote, and encourage the private sector to promote**, effective modalities for the **access and transfer, in particular to developing countries, of environmentally sound technologies by** means of…
  - (a) Formulation of policies and programmes for the **effective transfer of environmentally sound technologies that are publicly owned or in the public domain**;
  - (d) **Addressing**, in a framework which fully integrates environment and development, **barriers to the transfer of privately owned environmentally sound technologies and adoption of appropriate general measures to reduce such barriers while**

[293] *Id*., at par. 34.10.
[294] *Id*., at par. 34.11.
[295] *Id*., at par. 34.14(b).
[296] *Id*., at par. 34.15.

creating specific incentives, fiscal or otherwise, for the transfer of such technologies."[297]

- Par. 34.18(e) – "In the case of privately owned technologies, [by]…adopt[ing]…measures, in particular for developing countries [that]:..(ii) **Enhance[]…access to and transfer of patent protected environmentally sound technologies**…"; (iii) **Purchase…patents and licences on commercial terms for their transfer to developing countries on non-commercial terms** as part of development cooperation for sustainable development, taking into account the need to protect intellectual property rights"; [OR] (iv) **In compliance with and under the specific circumstances recognized by the relevant international conventions adhered to by States**, the undertaking of measures to **prevent the abuse of intellectual property rights**, **including rules with respect to their acquisition through compulsory licensing**, **with the provision of equitable and adequate compensation**…"[298]

- United Nations General Assembly - *Millennium Declaration* - Resolution 55/2 (Sept. 8, 2000)[299]

  - "The Declaration called for global policies and measures, corresponding to the needs of developing countries and economies in transition."[300] It specifically:

    - "[C]ommitted [the United Nations] to making **the right to development** a reality for everyone and to freeing the entire human race from want",[301] and "resolve[d] to create an environment – at the national and global levels alike – which is conducive to development and to the elimination of poverty."[302]
    - The Declaration also "**reaffirm[ed]…support for the principles of sustainable development, including those set out in Agenda 21**, agreed upon at the United Nations Conference on Environment and Development."[303]
    - The *Millennium Declaration* **set forth 8 goals known as the "Millennium Development Goals"** to be achieved by 2015,[304] which are contained in "Section III – Development & Poverty Eradication":
      - 1. Eradicate extreme poverty & hunger (par. 19);
      - 2. Achieve universal primary education (par. 19);
      - 3. Promote gender equality and empower women (par. 20);
      - 4. Reduce child mortality (par. 19);

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[297] *Id*., at par. 34.18(a) & (d).
[298] *Id*., at par. 34.18(e)(ii)-(iv).
[299] *See* United Nations General Assembly 55th Sess., *Millennium Declaration - Resolution 55/2* (A/RES/55/2 9/8/00), available at: http://www.un.org/millennium/declaration/ares552e.pdf.
[300] *See* United Nations Millennium Declaration, *Millennium Summit of the United Nations* (Sept. 6-8, 2000), available at: http://www.un.org/en/development/devagenda/millennium.shtml.
[301] A/RES/55, *supra* at par. 11.
[302] *Id*., at par. 12.
[303] *Id*., at par. 22.
[304] See *We Can End Poverty – Millennium Development Goals and Beyond 2015*, United Nations, available at: http://www.un.org/millenniumgoals/.

- 5. Improve maternal health (par. 19);
- 6. Combat HIV/AIDS, malaria and other diseases (par. 19);
- 7. Ensure environmental sustainability (par. 20);
- 8. ***Global partnership for development (par. 20).*** **– Technology Transfer:**
  - "**Target 8.E – <u>In cooperation with pharmaceutical companies, provide access to affordable essential drugs in developing countries</u>**".[305]
  - "…**Target 8.F - <u>In cooperation with the private sector, make available benefits of new technologies, especially information and communications"</u>**.[306]

- Millennium Development Goal ("MDG") Gap Task Force[307] 2013 Report on Implementation of MDGs[308]

  - It reflects that:
    - "**Access to affordable essential medicines in developing countries remains costly, insufficiently available and often unaffordable**".[309] "Over and above limited access, patients in developing countries pay relatively high prices for the lowest-priced generic medicines."[310] "Another factor to consider is the difference in prices between originator brand medicines and generic medicines."[311]

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[305] *See Id*., at *Goal 8: Develop a Global Partnership for Development*, available at: http://www.un.org/millenniumgoals/global.shtml.

[306] *Id*.

[307] "The MDG Gap Task Force was created by the Secretary-General of the United Nations following the discussion of the Policy Committee on 1 May 2007 (Decision No. 2007/22) to improve monitoring of the global commitments contained in MDG 8, the Global Partnership for Development. The main purpose of the Task Force is to systematically track existing international commitments and to identify gaps and obstacles in their fulfilment at the international and country level in the areas of official development assistance, market access (trade), debt relief, access to essential medicines and new technologies." *See* United Nations, *MDG Gap Task Force*, available at: http://www.un.org/esa//analysis/mdggap/index.html. "The MDG Gap Task Force integrates more than 20 UN agencies, the International Monetary Fund (IMF), the Organization for Economic Co-operation and Development (OECD), the World Bank and the World Trade Organization (WTO). The Department of Economic and Social Affairs of the United Nations Secretariat (UN/DESA) and the United Nations Development Programme (UNDP) are the lead agencies in coordinating the work of the Task Force." *See* United Nations Department of Economic and Social Affairs ("DESA") Development Policy and Analysis Division, *MDG Gap Task Force - Bodies and Agencies Represented in the MDG Gap Task Force*, available at: http://www.un.org/en/development/desa/policy/mdg_gap/agencies.shtml.

[308] *See* United Nations Department of Economic and Social Affairs, *MDG Gap Task Force Report 2013: The Global Partnership for Development: The Challenge We Face* (2013), available at: http://www.un.org/en/development/desa/publications/mdg-gap-task-force-report-2013.html.

[309] *Id*., at Executive Summary, p. xiv; pp. 59-60. "The average availability of generic medicines in public sector health facilities in the group of sampled countries was 57 per cent (figure 1). In private sector facilities, the average availability was 65 per cent.8 Availability was extremely low in a number of countries." *Id*., at p. 60.

[310] *Id*., at p. 60. "Prices in low- and lower-middle-income countries were, on average, 3.3 times higher than international reference prices (IRPs) in public sector facilities and 5.7 times higher in private sector facilities. *Id*., at pp. 60-61.

[311] *Id*., at p. 61. "In a sample of low- and lower-middle-income countries, it was found that originator brand medicines were priced four times higher than the equivalent lowest-priced generic medicines, on average. The price difference was found to be as much as 18 times higher in the case of Indonesia." *Id*.

- Despite "an explosion in access to information and communication technologies (ICT)", measured by rapid global growth of "mobile cellular subscriptions" and "active mobile broadband subscriptions", and increased "penetration rates in Internet use in developing countries", and although "ICT services continued to become more affordable in 2011…**the difference in costs between developed and developing countries is still substantial**";[312]
- "**More still needs to be done to provide access to new disaster-mitigating technology**…to developing nations…particularly… vulnerable small island developing States."[313]

▪ It recommended that:

- "**Developing-country access to affordable medicines can be facilitated by certain flexibilities in intellectual property rights that are allowed under** the [WTO] Agreement on the Trade-related Aspects of Intellectual Property Rights (**TRIPS**)[314]...**Among the various flexibilities are the issuance of a 'compulsory licence' and authorization for "government use' of the medicine for a public, non-commercial purpose**."[315] "Another way that developing countries may obtain patented medicines at a reduced price is through **'parallel importation'**".[316]
  - Between 2003 and 2012 various developing and emerging economies issued compulsory licenses: Brazil (2007); Ecuador (2010, 2012); India (2012); Indonesia (2004, 2012); Malaysia (2003); Thailand (2007, 2008).[317]
- "**Regulation is essential to increasing access to ICT services**. A regulatory authority can protect the interests of consumers by, for instance, intervening to prevent excessive charging for services. **It can also promote competition by setting**

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[312] *Id*., at p. xv; pp. 74-77.

[313] *Id*. "Attending to environmental needs such as adaptation to and mitigation of the impact of climate change requires the development and transfer of technology to developing countries…Mitigating the impact of disasters also requires access to new technology. *Id*., at pp. 80-81.

[314] *See* Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, The Legal Texts: The Results of the Uruguay Round of Multilateral Trade Negotiations, 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1994) [hereinafter TRIPS], available at: http://www.wto.org/english/docs_e/legal_e/27-trips.pdf.

[315] *See* United Nations Department of Economic and Social Affairs, *MDG Gap Task Force Report 2013: The Global Partnership for Development: The Challenge We Face* (2013), *supra* at p. 65. "Under compulsory licensing, the patent-issuing Government must permit a third party, which could be a government agency, to produce or import a patented medicine without the permission of the patent holder. Usually, that party should first attempt to negotiate a voluntary licence with the patent holder, but this requirement does not apply in the case of a national emergency or when intended for public non-commercial use. In either case, the patent holder is entitled to 'adequate remuneration' for the authorized use of their innovation…To accommodate countries that do not have local production capacity, WTO members agreed to establish the so-called Paragraph 6 System, which allows generic medicines to be produced under compulsory licences exclusively for export to countries lacking domestic production capacity." *Id*.

[316] *Id*. "This can occur when a country has adopted a regime of 'international exhaustion', in which case the patent holder's distribution right in that country is exhausted regardless of where the first distribution took place. Thus, the patent holder cannot prevent the further importation and sale of medicines at a reduced price." *Id*.

[317] *Id*., at Table 1, p. 67.

minimum prices to prevent the dominance of some providers or set rules to allow subscribers to keep their mobile number when switching providers."[318]

- Governments should live up to their commitments to fund "the **Climate Technology Centre and Network (CTCN)**, the implementing arm of the 'Technology Mechanism' that had been agreed upon in 2010 as a means to focus international support for technological development for climate mitigation and adaptation. [319]...It **aims at accelerating the transfer of climate-related technology and expertise to developing countries** and expanding international partnerships to accelerate the diffusion of environmentally sound technologies."[320]

- United Nations Commission on Sustainable Development (CSD)[321] World Summit on Sustainable Development ("Johannesburg Summit", Jan. 2002)[322] Report:[323]

  - Johannesburg Declaration on Sustainable Development:[324]

    - "Reaffirm[ed the world's] "commitment to sustainable development."[325]
    - "…[R]ecognize[d] that poverty eradication, changing consumption and production patterns and protecting and managing the natural resource base for economic and social development are overarching objectives of and essential requirements for sustainable development."[326]

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[318] *Id*., at p. 79.

[319] *See* United Nations Framework Convention on Climate Change Conference of the Parties ("COP") 16th Sess., *Report of the Conference of the Parties, Addendum Part Two: Action taken by the Conference of the Parties* FCCC/CP/2010/7/Add.1 (Nov. 29-Dec. 10, 2010) at pars. 117-127, available at: http://unfccc.int/resource/docs/2010/cop16/eng/07a01.pdf#page=20. "The Climate Technology Centre and Network (CTCN) is the operational arm of the UNFCCC Technology Mechanism and it is hosted and managed by UNEP in collaboration with UNIDO and with the support of 11 Centres of Excellence located in developing and developed countries." *See* United Nations Development Programme, *Climate Change Technology Centre & Network – About Us*, available at: http://www.unep.org/climatechange/ctcn/AboutCTCN/tabid/106203/language/en-US/Default.aspx.

[320] *See* United Nations Department of Economic and Social Affairs, *MDG Gap Task Force Report 2013: The Global Partnership for Development: The Challenge We Face* (2013), supra at p. 81.

[321] "The United Nations Commission on Sustainable Development (CSD) was established by the UN General Assembly in December 1992 to ensure effective follow-up of United Nations Conference on Environment and Development (UNCED), also known as the Earth Summit." *See* United Nations Sustainable Development Knowledge Platform, *Commission on Sustainable Development*, available at: http://sustainabledevelopment.un.org/csd.html; *About the CSD*, available at: http://sustainabledevelopment.un.org/index.php?menu=1673. *See also* United Nations General Assembly, Forty-seventh Session, *Resolution 47/191 - Institutional Arrangements to Follow up the United Nations Conference on Environment and Development*, U.N. DOC A/RES/47/191 (Jan. 29, 1993), available at: http://www.un.org/documents/ga/res/47/ares47-191.htm.

[322] *See* United Nations Commission on Sustainable Development, *Johannesburg Summit 2002*, available at: http://www.un.org/jsummit/html/basic_info/basicinfo.html.

[323] *See* United Nations, *Report of the World Summit on Sustainable Development*, A/CONF.199/20 (Johannesburg, South Africa, Aug. 26-Sept. 4, 2002), available at: http://www.un.org/jsummit/html/documents/summit_docs/131302_wssd_report_reissued.pdf.

[324] *Id*., at Annex, pp. 1-5.

[325] *Id*., at par. 1.

[326] *Id*., at par. 11.

- "…[U]ndert[ook] to strengthen and improve governance at all levels for the effective implementation of Agenda 21, the Millennium development goals and the Plan of Implementation of the Summit."[327]
- "…[R]eaffirm[ed the] commitment to the principles and purposes of the Charter of the United Nations and international law, as well as to the strengthening of multilateralism [,and] support [of] the leadership role of the United Nations as the most universal and representative organization in the world, which is best placed to promote sustainable development."[328]

- Plan of Implementation of the World Summit on Sustainable Development (adopted by resolution)

  - "…The **Convention…on Biological Diversity**…is the key instrument for the conservation and sustainable use of biological diversity and the **fair and equitable sharing of benefits arising from use of genetic resources**. A more efficient and coherent implementation of the three objectives of the Convention and the achievement by 2010 of a significant reduction in the current rate of loss of biological diversity will require the provision of new and additional financial and technical resources to developing countries, and includes actions at all levels to:…(p) **Encourage successful conclusion of existing processes under the auspices of the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore of the World Intellectual Property Organization**, and in the ad hoc open-ended working group on article 8 (j) and related provisions of the Convention;"[329]
  - "…(r) With a view to enhancing synergy and mutual supportiveness, taking into account the decisions under the relevant agreements, **promote the discussions**, without prejudging their outcome, **with regard to the relationships between the Convention and agreements related to international trade and intellectual property rights, as outlined in the Doha Ministerial Declaration**;"[330]
  - "…X. Means of [I]mplementation…100. Address the public health problems affecting many developing and least developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics, while noting the importance of the Doha Declaration on the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) and public health, in which it was agreed that the TRIPS Agreement does not and should not prevent WTO members from taking measures to protect public health. **Accordingly, while reiterating our commitment to the TRIPS Agreement, we reaffirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all**."[331]

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[327] *Id*., at par. 30.
[328] *Id*., at par. 32.
[329] *Id*., at *Annex - Plan of Implementation of the World Summit on Sustainable Development*, par. 44(p).
[330] *Id*., at par. 44.
[331] *Id*., at par. 100.

ii. United Nations Secretariat[332]

- Department of Economic and Social Affairs (UNDESA)[333]

  - Post-Rio+20[334] United Nations Conference on Sustainable Development Study, *Transition to a Green Economy: Benefits, Challenges and Risks from a Sustainable Development Perspective* (2012):[335]

    - "The available evidence indicates that most innovation in climate mitigating technology does take place in **industrial countries** and that, therefore, firms from those countries **are the main holders of intellectual property rights**, but a number of major developing country firms (from Brazil, China and India, in particular) have already gained some market share in new technologies."[336]
    - "…[**G]iven the fact that most developing countries will be technology followers**, **there is a need to develop global institutional arrangements that increase international cooperation and collaboration on research and development** in all areas relevant for green growth, and **accelerate the spread of those technologies to developing countries**."[337]
    - "[T]here is a need to **increase international cooperation and collaboration on research and development in all areas relevant for green growth, and accelerate the transfer of those technologies to developing countries through open innovation systems**, publicly financed innovations, as well as global demonstration programs,

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[332] "The Secretariat — an international staff working in duty stations around the world — carries out the diverse day-to-day work of the Organization. It services the other principal organs of the United Nations and administers the programmes and policies laid down by them. *At its head is the Secretary-General, who is appointed by the General Assembly on the recommendation of the Security Council for a five-year, renewable term*. The duties carried out by the Secretariat are as varied as the problems dealt with by the United Nations. These range from administering peacekeeping operations to mediating international disputes, from surveying economic and social trends and problems *to preparing studies on human rights and sustainable development*" (emphasis added). *See* United Nations, *Secretariat*, available at: https://www.un.org/en/mainbodies/secretariat/.

[333] "Specifically, DESA is tasked with supporting deliberations in two major UN charter bodies: the UN General Assembly and UN Economic and Social Council (ECOSOC), as well as ECOSOC's subsidiary bodies. In this regard, DESA's main priorities are promoting progress toward and strengthening accountability in achieving UN development goals. Furthermore, DESA is responsible for ensuring civil society engagement with the UN by way of the ECOSOC body. DESA is also the lead 'author' Department of the UN Secretariat. Our research and analytical work covers a range of economic, social and environmental issues." See United Nations Department of Economic and Social Affairs, *About Us*, available at: http://www.un.org/en/development/desa/what-we-do.html.

[334] *See* United Nations website, *What is "Rio+20"?*, available at: http://www.un.org/en/sustainablefuture/about.shtml.

[335] *See* UNDESA DSD, UNEP, UNCTAD, *Transition to a Green Economy: Benefits, Challenges and Risks from a Sustainable Development Perspective*, Report by a Panel of Experts to Second Preparatory Committee Meeting for United Nations Conference on Sustainable Development (2012), available at: http://www.uncsd2012.org/content/documents/Green%20Economy_full%20report%20final%20for%20posting%20clean.pdf.

[336] *See* José Antonio Ocampo, *Summary of Background Papers*, in *The Transition to a Green Economy: Benefits, Challenges and Risks from a Sustainable Development Perspective*, supra, at p. 9.

[337] *Id*.

knowledge-sharing platforms, and a **global database on freely available technologies** and **best practices in licensing**."[338]

- "[A]n important measure ***to promote sustainable development*** is to **expand the space for technologies in the public domain, and to stimulate the transfer to developing countries of publicly-funded technologies. Industrial countries should influence the flow of such technologies directly, or through *requiring* the private sector and public institutes that receive R&D funding from government to be more active in transferring technologies to developing countries**."[339]
- "***A delicate balance must be struck* between these advantages and the costs that IPRs have for technologically-dependent countries**. For this reason, **the three contributions call for reforms of the global intellectual property regime that would:**
  - **[I]nclude broader room for compulsory licensing (replicating this and other aspects of the WTO Doha 2001 agreement on IPRs and public health)**[;]
  - **[S]trengthen patenting standards (particularly standards of breadth and novelty)**[;]
  - **[L]imit the length of patent protection**[;] and
  - **[A]llow innovators to use existing patented knowledge to generate new innovations**."[340]
- "[T]he key question with respect to the green economy is how…[intellectual property rights (IPRs)]…might help or hinder countries to gain access to cleaner technologies…So **the key goal is *balance*** – finding **the point at which [IPR] protection manages to provide incentives to innovate, but does not overly restrict dissemination and further innovation**."[341]
- In the interests of growing national innovative cultures that help push the global community toward a green economy, **IPR regimes should be tailored to countries' development status**…It can be argued, though, that **even at low levels of development IPRs play an important role. They may result in more imports of high-tech goods** that, in themselves, represent technology transfer – goods that exporters would be reluctant to export to countries with weak IP protection. Similarly, they **might result in increased incidence of firm-to-firm licensing of technologies**, which in its own way results in increased domestic technological capacity. The downside is that **strong IPRs at the same time will tend to wipe out low-tech innovators that rely on imitation**. **Again a *delicate balance* must be struck**."[342]

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[338] *See* José Antonio Ocampo, The Macroeconomics of the Green Economy, in *The Transition to a Green Economy: Benefits, Challenges and Risks from a Sustainable Development Perspective*, supra, at p. 34.
[339] *See* José Antonio Ocampo, *Summary of Background Papers*, in *The Transition to a Green Economy: Benefits, Challenges and Risks from a Sustainable Development Perspective*, supra, at pp. 9-10.
[340] *Id*., at p. 10; José Antonio Ocampo, The Macroeconomics of the Green Economy, in *The Transition to a Green Economy: Benefits, Challenges and Risks from a Sustainable Development Perspective*, supra, at pp., 26, 34.
[341] *See* Aaron Cosbey, *Trade, Sustainable Development and a Green Economy: Benefits, Challenges and Risks*, in *The Transition to a Green Economy: Benefits, Challenges and Risks from a Sustainable Development Perspective*, supra, at p. 45.
[342] *Id*., at p. 46.

- "[T]he **length of patent protection** is obviously a key issue. **Many IP provisions in modern free trade agreements go beyond WTO provisions** to provide for longer protection periods.
- **Scope** is also important – **some national patent regimes allow firms to use broad 'gateway' patents that can strategically block competitors from lucrative (and publicly valuable) lines of innovation**. "Stacking" multiple patents around various aspects of a single innovation has the same prohibitive effect."[343]

▪ "**All of this is well understood in the context of pharmaceutical patents**, which have been the subject of a great deal of analytical work, and for which WTO members have gone so far as to explicitly confirm the TRIPS Agreement's flexibilities. But **it is important to note the differences between pharmaceuticals and industrial patents in environmentally sound technologies**."[344]

- "Barton (2009) argues that while IPRs offer developers of particular medicines a solid monopoly on their products, **innovators in the area of wind power, biofuels and solar PV have many competitors to whom buyers can go for similar products, decreasing the power of patents to block affordable access**. This assumes, of course, that innovators will actually license their technologies. What limited evidence we have from clean energy technologies seems to indicate a willingness to licence more or less in line with that found in other sectors."
  - **NOTE**:** Not all holders of standard essential patents will be willing to license their patents at concessional royalty rates or free-of-charge.[345]

▪ "Beyond support to developing countries in meeting the challenges of a green economy, there are ways in which **international cooperation or agreement is needed** to allow the global community to move toward green economic growth:

- …Agreement on a concerted effort to 'oil the innovation chain' – to get new technologies more quickly to market. This might include global demonstration programs; support for open innovation programs and **national commitments to make public research common intellectual property**; international R&D cooperation; publicly backed patent pools; support for financing, etc. • **Agreement that IPR regimes, including TRIPS, should be sensitive to the country's level of development**, respecting the reality that strong national-level innovative capacity is in the global interest."[346]
- "The need for policy space, the role of intellectual property rights and international investment agreements, subsidies, investment incentives – these are all well-trodden roads of discourse."[347]

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[343] *Id*.
[344] *Id*., at p. 47.
[345] *See, e.g.*, Lawrence A. Kogan, *The Complementarity of Patents and Standards*, presented as Part 1–of the Panel on the Intersection of IP, Competition and International Trade, at The Inter-Pacific Bar Association 21st Annual Meeting & Conference (Kyoto, Japan, Apr. 24, 2011), Unabridged Outline, at 10–20, available at: http://nebula.wsimg.com/15dccc68de075cc70e0d80f74711c8eb?AccessKeyId=39A2DC689E4CA87C906D&disposition=0&alloworigin=1.
[346] *Id*., at p. 59.
[347] *Id*., at p. 60.

- "**A central aspect of technology development and transfer is** the building of local capacity to design and make technologies. Developing countries should be given the chance to climb the technological ladder from the initiation stage, where technology as capital goods are imported; to the internalisation stage, where local firms learn through imitation under **a flexible intellectual property rights regime**; and the final generation stage, where local firms and institutions innovate through their own research and development (UNCTAD 2007). **Whether IPRs constitute a barrier to technology transfer** depends on factors such as whether or not the particular technology is patented, whether there are viable and cost effective substitutes or alternatives, the degree of competition, the prices at which it is sold, and the degree of reasonableness of terms for licensing."[348]
- "…**Agenda 21 (chapter 34, paragraph 34.18a)** that "governments and international organisations should promote the formulation of policies and programmes for the effective transfer of environmentally sound technologies that are publicly owned or in the public domain." **Products that emerge from publicly funded R & D should be placed in the public domain. Those that are partially funded should be in the public domain to the extent to which it is publicly funded**."[349]
- "***For technologies that are patented***, there should be an understanding that patents should not be an obstacle to developing countries' access. **Agenda 21 (para 34.10)** states that:
  - '**Consideration must be given to the role of patent protection and intellectual property rights** along with an examination of their impact on the access to and transfer of environmentally sound technology, in particular to developing counties, as well as to further **exploring efficiently the concept of assured access for developing countries to environmentally sound technology in its relation to proprietary rights** with a view to developing effective responses to the needs of developing countries in this area.'"[350]
- "**Agenda 21 (para 34.18e)** also agreed that in the case of **privately owned technologies**, measures would be adopted particularly for developing countries, including developed countries creating incentives to their companies to transfer technology; purchase of patents and licenses for their transfer to developing countries; **prevention of the abuse of IPRs including through compulsory licensing with compensation**; providing funds for technology transfer; and developing mechanisms for technology access and transfer."[351]
- "**Under the TRIPS Agreement, there is considerable flexibility provided to WTO member states to grant compulsory licenses, and the grounds to do so are not restricted**.

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[348] *See* Martin Khor, *Challenges of the Green Economy Concept and Policies in the Context of Sustainable Development, Poverty and Equity*, in *The Transition to a Green Economy: Benefits, Challenges and Risks from a Sustainable Development Perspective*, supra, at pp. 86-87.
[349] *Id*., at p. 87.
[350] *Id*.
[351] *Id*., at pp. 87-88.

- **In developed countries**, there have been **many compulsory licenses** granted by the government **to facilitate cheaper products and technology** in the industrial sector.
- In many developing countries, **compulsory licenses have been issued for the import or local production of generic drugs**. Thus, **compulsory licensing is an option particularly when the patent-holder is unwilling to provide a voluntary license with reasonable conditions**."[352]

- "Some developing countries [had] previously **proposed at the WTO** that **countries be allowed not to patent environmentally-sound technology** so that its transferred and use can be facilitated. **The relaxation of the TRIPS rules in the case of climate-related technologies has also been proposed** by developing countries **in the UNFCCC**;[353] **however this was opposed by major developed countries**."[354]
- "In particular, greater financial resources can be made available to developing countries through…**a more development-oriented intellectual property system**…The treatment of the 'green economy' in Rio Plus 20 should be **consistent with the sustainable development concept**, principles and framework, and care should be taken that it does not detract or distract from 'sustainable development'".[355]
- ***Cf.* WTO Secretariat Contribution to Rio+ 20 Conference** concerning available WTO-consistent technology transfer and finance mechanisms:[356]
  - "The body of multilateral environmental law and policy instruments since the Rio Earth Summit 1992 addresses the role of technology in meeting environmental challenges in several ways, for instance…Agenda 21…Desertification Convention…the UNFCCC…the Convention on Biological Diversity…the Rio+20 outcome document (A/CONF.216/L.1)."[357]
  - "…**2. The role of patents and other IPRs in the innovation and diffusion of green technology - Green technologies**, particularly those relevant to the MEAs, **can be considered to be global public goods** since, in principle, the entire world can benefit from existing innovations as well as incentives to innovate given in any one part of the world. **The classical characteristics of a public good are non-excludability and non-rivalry. In the case of public goods, the problem is chronic underinvestment**

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[352] *Id*., at p. 88.
[353] *Id*.
[354] *Id*. *See* Lawrence A. Kogan, *Climate Change: Technology Transfer or Compulsory License?*, presented at The American National Standards Institute (ANSI) Monthly Caucus Luncheon, National Press Club (Wash., DC, Jan. 15, 2010), available at: http://nebula.wsimg.com/ca97555d1e891856a629c7089655e054?AccessKeyId=39A2DC689E4CA87C906D&disposition=0&alloworigin=1. *See also* Lawrence A. Kogan, *Commercial High Technology Innovations Face Uncertain Future Amid Emerging 'BRICs' Compulsory Licensing and IT Interoperability Frameworks*, 13 San Diego Intl. L.J. 201, 235-240 (2012), supra (discussing efforts undertaken between 2007 and 2010 by developing countries at the UNFCCC Secretariat to ensure that developed country UNFCCC Parties ensure transfer of environmentally sensitive technologies by means, if necessary, of compulsory license, which efforts ultimately failed).
[355] *Id*., at p. 93.
[356] *See* WTO Rio + 20 Conference, *WTO Secretariat Contribution Regarding a "Facilitation Mechanism that Promotes the Development, Transfer and Dissemination of Clean and Environmentally Sound Technologies"* (2012) available at: http://sustainabledevelopment.un.org/content/documents/1243wto.pdf.
[357] *Id*., at p. 1.

in their creation if markets are left to themselves, as they would fail to produce them in socially optimal quantities."[358]

- "…**Patents and some other relevant IPRs** restrict the use, reproduce and distribute new inventions, generally for a limited period of time and/or under certain conditions. This **helps inventors appropriate for themselves at least part of the social benefit of their innovations**, thus providing an incentive to invest in R&D toward the generation of green technologies."[359]
- "…**Patents also have transactional value** as they are useful instruments in obtaining initial finance (venture capital), as well as in agreeing to licences and other forms of contracts relating to technology sharing arrangements, including in patent pools. It is in this latter way **that patents on green inventions tend to be used as the business model is usually not one of exclusive production with the patent owner as the sole supplier, unlike in the pharmaceutical sector**. **Hence analogies with the access to medicines debate may well be misguided**…"[360]
- "…**Patents are granted separately in each jurisdiction and rights are independent of each other. This means that a patent granted in one country conveys no rights in any other country. Therefore, if no patent is applied for or granted in a particular jurisdiction, there are no restrictions on making, using or selling the patented technology in that jurisdiction**. Consequently, **in the great majority of developing countries and least-developed countries, much 'patented' green technology is likely already to be in the public domain, i.e. free to be used without legal constraint (provided there are no regulations, such as environmental laws, that prevent its use)**. Patent exceptions can allow some use of the invention before the patent expires: for example a research exception allows further innovation or use by governments or others for public interest reasons."[361]
- "…**Trade secrets** protect information of commercial value that is likely to be diminished by disclosure, and **includes the know-how to produce a particular product or use a certain process**. Trade secrets do not have a limited duration but are only protected against theft or other unfair means to obtain them and not against independent discovery. **The most relevant IPRs for the purposes of this section are perhaps patents and trade secrets, as these are considered crucial to the generation and effective transfer of technology**. In the area of climate adaptation technologies, patents or plant variety protection for climate-tolerant crops could be important. Indeed, much of the empirical work done so far focuses in the area of patents."[362]
- "…[**M]odels for collaborative innovation and shared technological platforms to support innovation…have typically been developed on a voluntary basis**, by technology holders who realize that the benefits of pooling technologies from several

[358] *Id*., at p. 2.
[359] *Id*.
[360] *Id*., at p. 3.
[361] *Id*.
[362] *Id*.

sources outweigh any immediate advantage of closely restricting access to their technology…A cluster of broadly similar concepts have been put forward:

- **'[O]pen source'** originated from a software development model that ensures access to the human-readable 'source code', and permits others to use and adapt the software, and to redistribute it, whether or not it is modified.
- …**'[O]pen innovation'** refers to a broader set of innovation models, emphasizing the interest of many firms in seeking synergies and collaboration with other actors working on related technologies, as opposed to closed innovation which would emphasize firm boundaries between rival companies.
- …**'[C]ommons-based peer production'** refers to the development of new products through widespread collaborative networks without a formal hierarchy, often brought about by a sense of collective purpose…
- …**'[D]istributed innovation'** refers to the development of innovative products through collective efforts in networks spanning different organizations, institutions or individuals."[363]
- "…[B]eyond the analysis of specific innovation models, **the debate over green technology has also gone to the heart of the *balance* of private incentive and public interest that defines the patent system**, particularly as to **whether the general rules set by TRIPS**, and the choices countries make in implementing them in practice, **have enough flexibility to allow for widespread access to innovative environmentally friendly technologies to all who need them**, with issues touching both on practical availability and the affordability of such technologies."[364]

- "**Three broad views are expressed in this debate**:
  - [1] a sense that **the existing system, while far from perfect, has worked reasonably well** given the right economic and regulatory settings, and can be made to work better with improved transparency tools and easier matching of supply and demand of technologies;
  - [2] **a critical approach that has led to some calls for patents to be excluded or revoked altogether** on certain green technologies or technologies on genetic materials; and
  - [3] **a view**, expressed for instance by some participants in the UNFCCC climate change negotiations, **that specific interventions are needed, as was done in 2001 for access to medicines in the Doha Declaration on TRIPS and Public Health**, so as to bolster or even expand the range of options countries have to leverage access to green technologies."[365]
  - **"3. TRIPS provisions relevant to IP and green technology**:
    - …**Article 7**…reflects the search for a ***balanced approach*** to IPR protection in the societal interest, taking into account the interests of creators and inventors and the interests of users of technology.

[363] *Id*., at p. 4.
[364] *Id*., at pp. 4-5.
[365] *Id*., at p. 6.

- **Article 8** also recognizes the right of WTO Members to adopt measures, to protect, inter alia, the public interest in sectors of vital importance to their socio-economic and technological development, provided those measures are consistent with TRIPS (for instance, in not being discriminatory). This provision also recognizes that Members may need to take appropriate measures (again provided they are TRIPS-consistent) 'to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology.'"[366]
- "**The *most relevant* TRIPS standards for the protection and dissemination of green technology** are to be found in **Section 5 (on patents) and Section 7 (on undisclosed information)** in Part II of the TRIPS Agreement.
  - **Article 27.1** – obliges "WTO Members…to **make patents available to applicants for any invention, whether product or process, in all fields of technology, provided three criteria are met**, namely that the invention is **new, non-obvious** or involves an inventive step and is **useful** or industrially applicable. Some exclusions to this rule are permitted, but are not required. WTO Members are further obliged **not to discriminate in the availability of patents or in the enjoyment of patent rights on the basis of field of technology**, place of invention or whether products are imported or locally produced. For example, this standard would preclude Members from legislating blanket exceptions for inventions pertaining to designated fields of environmental technologies."[367]
  - **Article 27.2** – "specifically mentions inventions that are **contrary to** human, animal or plant life or health or seriously **prejudicial to** the environment. However…**the use of this exception is subject to the condition that the commercial exploitation of the invention must be prevented and that this prevention must be necessary for the protection of ordre public or morality**. This provision does not allow exclusions, on environmental or other public policy grounds, from patent grant for inventions that are beneficial or desirable and that are actually permitted to be commercially exploited in a Member's jurisdiction."[368]
  - **Article 30** – "recognizes that Members may allow **limited exceptions to the exclusive rights** conferred by a patent [e.g., those that cover the use of the patented invention for private, non-commercial purposes and for research or experimental purposes…"[369]
  - **Article 31** – "**covers both compulsory licences granted to third parties for their own use, and use by or on behalf of governments without the consent of the right holder**…subject to conditions aimed at protecting the

[366] *Id*.
[367] *Id*., at pp. 6-7.
[368] *Id*., at p. 7.
[369] *Id*.

legitimate interests of the right holder that are detailed in Article 31…No restrictions are specified on the grounds for the grant of compulsory licences by national authorities, but…[a]s a general rule, an unsuccessful attempt must have first been made to obtain a voluntary licence on reasonable commercial terms and conditions within a reasonable period of time before a compulsory licence is granted…[except in cases of]…national emergencies or other circumstances of extreme urgency…(Article 31(b))…[I]n in this context, the term does not refer to the substantive grounds for issuing the compulsory license [and t]he right holder is to be paid adequate remuneration (Article 31(h)) and licences are to be predominantly for the supply of the domestic market of the Member authorizing such use (Article 31(f)).”[370]

- **Article 39.2** – “**sets out general obligations with respect to undisclosed information that cover both trade secrets and test data**, under the rubric of giving effect to Article *10bis* of the Paris Convention (a general provision on the suppression of unfair competition, which is itself incorporated into the TRIPS Agreement). Test data includes for example field trial data on the environmental impact of new pesticides and could be relevant to green technology. However, more relevant are trade secrets, including tacit know-how, which are protected against acquisition through dishonest commercial practices…[This provision]… **obliges Members to protect information that is secret, has commercial value because it is secret, and has been subject to reasonable steps to keep it secret**.”[371]

▪ “[**T]he effective impact of patents on innovation and technology diffusion is** not **determined predominantly by** the bare existence or otherwise of a patent but rather on **the way in which green innovators choose** to file for and then **to exercise patent rights**…**There are a range of regulatory interventions that can shape how patent rights are used** in the marketplace, including[:]

- **curbs on anticompetitive or otherwise inappropriately restrictive licensing practices**[;]
- **exceptions to patent rights** to permit legitimate research and use of technologies for regulatory purposes; and
- **compulsory licences and government use orders** to permit third parties to use technologies when the public interest dictates this need.”[372]

- **There are also “voluntary and collaborative mechanisms** to promote the use of patent rights, once granted, to further the uptake of green technologies[:]
  - **Patent commons**…allow technology holders to pledge their patented technologies for widespread use for **little or no royalty payment**, usually subject

[370] *Id*.
[371] *Id*., at p. 8.
[372] *Id*., at pp. 9-10.

to certain general conditions (for instance, agreement not to enforce rights over technologies resulting from access to the commons).

- **…Patent pools**…[in which]… participating patent holders agree to license their technologies to one another – some are termed 'joint licensing schemes'. Usually the technology is in a well-defined field, or specific patents may be identified.
- **…Licences of right** [which i]n some countries [e.g., the UK]…provides for a reduction in official fees for patent holders who agree to make their patented technology available to anyone requesting a license, **subject to terms that can be negotiated or determined by the authorities**.
- …**Non-assertion pledge or covenant**…[engender] patent holders…choos[ing] to make their technology widely available by legally **pledging not to assert their patent rights against anyone using the technology**.
- …**Humanitarian or preferential licensing**…[which] **provides highly favourable or free terms to certain beneficiaries**, for example, low income developing country recipients, social marketing programs or public sector/philanthropic initiatives.
- **Public-Private Partnerships**…[which] may include ex-ante arrangements on **maintaining IPRs in rich countries, while restricting them in poorer countries**, **or requiring access guarantees** for such countries.
- **…Placing in public domain**…[wherein]…**technologies are patented in a relatively small number of countries**, effectively placing them in the public domain in all other countries as soon as the patent applications are published."[373]

- United Nations Secretary-General[374]

  - **UN System Task Team on the Post-2015 UN Development Agenda** - Report: *Science, Technology and Innovation and Intellectual Property Rights: The Vision for Development* - Thematic Think Piece (May 2012)[375]

    - "Creativity and innovation are a natural resource in which every country and every community is potentially rich. **Intellectual property provides a policy framework that can enable these intangible resources to be transformed into sustainable development assets through the protection and promotion of creativity and innovation**."[376]
      - "**A major challenge for many developing countries** seeking to strengthen productive capacity, and to invest in private sector development and competitiveness

[373] *Id*., at pp. 10-11.
[374] *See* United Nations, *Secretariat*, supra; See also United Nations Secretary-General Ban-Ki Moon, *The Role of the Secretary-General*, available at: http://www.un.org/sg/sg_role.shtml.
[375] See *UN System Task Team on the Post-2015 UN Development Agenda*: *Science, Technology and Innovation and Intellectual Property Rights: The Vision for Development* - Thematic Think Piece (May 2012) available at: http://www.un.org/en/development/desa/policy/untaskteam_undf/thinkpieces/11_ips_science_innovation_technology.pdf.
[376] *Id*., at p. 4.

is the need to strengthen national innovation capacity. **Part of the solution to that lies in using the intellectual property (IP) system for the protection and promotion of domestic creations, innovations and inventions, for attracting foreign direct investments and, hence, contributing to the transfer of technology**, and to support the development of national scientific and technological infrastructure."[377]

- "In addressing the challenge of growth, productivity and job creation, policy makers are looking to create an enabling innovation eco-system where enterprises can be formed, flourish and ultimately expand. Small and Medium Size Enterprises (SMEs), are prime candidates for rapid creation and expansion…**While many factors play a role in ensuring the competitiveness of SMEs, evidence shows that effective use of intellectual property is an indicator of success**."[378]

- "There is evidence that **a *balanced and transparent* legal and administrative framework of intellectual property protection may provide a key incentive for innovation, investment and knowledge transfer** in many different circumstances and in agriculture in particular, for both, the public and the private sectors."[379]
- "Specifically, **access to essential medicines** as an aspect of the right to health has been an active concern over the last fifteen years, but the **policy focus has broadened to consider health 'systems': how to promote necessary innovation; address neglected health needs; and ensure access to vital medical technologies, such as diagnostic tools and modern vaccines**."[380]
- "The intellectual property (IP) system, and in particular the patent system, can play a pivotal role in relation to health-related development objectives as an incentive for innovation in the pharmaceutical field and as a policy tool to facilitate technology diffusion and access to essential drugs. Conversely, **poorly structured IP systems, with an inappropriate balance between innovation and access**, **can hamper the ability of governments to deliver one of their primary development objectives, safeguarding the health of their populations**."[381]
- "A pervasive remaining challenge in the post-2015 world will be the difficulty in **shifting the installed fossil-fuelled technological base towards a base of environmentally sound technologies in a manner which supports the three pillars of sustainable development**: economic, social and environmental development. **This shift to a new technology base requires policies that not only incentivize investments in R&D, but which also support the transfer, adaptation and widespread dissemination of these technologies.**"[382]
- **Possible ways to include science, technology and innovation and intellectual property systems** - Science, technology and innovation has a…supporting role to play in

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[377] *Id*., at p. 5.
[378] *Id*., at pp. 5-6.
[379] *Id*., at p. 6.
[380] *Id*., at p. 7.
[381] *Id*.
[382] *Id*., at p. 8.

advancing international ambitions on global growth, environment, food security, health and a variety of other public policies including disaster risk reduction. For that reason, **including specific targets with respect to science, technology and innovation, as part of broader public policy goals would present the most appropriate way ahead..**.The United Nations Secretary-General's High Level Panel on Global Sustainability has recommended 'a better interface between policymakers and the scientific community, which, in turn, can contribute to a deeper understanding of the causes and impacts of sustainable development and point to innovative and effective ways of addressing them'".[383]

- Among other things the High Level Panel recommends the **"[p]romot[ion of] access to information and communication technologies and support regulatory reform by government communication regulators** in order to create sustainable private/public partnerships that will encourage ICT investment and growth."[384]

- "More broadly, **within the UN family and the wider international community there has been, and will continue to be, a debate on *the appropriate role for intellectual property systems*, and how to *balance* the incentive to create and innovate with the need to share the fruits of creativity**."[385]
- "The *Millennium Project Task Force on Science, Technology and Innovation* sets out the contribution that can be made to human welfare, energy, health, water and sanitation, as well as political stability and global security."[386]
  - "**Protecting intellectual property rights is a critical aspect of technological innovation. But overly protective systems could have a negative impact on creativity**. It is therefore important to **design intellectual property protections systems that take the special needs of developing countries into account**. Provisions in international intellectual property agreements that provide for technology cooperation with developing countries need to be identified and implemented immediately."[387]
  - "To encourage innovation and unlock local capital, individuals and corporations need to feel that their research is protected; **where intellectual property rights have been violated, compensation must be provided. However, most countries developed without these protections being structured across the economy in any clear way**."[388]
  - "**One way of adjusting intellectual property rights based on a country's level of development would be to create a three-tier system**. **Tier A countries would be required to comply with all provisions of TRIPS, including the legal framework**

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[383] *Id*., at p. 10.
[384] *Id*., at p. 11.
[385] *Id*., at p. 12.
[386] *Id*.
[387] *See* Calestous Juma and Lee Yee-Cheong, UN Millennium Project 2005 - *Innovation: Applying Knowledge in Development*, Task Force on Science, Technology, and Innovation, United Nation Development Program (2005), at p. 112, available at: http://belfercenter.ksg.harvard.edu/files/tf-advance2.pdf.
[388] *Id*.

and "effective enforcement," as required under Article 41. Developing countries with per capita GDP of, say, more than $5,000 would fall into this category (alternatively, an export criterion could be used). **Tier B** could apply to countries with per capita GDP of $1,000–$5,000. These **countries would adopt the full legal framework required under TRIPS, perhaps with some minimal level of enforcement**. Countries with per capita GDP of less than $1,000 (**Tier C countries) would establish the legal framework required under TRIPS, perhaps with the exception of patent laws and protections for integrated circuits**."[389]

- "The TRIPS agreement represents an important step in establishing minimum standards for national laws governing intellectual property protection…**The need to strike a *balance* between enforcing intellectual property rights and meeting the technological needs of developing countries** became a key theme in the Uruguay Round of negotiations. **Article 8 of TRIPS** states that countries 'may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and **to promote the public interest in sectors of vital importance to their socioeconomic and technological development**, provided that such measures are consistent with the provisions of this Agreement.'"[390]
- "**Article 8.2** provides countries with the freedom to adopt measures that 'may be needed to prevent the abuse of intellectual property rights by rights holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology.' This **prevention of abuse clause deals primarily with measures that undermine competition**."[391]
- "**This flexibility suggests that developing countries need to formulate their interests through national policy and legislation**. The successful use of the flexibility granted in the TRIPS agreement will depend on the relationship between a country and its major trading partners in the industrial world, since most of the inventions that are likely to be affected by national laws belong to rights holders in the industrial world."[392]
- "**Developing countries are increasingly recognizing that traditional knowledge associated with biological diversity that is held by local and indigenous communities forms part of product development**…They are seeking to enhance their capacity to use such knowledge as part of their efforts to implement the relevant provisions of the United Nations Convention on Biological Diversity, especially those provisions dealing with traditional knowledge and access to genetic resources."[393]
- "**Developing countries are seeking intellectual property registration systems that identify and document the sources of genetic material and indigenous knowledge used in product development**. Such a system would allow for the sharing of benefits

[389] *Id*., at pp. 112-113.
[390] *Id*., at p. 13.
[391] *Id*., at pp. 113-114.
[392] *Id*., at p. 114.
[393] *Id*., at pp. 114-115.

arising from the use of such genetic material and knowledge in accordance with the Convention on Biological Diversity."[394]

- "**One of the most controversial areas of intellectual property protection relates to ownership of genetic information derived from the sequencing of the human genome and other organisms**. The private sector would like to extend intellectual property protection to the data using a variety of means. While such a measure would provide the incentives needed by the private sector to invest in product development, there is concern that such measures could undermine long-term research. **Open access to sequence data is an important tool for promoting innovation and should therefore be encouraged as part of the large pursuit to *balance* 'open science' and proprietary incentives embodied in intellectual property rights**."[395]

iii. United Nations Office of the High Commissioner for Human Rights (OHCHR)[396]

- Resolution 2000/7 on Intellectual Property Rights and Human Rights (Aug. 17, 2000)[397]
  - Declares WTO TRIPS Agreement Conflicts With Human Rights
    - "Declares…that since the implementation of **the TRIPS Agreement does not adequately reflect the fundamental nature and indivisibility of all human rights**, including the right of everyone to enjoy the benefits of scientific progress and its applications, the right to health, the right to food and the right to self-determination, **there are apparent conflicts between the intellectual property rights regime embodied in the TRIPS Agreement, on the one hand, and international human rights law, on the other"**;[398]
    - "…Requests the **World Trade Organization**, in general, and the Council on TRIPS during its ongoing review of the TRIPS Agreement, in particular, to **take fully into**

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[394] *Id*., at p. 115.
[395] *Id*.
[396] *See* United Nations Office of the High Commissioner for Human Rights, *About Us - Who We Are*, available at: http://www.ohchr.org/EN/AboutUs/Pages/WhoWeAre.aspx. "The Office of the United Nations High Commissioner for Human Rights (OHCHR) represents the world's commitment to universal ideals of human dignity. We have a unique mandate from the international community to promote and protect all human rights. The High Commissioner for Human Rights is the principal human rights official of the United Nations. The High Commissioner heads OHCHR and spearheads the United Nations' human rights efforts…We are a part of the United Nations Secretariat…" *Id*.
[397] *See* United Nations High Commissioner for Human Rights, Sub-Commission on the Promotion and Protection of Human Rights, *Intellectual Property and Human Rights* Resolution 2000/7, 52nd Sess., 25th mtg., U.N. Doc. E/CN.4/Sub.2/Res/2000/7 (Aug. 17, 2000), available at: http://www.unhchr.ch/Huridocda/Huridoca.nsf/TestFrame/c462b62cf8a07b13c12569700046704e?Opendocument. This highly debated resolution was later recycled and adopted again, without a vote, in August 2001. *See* United Nations High Commissioner for Human Rights, Sub-Commission on the Promotion and Protection of Human Rights, *Intellectual Property and Human Rights* Resolution 2001/21, 52n Sess., 26th mtg., U.N. Doc. E/CN.4/Sub/2/2001/L.21 (Aug. 16, 2001), available at: http://www.unhchr.ch/huridocda/huridoca.nsf/(Symbol)/E.CN.4.SUB.2.RES.2001.21.En?Opendocument.
[398] *See* Resolution 2000/7, *supra* at par. 2.

account the existing State obligations under international human rights instruments;[399]

- "Requests the Special Rapporteurs on globalization and its impact on the full enjoyment of human rights to include **consideration of the human rights impact of the implementation of the TRIPS Agreement** in their next report;"[400]
- "Requests the United Nations High Commissioner for Human Rights **to undertake an analysis of the human rights impacts of the TRIPS Agreement**;"[401]
- …Recommends to the World Intellectual Property Organization, the World Health Organization, the United Nations Development Programme, the United Nations Conference on Trade and Development, the United Nations Environment Programme and other relevant United Nations agencies that they **continue and deepen their analysis of the impacts of the TRIPS Agreement, including a consideration of its human rights implications**;"[402]
- "**Commends the Conference of Parties to the Convention on Biological Diversity for its decision to assess the relationship between biodiversity concerns and intellectual property rights**, in general, and between the Convention on Biological Diversity and TRIPS, in particular, and urges it also to consider human rights principles and instruments in undertaking this assessment;"[403]

iv. World Health Organization[404]

- Summary Report of WHO Meeting of Senior Officials and Ministers of Health, at World Summit on Sustainable Development (Jan. 2002)[405]

  - Annex 3: Background Paper on Health and Sustainable Development emphasized how:

    - "2. **Sustainable development aims at improving the quality of life of all the world's people without increasing the use of our natural resources beyond the earth's carrying capacity**. This requires integrated action towards economic growth and equity, conservation of natural resources and the environment, and social development. Each of these elements is mutually supportive of the others, creating an interconnected **sustainable development triad**."[406]

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[399] *Id*., at par. 8.
[400] *Id*., at par. 9.
[401] *Id*., at par. 10.
[402] *Id*., at par. 12.
[403] *Id*., at par. 13.
[404] "WHO is the directing and coordinating authority for health within the United Nations system. It is responsible for providing leadership on global health matters, shaping the health research agenda, setting norms and standards, articulating evidence-based policy options, providing technical support to countries and monitoring and assessing health trends. In the 21st century, health is a shared responsibility, involving equitable access to essential care and collective defence against transnational threats." *See* World Health Organization, *About WHO*, available at: http://www.who.int/about/en/.
[405] *See* World Health Organization, *Health and Sustainable Development Meeting of Senior Officials and Ministers of Health Summary Report* (2002), available at: http://www.who.int/mediacentre/events/HSD_Plaq_02.7_def1.pdf.
[406] *Id*., at *Annex 3 - Background paper: "Health and Sustainable Development"*, par. 2.

- "3. **Health is recognised as a key goal of sustainable development in the first principle of the Rio Declaration on Environment and Development**, which states that: 'Human beings are at the centre of concerns for sustainable development. They are entitled to a healthy and productive life in harmony with nature'."[407]
- "…Table 3…**G]lobalisation can [h]arm [h]ealth…"The implications of the use of international trade and intellectual property rights agreements which are blind to their consequences on the health of people in poor countries** has been most explicitly illustrated in the case of drugs for treating HIV/AIDS, and other conditions prevalent in the developing world."[408]

- World Health Assembly[409] (WHA) Resolution 56.27 (May 2003)[410]

  - WHA 56.27, adopted in May 2003 at the Fifty-sixth World Health Assembly, was based on a WHO Secretariat Report entitled, *Intellectual Property Rights, Innovation and Public Health*.[411] Said report concluded that, "Rigorous analysis of the **scientific, legal, economic, ethical, and human rights aspects of intellectual property as it relates to public health**, and careful monitoring of this relationship in different national contexts, could prove invaluable for national and international policies and practices that ensure both innovation to respond to unmet needs and access to existing technologies for health."[412]

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[407] *Id*., at par. 3.
[408] *Id*., at Table 3, p. 37.
[409] "The World Health Assembly is the decision-making body of WHO. It is attended by delegations from all WHO Member States and focuses on a specific health agenda prepared by the Executive Board. The main functions of the World Health Assembly are to determine the policies of the Organization, appoint the Director-General, supervise financial policies, and review and approve the proposed programme budget. The Health Assembly is held annually in Geneva, Switzerland." *See* World Health Organization, Media Centre, *World Health Assembly*, available at: http://www.who.int/mediacentre/events/governance/wha/en/.
[410] *See* World Health Organization, 56th World Health Assembly - Agenda Item 14.9, *Intellectual Property Rights, Innovation and Public Health*, WHA 56.27 (May 28, 2003), available at: http://apps.who.int/gb/archive/pdf_files/WHA56/ea56r27.pdf.
[411] *See* World Health Organization, 56th World Health Assembly – Provisional Agenda Item 14.9, *Intellectual Property Rights, Innovation and Public Health - Report by the Secretariat*, A56/17 (May 12, 2003), available at: http://apps.who.int/gb/archive/pdf_files/WHA56/ea5617.pdf.
[412] *Id*., at par. 23. The Secretariat Report had taken note of several studies concerning the role of intellectual property rights in health innovation that had been previously prepared by "high-level bodies at national and international levels, in particular in relation to the pharmaceutical sector." *Id*., at par. 16. These studies focused on finding the *right balance between access and innovation* in developing countries. *See* National Institute for Health Care Management Issue Brief, *Prescription Drugs and Intellectual Property Protection: Finding the Right Balance Between Access and Innovation*, Washington, DC, (Aug. 2000), available at: http://www.nihcm.org/pdf/prescription.pdf (concluding that, 1) "[n]otwithstanding the efforts of *Waxman-Hatch* to balance innovation with expanded access to affordable medicine, increasing intellectual property protection has delayed the entry of some generic drugs into the U.S. market and forced consumers to incur billions of dollars in drug costs that they otherwise may not have paid. More affordable medications would be particularly welcomed by most uninsured Americans, who are keenly aware of the high cost of drugs"; and 2) "the effect of intellectual property protection on the quality as well as the quantity of innovation deserves examination…[s]ince the overwhelming majority of pharmaceutical research and development efforts end in dry holes, [and] costs must be covered by the rare 'blockbuster' drug that emerges from a wide portfolio of projects"; and consequently, that 3) "*[p]olicy makers must consider the sort of innovation it is in the public interest to reward*") (emphasis added). *Id*., at p. 11. *See also* Commission on Intellectual Property Rights, *Integrating Intellectual Property Rights and Development Policy*, (London, Department for International

- WHA 56.27 called for the creation of the **Commission on Intellectual Property Rights, Innovation and Public Health (CIPIH)**, which was charged with "review[ing] the interfaces and linkages between intellectual property rights, innovation and public health in the light of current evidence and examin[ing] in depth how to stimulate the creation of new medicines and other products for diseases that mainly affect developing countries."[413]
  - CIPIH noted "that the TRIPS Agreement contains flexibilities and that in order to use them adequately, Member States need to adapt national patent legislation", and recognized "the importance of intellectual property rights in fostering research and development in innovative medicines and the important role played by intellectual property with regard to the development of essential medicines…"[414]
  - CIPIH urged *inter alia* WHO Member States to:
    - "(1)…[R]eaffirm that public health interests are paramount in both pharmaceutical and health policies;
    - (2)…[**C]onsider, whenever necessary, adapting national legislation in order to use to the full the flexibilities contained in the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)**;
    - (3) [M]aintain efforts aimed at reaching, within WTO and before the Fifth WTO Ministerial Conference, a consensus solution for paragraph 6 of the Doha Declaration, with a view to meeting the needs of the developing countries…"[415]

Development, 2002), available at: http://www.iprcommission.org/papers/pdfs/final_report/ciprfullfinal.pdf (recommending *inter alia* that: 1) "[r]egulation of IP rights, particularly in relation to matters of special public interest (*as with compulsory licensing*) or in relation to controlling anti-competitive practice by rights holders should be given high priority in the design of public policy and institutional infrastructure [and that]…an important part of effective regulation is the undertaking of regular, periodic reviews of all aspects of the national IP regime, to ensure that these are relevant and appropriate"; 2) "*WIPO should act to integrate development objectives into its approach to the promotion of IP protection in developing countries*. It should give explicit recognition to both the benefits and costs of IP protection and the corresponding need to adjust domestic regimes in developing countries to ensure that the costs do not outweigh the benefits" and that "[u]nless they are clearly able *to integrate the required balance* into their operations by means of appropriate reinterpretation of their articles, WIPO member states should revise the WIPO articles to allow them to do so"; 3) "*LDCs should be granted an extended transition period for implementation of TRIPS* until at least 2016. The TRIPS Council should consider introducing criteria based on indicators of economic and technological development for deciding the basis of further extensions after this deadline"; and 4) "…if they think it is in their interests to do so, *developed countries should review their policies in regional/bilateral commercial diplomacy with developing countries* so as to ensure that they do not impose on developing countries standards or timetables beyond TRIPS" (emphasis added)). *Id*., at pp. 148, 159, 162, and 164. *See also* European Commission, *High Level Group on Innovation and Provision of Medicines in the European Union: Recommendations for Action* (G10 Medicines report), (Brussels, May 7, 2002), available at: http://ec.europa.eu/health/ph_overview/Documents/key08_en.pdf (concluding that "it is… important is *to ensure an appropriate balance* between providing sufficient intellectual property protection for innovative medicines and the introduction of a Bolar provision (to ease access to the market for generic medicines)", and recommending that "the European Institutions agree a way forward on intellectual property rights issues (especially data exclusivity and Bolar) covered in the Commission's proposed legislation" (emphasis added)). *Id*., at p. 14.

[413] *See* World Health Organization, Commission on Intellectual Property Rights, Innovation and Public Health (CIPIH), *Background on the Commission*, available at: http://www.who.int/intellectualproperty/background/en/.

[414] *See* WHA 56.27, *supra* at Preamble, pars. 7 and 10.

[415] *Id*., at pars. 1-3.

- WHA Resolution 57.14 (May 2004)[416]

  - WHA 57.14 urged Member States *inter alia* to:

    - "[**C]onsider whenever necessary, adapting national legislation in order to use the full flexibilities contained in the [TRIPS]…Agreement**…;
    - …[T]ake into account in bilateral trade agreements the flexibilities contained in the [TRIPS]…Agreement…and recognized by the Declaration on the TRIPS Agreement and Public Health adopted by the WTO Ministerial Conference (Doha, 2001)".[417]

- CIPIH Report - *Public Health, Innovation and Intellectual Property Rights* (Apr. 2006)[418]

  - "**Intellectual property rights are important, but as a means not an end**. How relevant they are in the promotion of the needed innovation depends on context and circumstance. We know they are considered a necessary incentive in developed countries where there is both a good technological and scientific infrastructure and a supporting market for new health-care products. **But they can do little to stimulate innovation in the absence of a profitable market for the products of innovation**, a situation which can clearly apply in the case of products principally for use in developing country markets. **The effects of intellectual property rights on innovation may also differ at successive phases of the innovation cycle** – from basic research to a new pharmaceutical or vaccine. We considered the impact of TRIPS, the flexibilities in TRIPS confirmed by the Doha Declaration, and also the impact of bilateral and regional trade agreements as they might affect public health objectives."[419]

    - "The purpose of **the requirement for data protection under the TRIPS agreement** is to ensure that the collection of data which involves considerable investment (e.g. the trials data required for marketing approval) for new chemical entities are protected against unfair commercial use…**Article 39.3**, **unlike the case of patents, does not require the provision of specific forms of rights**. But it does oblige Members to protect undisclosed test or other data against unfair commercial use. **It does not create property rights, nor a right to prevent others from relying on the data for the marketing approval of the same product by a third party, or from using the data except where unfair (dishonest) commercial practices are involved. Thus, the TRIPS agreement**

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[416] *See* World Health Organization, World Health Assembly , *Scaling Up Treatment and Care Within a Coordinated and Comprehensive Response to HIV/AIDS*, U.N. Doc. 57.14 (May 22, 2004), available at http://www.who.int/gb/ebwha/pdf_files/WHA57/A57_R14-en.pdf.

[417] *Id*., at pars. 4 and 6.

[418] *See* World Health Organization, *Public Health, Innovation and Intellectual Property Rights*, Report of the Commission on Intellectual Property Rights, Innovation and Public Health (CIPIH) (April 2006), available at: http://www.who.int/intellectualproperty/documents/thereport/ENPublicHealthReport.pdf.

[419] *Id*., at Preface, p. x.

does not refer to any period of data protection, nor does it refer to data exclusivity."[420]

- "**Weak intellectual property regimes in the past facilitated technological learning for all the countries studied**. The policy environment which facilitated this (e.g. the absence of product patents in India, or weak intellectual property protection in the first decades of technology development in Egypt and the Republic of Korea) has now changed for most developing countries as a result of the TRIPS agreement. **That is one reason why, in countries such as China and India, intellectual property protection and enforcement have become controversial issues**."[421]
- "**Intellectual property rights, in particular patents, may impinge upon the transfer of technology in a number of ways**. As we have noted, weak intellectual property rights may facilitate learning in the early stages of development and some countries have used this, as in the case of India, to generate capacities in pharmaceutical R&D and then in biotechnology. Now, all of the developing countries with significant R&D capacity have TRIPS-consistent frameworks. In these circumstances, technology needs to be used or acquired through licensing, or patents have to be invented around. Participants in the public and private sectors have to understand what this means for acquiring technologies needed from others, and what it means for the technologies they may produce."[422]
- "**Some of the most important impediments to the effective management of the growing body of developing country knowledge, particularly in the public sector, are the limited institutional resources in the form of skilled staff that can deal with intellectual property issues**. There are diverse activities that the management of intellectual property entails, including negotiation of agreements on material transfer, confidentiality, and product development, not to mention expertise in patenting…[T]he main point that needs to be emphasized here is the need to build the required institutional framework (e.g. patent office, administrative and court procedures) and the requisite skill set."[423]
  - "**Technical assistance provided from outside needs to be neutral in the way it provides advice on how developing countries can use the intellectual property system to develop their innovative capacity**. Not all developing countries find the advice they receive on this issue from established providers of technical assistance is well adapted to their particular needs."[424]

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[420] *Id*., at p. 124. "In some countries, however, such as the United States, a *sui generis* regime was adopted prior to the TRIPS agreement under which, for a period of five years from marketing approval, no other company may seek regulatory approval of an equivalent product based on that data without the approval of the originator company. In the European Union the period has now become up to 10 years, during which generic companies are allowed to develop the product, and may submit an application for authority to market it after eight years. Some developing countries have also adopted this regime in one form or another. If the patent period has expired, or there is no patent on the product, this sui generis data exclusivity may act independently of patent status to delay the entry of any generic companies wishing to enter the market." *Id*., at pp. 124-125.

[421] *Id*., at p. 148.

[422] *Id*., at p. 150.

[423] *Id*., at p. 151.

[424] *Id*.

- "**In respect of traditional knowledge generally, and traditional medical knowledge in particular, there is an ongoing debate about how intellectual property rights might be responsible for unfairly depriving communities of the benefits of their knowledge** (e.g. when a company uses such knowledge to create commercial value, none of which flows back to the community from which the knowledge originated). Such practices are sometimes called biopiracy or misappropriation. Nevertheless it is also argued that patenting is essential to the commercialization of inventions based on legitimately accessed traditional knowledge, or associated genetic resources, and measures to restrict it would be harmful to the effort to develop new products that benefit public health. Intimately linked to this debate is the question of how benefits should be shared between traditional knowledge holders (whether individuals or communities) and those who make use of their knowledge. **The Convention on Biological Diversity requires that recipients of genetic resources covered by the Convention share 'in a fair and equitable way the results of research and development and the benefits arising from the commercial and other utilization of genetic resources…upon mutually agreed terms'**…"[425]
  - As a result of these and other debates surrounding traditional knowledge and access and benefit sharing which gave rise to interim initiatives,[426] the Conference of the Parties to the Convention on Biological Diversity adopted ***The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity***[427] "at its tenth meeting on 29 October 2010 in Nagoya, Japan. The *Nagoya Protocol* will enter into force 90 days after the date of deposit of the fiftieth instrument of ratification."[428] As of the date of this writing, only 26 ratifications have been received.[429]
- "[The] tragic failure by all governments to address poverty and sickness in developing countries has become a worldwide subject of great concern. Since the beginning of this century, there has been a heightened global consciousness about this issue. This is not just because it represents an affront to commonly held basic human values. It is also in recognition of our interdependence, and the potentially serious consequences of failure to

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[425] *Id*., at p. 164. "…A few countries have recently introduced *sui generis* intellectual property protection for traditional knowledge which may suit their particular conditions. The purpose of intellectual property protection should be to stimulate new invention and innovation. However, in practice, regimes being considered for traditional knowledge principally seek to address the question of equitable benefit sharing, not that of stimulating innovation derived from traditional knowledge. The risk is that introducing a form of intellectual property protection for traditional knowledge may actually have the effect of restricting access by others, thereby inhibiting downstream innovation." *Id*.

[426] *See* United Nations Convention on Biological Diversity, Access and Benefit Sharing, *ABS Developments under the CBD Prior to the Nagoya Protocol*, available at: http://www.cbd.int/abs/pre-protocol/.

[427] *See* Secretariat of the Convention on Biological Diversity, United Nations Environmental Programme, *Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity Text and Annex* (2011), available at: http://www.cbd.int/abs/doc/protocol/nagoya-protocol-en.pdf.

[428] *See* United Nations Convention on Biological Diversity, Access and Benefit Sharing, *The Nagoya Protocol on Access and Benefit-sharing*, available at: http://www.cbd.int/abs/.

[429] See United Nations Convention on Biological Diversity Access and Benefit Sharing, *Status of Signature, and Ratification, Acceptance, Approval or Accession*, available at: http://www.cbd.int/abs/nagoya-protocol/signatories/default.shtml.

deal with this, for all members of the world community. **The endorsement of the MDGs in 2000 emphasized the importance of investing in health improvements for economic development, as well as improving the health of poor people. In 2001, the Doha Declaration on TRIPS and Public Health stated that the TRIPS agreement should be interpreted in a manner supportive of the right to protect public health**…"[430]

- **CIPIH Recommendations Relating to Intellectual Property Rights and Public Health include the following**:
  - "WHO, WIPO and other concerned organizations should work together to strengthen education and training on the management of intellectual property in the biomedical field, fully taking into account the needs of recipient countries and their public health policies."[431]
  - "**Developed countries, and pharmaceutical companies (including generic producers), should take measures to promote the transfer of technology and local production of pharmaceuticals in developing countries**, wherever this makes economic sense and promotes the availability, accessibility, affordability and security of supply of needed products."[432]
  - "**Developed countries should comply with their obligations under article 66.2 of the TRIPS Agreement** and paragraph 7 of the Doha Declaration."[433]

- WHA Resolution 59.24 (May 2006)[434]

  - "Note[d] that the report of the Commission requests WHO to prepare a global plan of action to secure enhanced and sustainable funding for developing and making accessible products to address diseases that disproportionately affect developing countries".[435]

  - "Urge[d]" WHO Member States and regional economic integration organizations *inter alia* "to **encourage trade agreements to take into account the flexibilities contained in the Agreement on Trade-Related Aspects of Intellectual Property Rights and recognized by the Doha Ministerial Declaration on the TRIPS Agreement and Public Health**;"[436]

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[430] *Id*., at pp. 174-175.
[431] *Id*., at pp. 151, 183, Recommendation 5.3.
[432] *Id*., at pp. 153, 183 Recommendation 5.4.
[433] *Id*., Recommendation 5.5. TRIPS Article 66.2 provides that, "Developed country Members *shall* provide incentives to enterprises and institutions in their territories for the purpose of promoting and encouraging technology transfer to least-developed country Members in order to enable them to create a sound and viable technological base" (emphasis added). Paragraph 7 of the Doha Declaration on the TRIPS Agreement and Public Health provides that, "We reaffirm the commitment of developed-country members to provide incentives to their enterprises and institutions to promote and encourage technology transfer to least-developed country members pursuant to Article 66.2…"
[434] World Health Organization, World Health Assembly, *Public Health, Innovation, Essential Health Research and Intellectual Property Rights: Towards a Global Strategy and Plan of Action*, WHA Resolution 59.24, U.N. Doc. A59VR/9, (May 26, 2006), available at: http://apps.who.int/phi/Res59_R24-en.pdf.
[435] *Id*., at Preamble par. 24.
[436] *Id*., at par. 2(4). See also Preamble pars. 17-20.

- Provided for the World Health Assembly's **"establish[ment of] an intergovernmental working group…to draw up a global strategy and plan of action in order to provide a medium-term framework based on the recommendations of the [WHO] Commission [on Intellectual Property Rights, Innovation and Public Health]**;

  - [S]uch strategy and plan of action would aim, inter alia, at securing an enhanced and sustainable basis for needs-driven, essential health research and development relevant to diseases that disproportionately affect developing countries, proposing clear objectives and priorities for research and development, and estimating funding needs in this area."[437]
  - [Said] working group [was directed to] report to the Sixtieth World Health Assembly through the Executive Board on the progress made, giving particular attention to needs-driven research and other potential areas for early implementation".[438]

- WHO Intergovernmental Working Group on Public Health, Innovation and Intellectual Property (WHO IGWG) Draft Strategy and Plan of Action (July 2007)[439]

  - "The focus of the strategy will be on diseases or conditions of significant public health importance in developing countries for which an adequate treatment for use in resource-poor settings is not available – either because no treatment exists or because, where treatments exist, they are inappropriate for use in countries with poor delivery systems, or unaffordable. **The [CIPIH] Commission highlighted the need to focus on Type II and Type III diseases and the needs of developing countries in relation to Type I diseases.**"[440]

  - "…**Element 4. Transfer of Technology**…North–South and South–South development cooperation, partnerships and networks need to be supported in order to build and improve transfer of technology related to health innovation. **The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner**

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[437] *Id*., at par. 3(1).
[438] *Id*., at par. 3(3).
[439] *See* World Health Organization, Intergovernmental Working Group on Public Health, Innovation and Intellectual Property 2d. Sess., *Draft Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property* A/PHI/IGWG/2/2 (July 31, 2007), available at: http://apps.who.int/gb/phi/pdf/igwg2/PHI_IGWG2_2-en.pdf.
[440] *Id*., at par. 6. "The Commission's definitions of Type I, Type II and Type III diseases, and the specific diseases on which this draft strategy focuses, are as follows: *Type I diseases* are incident in both rich and poor countries, with large numbers of vulnerable populations in each. The strategy will focus on the following Type I diseases, increasingly prevalent in developing countries: diabetes, cardiovascular disease and cancer. *Type II diseases* are incident in both rich and poor countries, but with a substantial proportion of the cases in poor countries. For the purposes of the strategy, the focus is on HIV/AIDS and tuberculosis. *Type III diseases* are those that are overwhelmingly or exclusively incident in developing countries. For the purposes of the strategy, the focus is on the nine neglected infectious diseases that disproportionately affect poor and marginalized populations prioritized by the UNICEF/UNDP/World Bank/WHO Special Programme for Research and Training in Tropical Diseases: Chagas disease, dengue and dengue haemorrhagic fever, leishmaniasis, leprosy, lymphatic filariasis, malaria, onchocerciasis, schistosomiasis and human African trypanosomiasis." *Id*., at fn#1.

conducive to social and economic welfare, and to a *balance of rights and obligations*."[441] "**The actions to be taken in relation to this element are as follows**:

- (4.1) **promoting transfer of technology and the production of health products in developing countries**
  - (a) devise a mechanism, or make better use of existing ones, to facilitate transfer of technology and technical support
  - (b) promote transfer of technology and production of health products in developing countries through investment and capacity building.
- (4.2) **supporting improved collaboration and coordination of technology transfer**
  - (a) encourage North–South and South–South collaboration, and collaboration between institutions in developing countries and the pharmaceutical industry
  - (b) support technology transfer related to research and development on natural products
  - (c) facilitate local and regional networks for collaboration on research and development
  - (d) **promote compliance with obligations under Article 66.2 of the Agreement on Trade-Related Aspects of Intellectual Property Rights**.
- (4.3) developing mechanisms to **manage intellectual property in order to promote transfer of and access to key technologies**
  - (a) promote patent pools of upstream and downstream technologies
  - (b) develop other effective and sustainable mechanisms to promote innovation of products for priority diseases in developing countries
  - (c) examine best practices in areas such as competition, transparency and proper remuneration for patent holders."[442]

- "**Element 5. Management of intellectual property**…**Intellectual property is a vital concept** in ensuring that development of new health products continues. **However, complementary, alternative and/or additional incentive schemes for research and development, especially on Type II and Type III diseases and the special needs of developing countries in respect of Type I diseases, need to be explored and implemented**. There is a crucial need to strengthen capacities in developing countries to manage intellectual property."[443] "**The actions to be taken in relation to this element are as follows**:

  - (5.1) supporting information sharing and capacity building in the management of intellectual property
    - (a) promote national and/or regional institutional frameworks in order to build capacity and manage intellectual property

[441] *Id*., at par. 14.
[442] *Id*., at par. 15.
[443] *Id*., at par. 16.

- (b) compile and maintain national databases on patent status of relevant health-related products and promote exchange of information between relevant government departments
- (c) WHO and WIPO to improve dissemination of relevant information and existing databases at international level
- (d) **WHO, in collaboration with WIPO and WTO, to strengthen education and training in the management of intellectual property**.

▪ (5.2) upon request, providing support for application of the flexibilities consistent with the Agreement on Trade-Related Aspects of Intellectual Property Rights
- (a) **promote legislation to apply flexibilities consistent with the Agreement on Trade-Related Aspects of Intellectual Property Rights and other international agreements**, by means including the dissemination of best practices
- (b) **promote bilateral trade agreements that do not incorporate "TRIPS-plus" protection in ways that might reduce access to medicines in developing countries**
- (c) **encourage trade agreements that take into account the flexibilities contained in the Agreement on Trade-Related Aspects of Intellectual Property Rights (as recognized by the Doha Declaration on the TRIPS Agreement and Public Health)**.

▪ (5.3) **exploring and promoting complementary incentive schemes for research and development**
- (a) explore and implement complementary incentive schemes for research and development that separate the incentives for innovation from the prices of health-care products (for example, the prize fund model)
- (b) expand the advance-market commitment approach
- (c) **assess the impact of data-exclusivity regulations**
- (d**) examine measures to comply with the requirements of the Agreement on Trade-Related Aspects of Intellectual Property Rights for the protection of undisclosed test data against unfair commercial use**."[444]

o During August-September 2007, the WHO IGWG convened public hearings and solicited contributions from interested members of the global public.[445]

▪ Those public comments addressing the WHO IGWG's *Draft Global Strategy and Plan of Action* are accessible online.[446]

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[444] *Id*., at par. 17.

[445] *See* World Health Organization, Public Health, Innovation and Intellectual Property, *WHO's Second Public Hearing on Public Health Innovation and Intellectual Property*, available at: http://www.who.int/phi/public_hearings/second/en/index.html; World Health Organization, Public Health, Innovation and Intellectual Property, *Submissions to Section 1 - Draft Global Strategy and Plan of Action* (Aug. 15-Sept. 30, 2007), available at: http://www.who.int/phi/public_hearings/second/en/index.html.

[446] *See* World Health Organization, Public Health, Innovation and Intellectual Property, *Contributions to the Second Public Hearing - Section 1, Draft Global Strategy and Plan of Action*, available at: http://www.who.int/phi/public_hearings/second/contributions_section1/en/index.html. *See, e.g.*, Comments of *Lawrence*

- During mid-May 2008, the WHO IGWG released its Report on the *Draft Global Strategy and Plan of Action* reflecting areas of consensus and those outstanding items requiring closure.[447]

  - "The Working Group…considered that the [WHO] Secretariat should initiate the early implementation of a number of specific actions, for which WHO has been identified as the lead stakeholder."[448]

- Late May 2008, the WHO General Assembly, pursuant to WHA Resolution 61.21, "adopt[ed] the global strategy and the agreed parts of the plan of action on public health, innovation and intellectual property".[449] By May 2009, the WHO General Assembly had resolved the 'open items' on the plan of action and adopted them pursuant to WHA Resolution 62.16.[450]

v. World Intellectual Property Organization[451]

Kogan - Institute for Trade, Standards, and Sustainable Development, USA, available at: http://www.who.int/phi/public_hearings/second/contributions_section1/Section1_ITSSD_Full%20Contribution.pdf; Public Hearings, Intergovernmental Working Group on Public Health, Innovation and Intellectual Property, *Proposals, Recommendations Made* (2011), at p. 14, available at: http://www.who.int/phi/news/igwg_public_hearings_proposals_recommendations_2011.pdf ("Proposal(s) recommended for further exploration: General Public License (GPL) model of open source.").

[447] See World Health Organization, Sixty-First World Health Assembly, Agenda Item 11.6 - *Report of the Intergovernmental Working Group on Public Health, Innovation and Intellectual Property*, A61/9 (May 19, 2008), available at: http://apps.who.int/gb/ebwha/pdf_files/A61/A61_9-en.pdf.

[448] *Id*., at par. 10.

[449] *See* World Health Organization, Sixty-First World Health Assembly, Agenda Item 11.6 - *Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property*, WHA61.21 (May 24, 2008), at par. 1, available at: http://apps.who.int/gb/ebwha/pdf_files/A61/A61_R21-en.pdf.

[450] *See* World Health Organization Sixty-second World Health Assembly, Agenda item 12.8, *Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property*, WHA 62.16 (May 22, 2009), available at: http://apps.who.int/gb/CEWG/pdf/A62_R16-en.pdf;

[451] The World Intellectual Property Organization (WIPO) is a specialized agency of the United Nations that "administers several treaties aimed at creating a standard global system…[by] tak[ing] patent law in the direction of international harmonization." *What is WIPO?, About WIPO*, WIPO, http://www.wipo.int//about-wipo/en/what_is_wipo.html. (These several treaties include the Patent Cooperation Treaty (PCT), the Patent Law Treaty (PLT) and the Budapest Treaty (BT)). *See* Patent Cooperation Treaty, Contracting Parties, June 19, 1970, 28 U.S.T. 7645, 1160 U.N.T.S. 231, available at http://www.wipo.int/pct/en/texts/articles/atoc.htm (showing 142 contracting parties when last modified on Oct. 3, 2001, with the supplementing Regulations under the Patent Cooperation Treaty of Jan. 1, 2004); *see also* Patent Law Treaty, Contracting Parties, June 1, 2000, 39 I.L.M. 1047, available at: http://www.wipo.int/patent-law/en/plt.htm (showing 18 contracting parties when adopted at Geneva on June 1, 2000, with the supplementing Regulations under the Patent Law Treaty, adopted the same date); *see also* Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure, Contracting Parties, Apr. 28, 1977, 32 U.S.T. 1241 1861 U.N.T.S. 361, available at http://www.wipo.int/treaties/en/registration/budapest (showing 72 contracting parties when amended Sept. 26, 1980; the Regulations Under the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure were adopted Apr. 28, 1977 and amended Jan. 20, 1981 and Oct. 1, 2002).

- WIPO Standing Committee on the Law of Patents (SCP)[452] Reports
  - SCP/12/3 Rev.2 - *Report on the International Patent System* (June 2008; Feb. 2009)[453]
    - "101.…**With the increase of globalization and transnational trade flows, the link between patents and technology transfer has been increasingly recognized** at the national and international levels, as can be seen, for example, from Articles 7 and 8 of the TRIPS Agreement or Article 16 of the Convention on Biological Diversity. **This relationship is generally understood to have** both positive aspects, namely where useful technology is indeed transferred to the recipient, and **a negative component, namely where patent rights OR an abusive use of such rights, may equally hinder a transfer of technology**."[454]
    - "103. **One argument that is put forward in favor of technology licensing in developing countries claims that such policies** would create incentives for building technical know-how and expertise in those countries, which **could encourage the creation of local industries. On the other hand, some question whether licensing is sufficient to achieve this purpose, considering that the licensing agreements do not necessarily disclose all the know-how necessary to exploit the technology**, and suggest that more should be invested in tuition and education, as well as in improved public-private partnerships. In addition, **it is sometimes also argued that in certain specific areas, for example, the health sector in developing countries, a licensing system based on the existing patent system will not produce the desired results**, as this may rather attract funding into research that may result in profitable patents, but will not foster research into diseases targeting particularly developing countries, because developing markets cannot afford the costs of the resulting products… **In this respect, a sensible use of the patent system, and of its use for both international transfer of technology and public-private partnerships at the different stages of research and development should be considered carefully, taking into account the flexibilities that the system offers in order to avoid abuses**."[455]
    - "104. An issue which is different from the question of whether and which national licensing policies should be adopted by the various countries relates to making technologies from industrialized countries available to developing countries at affordable conditions, in order to increase flows of technology to developing countries. **While many governments, sometimes for constitutional reasons, may not be in a position to dictate the conditions at which their companies have to give away their technologies,**

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[452] "The SCP was created in 1998 to serve as a forum to discuss issues, facilitate coordination and provide guidance concerning the progressive international development of patent law." *See* World Intellectual Property Organization, *Standing Committee on the Law of Patents*, available at: http://www.wipo.int/policy/en/scp/.

[453] *See* World Intellectual Property Organization, *Report on the International Patent System*, SCP/12/3 Rev.2 (Feb. 3, 2009), available at: http://www.wipo.int/edocs/mdocs/scp/en/scp_12/scp_12_3_rev_2.pdf. See also *Comments on the Report on the International Patent System Received From Members and Observers of the SCP*, SCP/12/3 Rev.2 ANNEX III, available at: http://www.wipo.int/edocs/mdocs/scp/en/scp_12/scp_12_3_rev_2-annex3.pdf.

[454] *Id*., at par. 101.

[455] *Id*., at par. 103.

they may nevertheless provide various incentives, for example, of a fiscal nature, for such a transfer. **In addition, they may consider establishing technology transfer programs that cover state-owned technologies.**"[456]

- "105. The relationship between patents and transfer of technology is clearly a multifaceted one. In the further analysis that may be made on the subject, **aspects such as the impact of patents on transfer of technology in respect of the decision to transfer, the method chosen to transfer technology, the effects on local innovation, and the broader issue of how the legal framework is adapted to contribute to technology transfer may be considered**."[457]
- "106. **Licensing** is important for economic development and consumer welfare, as it helps disseminate innovation. But equally important is competition as one of the main driving forces of innovation, and **it is thus important to find the right *balance* between protecting competition and protecting intellectual property rights**."[458]
- "107…[**P]rovisions in licensing agreements having monopoly effect or conflicting with the prohibition of antitrust or anti-competitive practices** are usually considered null and void. The most important forms of **abuse** include, for example, **tie-in clauses, export bans, tied royalties, grant-backs, conditions preventing challenges to validity and coercive package licensing**."[459]
- "108. **The above restrictions of the freedom of contract are reflected at the international level**…WTO Members are free, according to the **TRIPS Agreement**, to specify in their legislation licensing practices or conditions that may in particular cases constitute an abuse of intellectual property rights having an adverse effect on competition in the relevant market."[460]
- "109. **One issue that is at the heart of the potential conflict between patent law and competition law concerns the situation where many patent rights cover one technology, so that the sum of the licensing fees becomes prohibitive, not mentioning the difficulty to negotiate separate agreements with all rightholders**. One way to deal with the situation where different patentees own a number of patents relevant to a technology is called a **patent pool**, which is an agreement enabling participating patentees to use the pooled patents, provide a standard license for the pooled patents to licensees who are not members of the pool, and to allocate each member of the pool a portion of the licensing fees in accordance with the agreement. Such patent pools are most frequent in **the process of standardization, which, in certain areas such as digital technology and telecommunication**, frequently involves many patents."[461]
- "111. **Interoperability is the key to the interplay of different technological components, in particular in, but not limited to, the field of information and communication technologies (ICT). More and more products need to be compatible**

[456] *Id*., at par. 104.
[457] *Id*., at par. 105.
[458] *Id.,* at par. 106.
[459] *Id*., at par. 107.
[460] *Id*., at par. 108.
[461] *Id*., at par. 109.

and to interoperate, and this is often achieved by so-called technical standards, which are technical specifications allowing the replacement of one part of a given product with another part, or the assembly of such parts. **Standards reduce transaction costs by providing uniform technical platforms and economies of scale for all the companies involved in a particular technical field**. Standards create predictability, interoperability and competition between implementations, without imposing homogeneity."[462]

- "115. Patents and standards serve common objectives, insofar as they both encourage investment in innovation as well as the diffusion of technology…"[463]
- "116. At the same time, **inherent tensions exist between patents and standards**, which become apparent when the implementation of a standard calls for the use of technology covered by one or more patents…"[464]
- "117. **In order to *balance* these competing interests**, many SSOs have established patent policies that encourage the parties involved in the standard-setting process to disclose, to other members of the SSO, the existence of any relevant patents (and, sometimes, also patent applications) on technologies essential for the implementation of the technical standard under consideration, so that this fact can be taken into account during the standard setting process. In addition, SSOs typically require the patentee to agree to license the patented technology on reasonable and non-discriminatory (RAND) terms."[465]
- "119. **From a policy standpoint**, the most essential objective appears to be, while keeping in mind the encouragement of innovation, to **strike a *balance* between the interest of patent holders in exploiting their patents, the producers who want to license and produce the goods covered by the standard at a reasonable price, and the public which seeks the widest possible choice among interoperable products**. Some of the main concerns that have been put forward as possibly threatening this balance are:" concealed patents used to block implementation of a standard; high royalties rendering production of the standard difficult or adversely impacting the price of standardized technology; price agreements reached during the standardization process that exclude third parties.[466]
- "120. With the growing importance of standards, **several avenues are being pursued to prevent conflicts from arising: one is to improve the self-regulatory mechanisms of SSOs [standard-setting organizations]** i.e., their patent policies, including considering patent searches, further encouraging early disclosure of essential patents and patent applications, and finding solutions to the issue of cumulative royalties by introducing criteria and mechanisms such as RAND or FRAND (fair, reasonable and non-discriminatory) criteria in respect of licenses granted by patent holders. **A second avenue which is being looked into involves the application of legal mechanisms either**

[462] *Id*., at par. 111.
[463] *Id*., at par. 115.
[464] *Id*., at par. 116.
[465] *Id*., at par. 117.
[466] *Id*., at par. 119.

internal or external to the patent system. The latter relates, in particular, to competition law that allows addressing certain aspects of the problem, such as abuse of a dominant position in fixing license fees or the violation of a SSO patent policy."[467]

- "121. Among technology standards, there is particular interest for "open standards". While there is no universally accepted definition of that term, **all open standards have the following common characteristics**: (i) **the specification is publicly available without cost or for a reasonable fee to any interested party**; (ii) any IP rights necessary to implement the standard are **available to all implementers on RAND terms, either with or without payment of a reasonable royalty or fee**; **and** (iii) **the specification should be in sufficient detail to enable a complete understanding of its scope and purpose and to enable competing implementations by multiple vendors**. Some define open standards as publicly available technical specifications that have been established in a voluntary, consensus-driven, transparent and open process, **others appear to add to this definition the requirement that an open standard *has to be* available royalty-free**."[468]
- "122. In this context, the notion of "open source" is often mentioned, but it should not be confused with open standards…**When governments and other users are in the process of selecting a specific technology to meet their needs for interoperability and/or free use of that technology**, in addition to the open or proprietary nature of any software involved, factors such as overall costs, the maturity of the technology, and the support offered, should be taken into account."[469]
- "123. In a more and more complex world, **research has not only become more international**, but it has become **dependent on** a broad range of different - and often newly emerging - technologies, on **increased cooperation between various research teams** and on sufficient funding to face the exponential rise of costs over the past years."[470]
- "124…**Others have voiced** disagreement with this approach, as **the patent system may stand in the way of the above-mentioned collaborative approaches to research and developmen**t by, in particular, blocking access to or use of necessary information. They argue, in particular, that **the patent system prevents access to certain inventions needed for further research, increases cost and complexity by encouraging a system creating multiple licenses and does direct research towards products that are only expected to generate high benefits, thereby neglecting, for example, diseases that affect specifically poor countries**. Therefore, **according to these voices, collaborative models rather than exclusive rights have to be promoted**."[471]
- "125. The open source model has been well known for many years in the area of software, where it has been established as a distribution model that is based on

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[467] *Id*., at par. 120.
[468] *Id*., at par. 121.
[469] *Id*., at par. 122. *See also* World Intellectual Property Organization, Standing Committee on the Law of Patents, Mar. 23–27, 2009, *Standards and Patents*, U.N. Doc. SCP/13/2/PROV, 13th Sess. (Feb. 18, 2009), *infra*, at par. 44, available at: http://www.wipo.int/edocs/mdocs/scp/en/scp_13/scp_13_2.pdf.
[470] *Id*., at par. 123.
[471] *Id*., at par. 124.

intellectual property rights (in the case of software, often copyright). **'Open source' software is often used as a general expression for many forms of non-proprietary software**, which differ principally in respect of the licensing terms under which changed versions of the source code may be further distributed."[472]

- "Although some of the open source features developed in the area of **software** cannot be simply transposed to other areas, **the main principle that certain parts of the commons should not be the subject of a proprietary right has been found interesting enough to be tested and applied in other areas**."[473]

- SCP/13/2 - *Report on Patents and Standards* (March 2009)

  - "5…So long as the patent system motivates companies to contribute their technologies to standardization, and consequently, the best solution is adopted as a standard for a wide use in the market at reasonable cost, the patent system and the standardization process share the objective of promoting innovation and diffusion of technology. However, **if patent rights are enforced in a way that may hamper the widest use of standards, some antagonism between the two systems may arise**."[474]
  - "8. **In order to prevent potential conflicts from arising between the patent and standard systems, several avenues have been pursued**. One is to improve the **self-regulatory mechanisms of SSOs (SSOs'patent policies)** so as to increase transparency and accessibility to patented technologies that cover the standards. A second approach is to seek **pragmatic solutions in the market, such as forming a patent pool** to reduce the transaction cost for licensing arrangements. A third relates to the **application of legislative measures, which may be internal or external to the patent law itself**, and may relate, in particular, to the application of **competition law**."[475]
  - "16. **When technologies under standards are protected by patents, some specific competition law concerns may arise**. Once a standard is adopted covering a technology that falls under patent protection, a patentee may be in a position to demand higher royalties or other unreasonable terms and conditions to license his technology to the implementers of such standard in view of the absence of alternative technology. **In this document, competition concerns relating to non-disclosure of essential patents against the patent policy of SSO, ex ante disclosure of licensing terms during the standardization process, and patent pools are further described.**"[476]
  - "117. **While there are some inherent limits to the self-regulation model, such as nonapplicability of IPR policies to non-members of SSOs**, **the IPR policies have been playing an important role in addressing potential tensions between patents and standards from the practical and pragmatic standpoint**. In general, SSOs observed that their IPR policies were fairly effective as evidenced by the infrequency of IPR

[472] *Id*., at par. 125.
[473] *Id*., at par. 126.
[474] *See* SCP/13/2, *supra*.
[475] *Id*., at Executive Summary, par. 8.
[476] *Id*., at par. 16.

problems associated with their standards. **However, a *balance* that SSOs intend to strike is a very fine one**. **If a patent policy is too stringent to technology holders, it may slow down standards development, raise costs, and scare away the technology holders from the standardization process. On the other hand, if the policy is too much in favor of the technology holders, wide implementation of standard may be at risk**. **While practitioners involved in standardization believed that such policies are not "broken"**, they are of the view that standards bodies should consider improvements to their IPR policies in a studied and thoughtful way."[477]

- "139. Broadly stated, measures such as the patent policies of SSOs, cross-licensing and patent pools are contractual solutions among parties designed to increase legal certainty for the sake of efficient and effective implementation of technologies under standards. Naturally, enforcement of those contracts is governed by the applicable law of contracts. **The contractual approach has an advantage of providing flexible solutions agreeable by both parties that best fit to the needs under each specific situation, and avoid a rigid "one-size-fits-all" approach. On the other hand, contractual solutions can only bind the parties under the contract, and the negotiation power of the parties concerned could be substantially uneven.**"[478]
- "140. Therefore, **in view of increasing concerns as to legal certainty and enforceability, the application of <u>legal mechanisms either *internal or external* to the patent system is another possible avenue which has been looked at</u>**. **<u>The advantages of these solutions are that they are universal, and also apply to non-participants in the standard-setting process</u>**. Opponents of a legislative approach argue, however, that interfering too much in the standard-setting process via legislative measures would have an adverse impact on incentives to investment and innovation, stifling this mainly industry-driven process under which a balanced solution is found through fair competition in the market, and preventing the adoption of the optimal technologies in a standard."[479]
- "141. **With respect to legislative measures <u>*internal*</u> to the patent system**, **<u>exclusions from patentable subject matter, and exceptions and limitations to the enforcement of patent rights</u>**, have been pointed out as relevant mechanisms. As to the latter, the international legal framework in this respect is provided in the TRIPS Agreement and the Paris Convention. Article 30 of the TRIPS Agreement allows Members to provide **<u>exceptions to the exclusive rights conferred</u>**, provided that such exceptions do not conflict with the normal exploitation of the patent and do not prejudice the legitimate interests of the patent owner, taking into account the legitimate interests of third parties. Further, Article 31 of the TRIPS Agreement provides that a Member may allow, under the stipulated conditions laid down in that Article, use other than that allowed under Article 30 without authorization of the right holder **<u>(so-called "governmental use" and "compulsory licenses")</u>**…"[480]

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[477] *Id*., at par. 117.
[478] *Id*., at par. 139.
[479] *Id*., at par. 140.
[480] *Id*., at par. 141.

- "142. Taking into consideration the above international rules, a number of countries provide in their national legislations certain exceptions and limitations to the exclusive patent rights. The scope of the exclusive patent right is carefully designed under national patent laws in order to strike a balance between the legitimate interests of right holders and third parties. **To the knowledge of the International Bureau, no national legislation includes a specific provision limiting the right conferred by a patent the exploitation of which is essential for the implementation of a standard. On the other hand, existing provisions under national laws concerning exceptions and limitations, including a compulsory license provision, may be applicable to essential patents relating to standards in the same manner as to other classes of patents**…"[481]
- "143. **Some have proposed that the mechanism of the so-called "license of right" under the patent law should be explored in order to ensure access to the technologies incorporated in standards at a reasonable cost**. Many national patent laws provide a mechanism allowing a patentee to voluntarily file a statement with the patent office that he is prepared to allow any person to use the invention as a non-exclusive licensee. Such a statement will be published in the official gazette, and the patentee typically enjoys a reduction of the maintenance fee. Adequate remuneration is to be agreed upon between the parties, or in the absence of such an agreement, a party may request the patent office to establish appropriate terms and conditions. **In the standardization context, this means that if essential patents were subject to such a license of right, the patentee would be entitled to remuneration which would be primarily agreed upon between the parties. However, the patentee would not be able to seek injunctive relief**…"[482]
- "144. With respect to **legal mechanisms *external* to the patent system, competition law**, in particular, addresses certain aspects of the problem, such as **abuse of a dominant position** in fixing license fees. **While certain exchange of information and coordination among companies, which are often competitors in the market, may facilitate adoption and implementation of standards, such coordination among competitors often raise competition concerns**…"[483]
- "146. **A patent does not automatically confer market power upon the patentee**. There is often a substitute or alternative technology available, and above all, complementary assets are required to be in a position to exercise market power. **Even if a patent allows a patentee to obtain a monopoly position, in principle, acquiring a monopoly position by lawful means does not constitute the violation of a competition law**. **However, if competition is distorted by an abusive behavior by a patentee dominating a market or anti-competitive practices that tend to lead to such a dominant position, competition law would be applied to restore fair competition in the market**. Similarly, patent licensing agreements have competitive elements in the sense that they promote efficient transfer of technology by integrating a licensed technology to the licensee's complimentary assets. **Certain limitations in licensing**

[481] *Id*., at par. 142.
[482] *Id*., at par. 143.
[483] *Id*., at par. 144.

agreements, such as territorial limitations or limitations as to field of use, may be pro-competitive under certain circumstances since such limitations may allow both licensor and licensee to exploit the patented technology as efficiently and effectively as possible. However, a competition law concern may arise if a licensing agreement contains restraints that adversely affect competition among entities that would have been competitors in the relevant market in the absence of the license. For example, if a licensing agreement that divides a market between competitors who would otherwise have competed each other adversely affects competition, it may be contrary to competition law requirements."[484]

- SCP/13/3 – *Exclusions From Patentable Subject Matter and Exceptions and Limitations to the Rights* (March 2009)[485]

  - "2…Although the definition of "invention" is different from one country to the other, **many national laws consider** that, in particular, discoveries, abstract ideas and non-technical creations are not "inventions" within the meaning of patent law. Secondly, only those inventions that meet the three patentability criteria, i.e., novelty, inventive-step (non-obviousness) and industrial applicability (utility) are entitled to patent protection, **so that only inventions that contribute to technical progress are rewarded. Even those latter inventions, however, do not necessarily support the ultimate goal of the patent system, that is, to enhance public welfare. In this case, from a public policy perspective, they may be excluded from patentability, even if they represent a significant scientific or technological advancement.**"[486]
  - "3. Although many countries share general public policy objectives, the concrete means as to how to reach those objectives often vary from one country to the other. **Public policy consideration may be influenced by the socio-economic conditions and the country's priorities, and vice versa. Historical, cultural and religious conditions may be important factors for shaping ethical and moral considerations. Therefore, public policy considerations are hardly ever static: they change over time, reflecting the needs and realities of the various countries**."[487]
  - "5. As regards the international legal framework, **the Paris Convention and the Patent Cooperation Treaty (PCT) do not address exclusions from patentable subject matter**, although Article *4quater* of the Paris Convention and Rules 39 and 67 of the Regulations under the PCT touch upon some related issues. **The TRIPS Agreement, in Article 27.2 and 27.3, provides specific categories of subject matter that the WTO Members are entitled to exclude from patentability**. Further, Article 73 recognizes a

[484] *Id*., at par. 146.
[485] See World Intellectual Property Organization, Standing Committee on the Law of Patents, Mar. 23-27, 2009, *Exclusions From Patentable Subject Matter and Exceptions and Limitations to the Rights: Rep. of the WIPO Secretariat*, U.N. Doc. SCP/13/3, 13th Sess. (Feb. 4, 2009), available at: http://www.wipo.int/edocs/mdocs/scp/en/scp_13/scp_13_3.pdf.
[486] *Id*., at Executive Summary, par. 2.
[487] *Id*., at par. 3.

freedom of the Members to take certain actions which they consider necessary for the protection of their essential security interests."[488]

- "6. At the national/regional level, the exclusions from patentable subject matter provided for in national/regional legislation vary significantly. Nevertheless, **certain categories of subject matter are considered to be excluded from patentability in many countries** (**see Annex II of document SCP/12/3 Rev.2**). They include:
  - - inventions the exploitation of which is against ordre public or morality;
  - - diagnostic, therapeutic and surgical methods for the treatment of humans and animals;
  - - plant and animal varieties;
  - - plants and animals other than micro-organisms;
  - - essentially biological processes for the production of plants and animals;
  - - inventions affecting national security."[489]
- "9. In principle, the granting of exclusive **patent rights** is considered as an incentive for investment in innovative activities and the production of knowledge. To correct the potential inefficiencies of the market power created by such exclusive rights, a number of mechanisms are provided in the patent system, such as the patentability or the disclosure requirements. Nevertheless, **granting full exclusive rights in all circumstances may not always meet the goal of promoting innovation and enhancing the public welfare**. **Consequently, in many, if not all, patent laws, the scope of the enforceable exclusive rights is carefully *balanced* with the interests of other parties, who may be prevented from using the patented invention for a limited period of time**."[490]
- "10. Generally speaking, **there are two types of exceptions and limitations that allow States to fine-tune the different interests among stakeholders**. **First**, there are **provisions that exclude, or allow for the exclusion of, certain uses of a patented invention from being addressed in infringement proceedings** in national laws as well as under international treaties. The **second** type of exceptions and limitations is characterized by the fact that **a patentee cannot stop third parties from using his patented invention, but is entitled to remuneration against such use**. In other words, although the injunctive relief is significantly limited, a right to remuneration against the use of the invention is maintained. So-called **compulsory licenses (or non-voluntary licenses)** are often used to put this type of limitation in place."[491]
- "12. As regards the international treaties, Article 5.A of the Paris Convention provides certain rules regarding compulsory licenses. Further, certain limitations to the exclusive rights **in view of the safeguard of the public interest** to maintain the freedom of transport is regulated in Article 5ter of that Convention…"[492]
- "13. **Articles 30 and 31 of the TRIPS Agreement provide the exceptions and limitations to the rights which may be provided by the WTO Members**. According to

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[488] *Id*., at par. 5.
[489] *Id*., at par. 6.
[490] *Id*., at par. 9.
[491] *Id*., at par. 10.
[492] *Id*., at par. 12.

Article 30, a Member may provide **limited exceptions** to the exclusive rights conferred by a patent, provided **that** such exceptions **do not unreasonably conflict with the normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties**. The *Canada-Patent Protection of Pharmaceutical Product* case (DS114) offers some guidance in interpreting Article 30 [defining the scope of a "limited exception"]. **Article 31** provides that a Member may allow, under the stipulated conditions, other use by third parties or by the Government than that allowed under Article 30 without authorization of the right holder. **The Declaration on the TRIPS Agreement and Public Health, adopted by the Fourth Session of the WTO Ministerial Conference at Doha on November 14, 2001, provides some guidance to the application of Article 31**. **Further, the Decision of the General Council of August 30, 2003, on the Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health allows WTO Members to "waive" the limitation on exports under compulsory licenses to least-developed country Members and other Members that have insufficient or no manufacturing capacities in the pharmaceutical sector for the patented product in question**. Following the Decision of the General Council of December 6, 2005, on the Amendment of the TRIPS Agreement, an amendment to the TRIPS Agreement will replace the Decision of the General Council of August 30, 2003, when it is accepted by two thirds of the membership. Further, TRIPS Article 73 recognizing the freedom of the Members to protect essential security interests may be also relevant."[493]

- "14. At the national/regional level, the exceptions and limitations to the rights provided for vary significantly. However, some convergence can be found. **There are certain exceptions and limitations which are found in the legislations of many countries (see Annex II of document SCP/12/3 Rev.2)**. They include:
  - - private acts for non-commercial purposes;
  - - acts for the purpose of teaching;
  - - acts for experimental purposes or scientific research;
  - - preparation of medicines prescribed by doctors;
  - - continued use by a prior user;
  - - certain uses on foreign vessels, aircraft and land vehicles which temporarily or accidentally entered the national territory;
  - - acts for obtaining regulatory approval for pharmaceuticals;
  - - acts performed for a farmer's own use and for the development of new varieties."[494]
- "15. **Further, many national/regional laws provide for various situations under which compulsory licenses and government's use of patented inventions without the authorization of the patent owner may be allowed**. The present document summarizes

[493] *Id*., at par. 13. *See also* pars. 78-81, 84-94 (discussing the distinct but related issues of compulsory licensing and exhaustion).
[494] *Id*., at par. 14.

the scope of each of those exceptions under national/regional laws and outlines a number of issues being discussed in relation to each type of subject matter."[495]

- "27. Since the mandate given to the International Bureau by the SCP was to prepare a preliminary study on the exclusions from patentable subject matter, in principle, **this preliminary study focuses on subject matter which can be generally categorized as patentable subject matter (or inventions) but which is excluded from patent protection**."[496]
- "31. Generally speaking, **the choice of exclusions from patentable subject matter is carefully determined taking into account two aspects which are closely related: one aspect is whether a given invention should be excluded from protection with a view to discourage innovation. The second aspect relates to the question of whether a given invention should be excluded with the view to a risk of excluding access to the patented technology by third parties**. The two aspects are closely related because, on the one hand, there will be no question of access to innovation, if innovation does not exist in the first place. Secondly, if the access to the patented technology is unreasonably hampered, innovation may not be encouraged in an efficient and effective manner."[497]
- "53. **Many countries exclude inventions concerning diagnostic, surgical or therapeutic methods for the treatment of humans or animals from patentability**. This exclusion is **based on humanitarian and public health considerations**: new techniques in the area of diagnostic, therapeutic and surgical methods should be disseminated as widely as possible among the medical and veterinary practitioners without them having to fear a possible infringement of patents…"[498]
- "54. It should be noted that, **in some countries**, inventions concerning diagnostic, surgical or therapeutic methods for the treatment of humans or animals are **not patentable because they are not regarded as inventions that meet the requirement of industrial applicability**."[499]
- "55. The term "diagnostic methods" allows for some room for interpretation…"[500]
- "58. Since **the TRIPS Agreement provides a certain flexibility**, the exclusions from patentable subject matter concerning **inventions relating to plants and animals** vary significantly among the different laws. **In some countries, no provision exists that excludes this category of inventions from patentability**. **Other countries exclude some or all of the inventions relating to plants and animals, such as plant and animal varieties, plants and animals in general (other than microorganisms) and essentially biological processes for the production of plants or animals (other than non-biological or microbiological processes)**, but not all of those inventions are always excluded in all countries…"[501]

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[495] *Id*., at par. 15.
[496] *Id*., at par. 27.
[497] *Id*., at par. 31.
[498] *Id*., at par. 53.
[499] *Id*., at par. 54.
[500] *Id*., at par. 55.
[501] *Id*., at par. 58.

- "67. **With respect to patents on genetic material, concerns have been expressed with respect to the compliance with the Convention on Biological Diversity (CBD)**. It is argued that **patenting genetic material limits access to such genetic material** and can conflict with the sovereign rights of countries over their genetic resources. In the Council for TRIPS, concerns have been expressed about the granting of patents covering genetic material in its natural state or genetic material that has been merely isolated from nature and not otherwise modified in connection with the criteria for patentability. **It was said that the granting of overly broad patents could impede access to and use of genetic resources in a way which gave rise to questions of compatibility with the CBD, and restricted research by third parties**…"[502]
- "70. **Some countries exclude from patentability essentially biological processes for the production of plants and animals other than microbiological processes**. While the exact scope of the expressions "essentially biological processes" and "microbiological processes" should be referred to the applicable national law, in general, **it is understood that the provision excludes naturally-occurring biological processes from patentable subject matter, while providing the possibility of patenting, for example, gene manipulation processes**…"[503]
- "73. Many States believe that granting full exclusive rights in all circumstances does not meet the ultimate goal of promoting innovation and enhancing public welfare in all circumstances. Therefore, **the scope of the enforceable exclusive rights is carefully designed under national patent laws in order to strike the right *balance* between the legitimate interests of the right holders and the legitimate interests of third parties**."[504]
- "95. **It could be said that the exclusive rights conferred by a patent and the exceptions and limitations to such rights are two sides of the same coin seeking to *balance* the legitimate interests of the patent owner and the legitimate interests of third parties with a view to promote innovation, disseminate technical knowledge and encourage transfer of technology**. **Since the socio-economic conditions in a country and its priorities do influence the public policy considerations that underpin the adjustment of the different interests at stake**, it may not come as a surprise that the different laws contain a variety of provisions addressing exceptions and limitations."[505]
- "102. **A number of countries provide a so-called research exemption** either in their law or through case law in the common law countries. In general, the research exemption **enables researchers to examine the stated effects of patented inventions and improve such patented inventions without having to fear infringing the patent**. **Such a contribution to a positive environment for research activities is expected to add to the development of technologies, which is precisely one of the objectives of the patent system**…"[506]

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[502] *Id*., at par. 67.
[503] *Id*., at par. 70.
[504] *Id*., at par. 73.
[505] *Id*., at par. 95.
[506] *Id*., at par. 102. *See generally* pars. 100-114.

- "103. In the *Canada-Patent Protection of Pharmaceutical Product* case (DS114), the WTO Dispute Settlement Panel referred to the research exemption in conjunction with its ruling on Article 30 of the TRIPS Agreement…"[507]
- "116. **Many countries allow a third party to continue using a patented invention if he had used the invention for the purpose of his business in good faith before the filing date** (or the priority date) or had made effective or serious preparations for that purpose. **There are cases where a patent may be granted even if the patented invention had been used by a third party before the patent application was filed**. For example, if the third party was using the invention in his business prior to the filing date (priority date) in secret, such use **would not be regarded as prior art**, and consequently, a patent would be issued."[508]
- "117. **In many countries, continued prior use complying with the conditions laid down in the applicable law is excluded from infringement actions**…"[509]
- "127. **Many countries provide an exception relating to the use of patented products (particularly pharmaceutical products) for the purpose of obtaining regulatory approval to place the product on the market**. Such exception is often called "**Bolar exception**" because of the case *Roche Products v Bolar Pharmaceuticals* decided by the US Court of Appeals for the Federal Circuit (CAFC) in 1984. The CAFC ruled that **the research exemption in the United States of America did not cover Bolar's acts to carry out equivalent tests for the regulatory approval of the generic medicine before the expiration of the relevant patent owned by Roche.** The US legislators considered that **it was not appropriate to prevent generic pharmaceutical manufactures from starting to prepare and obtain regulatory approval for the generics**, since it would delay the entrance of generic medicines on the market for a substantial period, extending the effective protection period beyond the patent term. **Consequently, an explicit exception was introduced in the patent law**, stating that **acts solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use or sale of drugs or veterinary biological products, other than those products primarily manufactured using certain genetic manipulation techniques, were not infringement acts**."[510]
- "129. The scope of the *Bolar*-type exceptions, however, varies among national laws. First, in some countries, the exception covers regulatory approval of any products, while in some other countries, the coverage of the exception is limited to pharmaceuticals or medicinal products…"[511]
- "134…European Directive 98/44 on the Legal Protection of Biotechnological Inventions…states that the protection conferred by a patent on a product containing or consisting of genetic information shall, in general, extend to all material in which the product is incorporated and in which the genetic information is contained and performs

[507] *Id*., at par. 103.
[508] *Id*., at par. 116.
[509] *Id*., at par. 117. *See also* pars. 117-124.
[510] *Id*., at par. 127.
[511] *Id*., at par. 129.

its function…[and]…that the protection conferred by a patent on biological material possessing specific characteristics as a result of the invention shall extend to any biological material derived from that biological material through propagation or multiplication in an identical or divergent form and possessing those same characteristics."[512]

- "135. **The EU Directive, however,** derogates from the rights of patentees, which extend to the propagated and multiplicated materials, if the propagating material incorporating the patented invention is sold to a farmer for farming purposes by the patentee or with his consent. More specifically, the EU Directive **stipulates that the sale or other form of commercialization of plant propagating material to a farmer by the patentee or with his consent for agricultural use implies the authorization for the farmer to use the product of his harvest for propagation or multiplication by him on his own farm**, to the extent and **under** the conditions provided for by the **applicable plant variety protection law**."[513]
- "138. **A large number of countries have, in their national legislation, provisions that allow the government and/or third parties, under certain circumstances and conditions, to use a patented invention without the authorization of the right holder**. Such provisions differ from other exceptions, since, while the injunctive relief is significantly limited, the right to remuneration for that use is maintained. In general, those provisions are considered as an instrument **to prevent abuses** of the exclusivity inherent in the patent rights. They are also considered as tools **to ensure** that the patent system contributes to the promotion of innovation in **a competitive environment** and to the transfer and dissemination of technology, meeting the objectives of the system **and** responding to the public interest at large. They are also seen **as safeguards for governments to ensure national security and to respond to national emergencies**. In order to meet such objectives, **national laws contain various conditions and grounds for granting compulsory licenses**, **taking into account the interests of various stakeholders including the right holder, third parties and the public at large**."[514]
- "140. **Some consider that the existence of a statutory provision on compulsory licenses as such is important to ensure a fair exercise of the patent rights**, such as encouraging the conclusion of voluntary licenses or inducing competition…"[515]
- "141. **The WTO Members have to comply with the conditions under Article 31 of the TRIPS Agreement, and are bound by the Decision of the General Council of August 30, 2003, on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health (Paragraph 6 Decision)**. Therefore, the national legislation often contains provisions which are imported from Article 31 of the TRIPS Agreement…"[516]

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[512] *Id*., at par. 134.
[513] *Id*., at par. 135.
[514] *Id*., at par. 138.
[515] *Id*., at par. 140.
[516] *Id*., at par. 141.

- "143. Many countries provide that, **where a patentee fails to work a patent, or such work by the patentee is insufficient**, a compulsory license may be granted, provided that all other requirements are met…A safeguard for the patentee is provided so that, in general, if he could justify his inactivity with legitimate reasons, a request for a compulsory license would be refused, as provided for in the TRIPS Agreement."[517]
- "144. Some national laws simply state that, if a patentee is not working or sufficiently working the invention without any legitimate justification, a third party may request a compulsory license…"[518]
- "158. **Some national laws provide the possibility of granting a compulsory license to prevent <u>abuses</u>** which might result from the exercise of the exclusive patent rights, other than nonworking or insufficient working of the patent. **Anti-competitive practices by patentees <u>abusing the economic power derived from the exclusivity of the patent</u> are one example**. The law of **<u>Brazil</u>**, for instance, contains a provision that covers the abusive exercise of the patent rights in general."[519]
- "160. **Some countries** provide specific provisions under the patent law that **allow the grant of compulsory license in order to remedy an <u>anti-competitive practice</u> engaged by the patentee**."[520]
- "164. In some countries, **if a voluntary license could not be concluded between the parties on reasonable terms and conditions within a reasonable period of time, a compulsory license may be granted**."[521]
- "167. **Many countries allow the grant of <u>compulsory licenses on grounds of public interest</u>. This notion includes, in particular, <u>national emergencies and extreme urgencies, national security and public health</u>**. In some countries, situations that are more specific are envisaged in the law, such as a compulsory license on a patent relating to diagnostics or on a patent concerning a biotechnological research tool or accessory. The exact scope of the grounds relating to public interest considerations varies from one country to the other, **reflecting different policy considerations among countries**."[522]
- "180. Many countries provide the possibility of requesting a compulsory license where the exploitation of a patent (second patent) cannot be exploited without infringing another patent (first patent) [**dependent patents**]…"[523]
- "181. **The justification for such a compulsory license is that the patent system should promote, rather than hamper, the exploitation of new technology**, i.e., the invention claimed in the second patent, although the legitimate interest of the right holder of the

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[517] *Id*., at par. 143.
[518] *Id*., at par. 144. *See also* pars. 145-157 (discussing different countries' compulsory licensing laws).
[519] *Id*., at par. 158. *See also* par. 159.
[520] *Id*., at par. 160. *See also* pars. 161-162. *Cf*. par. 163 (discussing how the U.S. addresses anti-competitive practices vis-à-vis mechanisms external to patent law - e.g., under the Federal Trade Commission Act to address unfair methods of competition and unfair or deceptive acts or practices).
[521] *Id*., at par. 164. *See also* pars. 165-166.
[522] *Id*., at par. 167. *See also* pars. 168-179.
[523] *Id*., at par. 180.

first patent should be respected. In general, the public is expected to enjoy the benefits of the latest technology through the exploitation of the second patent."[524]

- "185. In addition to the above, a number of countries lay down in their national laws **an explicit provision that entitles the government, or a third party who is authorized by the government, to use the patented invention without authorization of the patentee** under certain circumstances. In some countries, such government use is permitted **if the public interest, such as national security, nutrition, health or the development of other vital sectors of the national economy so requires or if the government use adequately remedies the anti-competitive practice engaged by the patentee or his licensee**. As in the case of the grounds for the grant of compulsory licenses, the grounds for government use are stricter in some jurisdiction, and more liberal in others."[525]

- SCP/15/3 – *Expert's Study on Exclusions From Patentable Subject Matter and Exceptions and Limitations to the Rights* (Sept. 2010; Oct. 2010)[526]

  - *See, e.g.*, SCP/15/3 Annex I - *Introduction*[527]
    - "**The most obvious change over the century is the proliferation of exclusions**. More specifically, by 1987 many countries have exclusions for (i) methods of treatment (ii) animal varieties (iii) plant varieties (iv) biological processes (v) nuclear technologies (vi) computer programs. A number of explanations can be offered for this expansion of the number of exclusions (and the standardisation of the menu of exclusions and the language in which they are couched). Some of these are social and some legal. **The most important social shift that occurred over the century may**

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[524] *Id*., at par. 181.

[525] *Id*., at par. 185. *See also* pars. 186-190.

[526] *See* World Intellectual Property Organization, Standing Committee on the Law of Patents, Oct. 15-11, 2010, *Expert's Study on Exclusions From Patentable Subject Matter and Exceptions and Limitations to the Rights*, U.N. Doc. SCP.15/3, 15th Sess. (Sept. 2, 2010), available at: http://www.wipo.int/edocs/mdocs/scp/en/scp_15/scp_15_3-main1.pdf. "At its thirteenth session, held from March 23 to 27, 2009, the Standing Committee on the Law of Patents (SCP) decided that the Secretariat would 'commission external experts a study on exclusions, exceptions and limitations focused on, but not limited to, issues suggested by members, such as public health, education, research and experimentation and patentability of life forms, including from a public policy, socio-economic development perspective, bearing in mind the level of economic development" (document SCP/13/7, paragraph 9(c)(i))…The present document contains in its Annexes the said external experts' study commissioned to a group of academic experts…coordinated by Professor Lionel Bently." *Id*., at pars. 1-3. The experts' study comprises 6 annexes, each of which is a separate expert study. *See* World Intellectual Property Organization, *Experts' Study on Exclusions from Patentable Subject Matter and Exceptions and Limitations to the Rights* (SCP/15/3) (Sept. 2, 2010), available at: http://www.wipo.int/meetings/en/doc_details.jsp?doc_id=141352. This author confronted Professor Bently about some of the thinking behind his study in October 2010 during the 15th Session of WIPO SCP. *See* Lawrence A. Kogan, *Commercial High Technology Innovations Face Uncertain Future Amid Emerging 'BRICs' Compulsory Licensing and IT Interoperability Frameworks*, 13 San Diego Intl. L.J. *supra* at 234; World Intellectual Property Organization, *Report Prepared by the Secretariat of the Standing Committee on the Law of Patents 15th Session* (SCP/15/6) (May 16, 2010), at pars. 34 and 56, available at: http://www.wipo.int/edocs/mdocs/scp/en/scp_15/scp_15_6.pdf.

[527] *See* Lionel Bently, Brad Sherman, Denis Borges Barbosa, Karin Grau-Kuntz, Shamnad Basheer, Coenraad Visser and Richard Gold, *Exclusions from Patentability and Exceptions and Limitations to Patentees' Rights*, A Study Prepared for the World Intellectual Property Organization Standing Committee on the Law of Patents, at Introduction (SCP/15/3 Annex I - Introduction), available at: http://www.wipo.int/edocs/mdocs/scp/en/scp_15/scp_15_3-annex1.pdf.

well have been in terms of what might be conceived as falling within the scope of patent law. **It is, after all, only when matter might be regarded as "patentable" that exclusions from patentability become necessary**. Although it is not easy to get to grips precisely with the nature of shifts in the perception of what might be patentable, it seems uncontroversial to suggest that **a host of factors – some religious, some economic, some technological – which prompted the formulation of these exclusions**."[528]

- "…There is now widespread recognition of the significance of technological innovation to wealth creation, and thus many economists accept the long-term dynamic benefits of short-term interference with the free-market. **The resistance to patenting that was exhibited in the name of economic liberalism and free trade in the nineteenth century has given way to a much wider acceptance of the benefits of patenting. However, limits to patenting emerged in relation to activities that were not regarded as "economic" or which countries sought to insulate from market mechanisms**. One explanation offered widely for the exclusion of "methods of treatment" from patentability was that medical provision was, or ought to be, outside the economic system."[529]
- "…**But perhaps the most obvious non legal explanation for the expansion of exclusions is changes in "technology" itself**…[I]t was only with the development of genetic engineering that the possibility of "creating" or "inventing" new animals (and with that possibility concomitant social concerns). **Many of the exclusions thus reflect reactions to changes in the technological possibilities that are foreseen**."[530]
- "…**A second factor in the standardisation of a menu of exceptions adopted is, bizarrely perhaps, the Patent Co-operation Treaty**. Although the Treaty established a system for the international application for national patents, and thus did not require substantive harmonization of national laws, indirectly the Treaty appears to have standardised a bundle of exclusions….**The third factor in the proliferation and standardisation of exceptions in this period was the process of development and expansion of the EPC [European Patent Convention]**. Indeed…the processes of formulating the EPC exerted a significant influence on the formulation of PCT."[531]
- "…**The fourth factor has been the activity of WIPO itself**. In particular, from 1979 the WIPO model law for developing countries has had a degree of influence" [particularly, Article 112].[532]
- "…Some commentators have attributed growing importance of exceptions to changes in the scientific, technological and economic environment…**As a result, then, of the perceived change in "the nature of science," many countries have sought to introduce or strengthen private use and experimental use exceptions so as to**

[528] *Id*., at p. 17.
[529] *Id*., at p. 18.
[530] *Id*.
[531] *Id*., at p. 19.
[532] *Id*., at p. 20.

ensure access to the basic building blocks of science that formerly fell outside the patent regime."[533]

- "…**Clearly, the growth in the number and types of exclusion in part reflects shifts in what counts as patentable subject matter. Medicines, chemicals, food are no longer eligible for exclusion from patentable subject matter, as a consequence in particular of the TRIPs Agreement. This has led, in part, to a migration to exceptions**, most obviously the introduction of provisions allowing use of such materials during patent term to obtain regulatory approval (so-called **"Bolar" exceptions**), and **compulsory licensing provisions** (most notably regarding the supply of pharmaceuticals to developing world countries). **Other exceptions have developed where countries, such as the United States, have abandoned exclusions for methods of medical treatment and business methods**."[534]
- "…A similar migration is anticipated by commentators on patenting of **computer implemented inventions**. **As some of the consequences of patenting such works become clear, commentators argue, it may be necessary to broaden existing exceptions (perhaps introducing a fair use concept) particularly to give full effect to fundamental rights of free speech**."[535]

- *See, e.g.*, SCP/15/3 Annex II - *Computer Programs As Excluded Patentable Subject Matter*[536]
  - "**The consensus that computer programs as such are not patentable subject matter** is a product of a range of factors, from the continued expansion of the European Patent Convention, the growth in bilateral free trade agreements that necessitate change, and the willingness of courts and patent offices to limit the scope of the subject matter limitations. Another factor that helped to produce a consensus was **the US Federal Court's 2008 *Bilski* decision which marked a** move away from the liberal approach to patent protection facilitated by the *State Street Bank* decision: **a change which served to bring American law with regard to computer programs more in line with the approaches adopted in many other jurisdictions**: a position which was **confirmed by the US Supreme Court** in June 2010 when the decision of *Bilski v Kappos* was handed down."[537]
  - "…[**T]here is also a growing consensus that although computer programs should be treated as excluded subject matter, this is not necessarily the case where an invention, viewed as a whole, happens to include a computer program**. In a growing number of jurisdictions, there is also a trend whereby computer programs as such, or at least aspects thereof, are treated as patentable subject matter**. While there may have been a move in some jurisdictions, notably the United States, away**

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[533] *Id*., at p. 31.
[534] *Id*.
[535] *Id*., at p. 32. See also Coenraad Visser,
[536] *See* Brad Sherman, *Computer Programs As Excluded Patentable Subject Matter*, in *Exclusions from Patentability and Exceptions and Limitations to Patentees' Rights*, A Study Prepared for the World Intellectual Property Organization Standing Committee on the Law of Patents, at Introduction (SCP/15/3 Annex II), available at: http://www.wipo.int/edocs/mdocs/scp/en/scp_15/scp_15_3-annex2.pdf.
[537] *Id*., at p. 2.

from a more liberal approach to computer programs as patentable subject matter, overall the trend has been towards more and more protection for computer programs and for computer-implemented inventions (that is, for **inventions that utilise computer programs**)."[538]

- *See, e.g.*, SCP/15/3 – Annex V - *Patent Exceptions and Limitations in the Health Context*[539]
  - "A fundamental distinction in **human rights law** is between the so-called civil and political rights ('first generation' rights), on the one hand, and **socio-economic rights** ('second generation' rights), on the other. The former are "negative" rights that curb state power by imposing a duty on it not to act in certain ways; the latter are 'positive rights' that **impose obligations on the state to secure for its citizens a basic set of social goods - education, health care, food, water, shelter, and access to land and housing**. **The most important international instrument on socio-economic rights is the International Covenant on Economic, Social and Cultural Rights (ICESCR) of 1966, which has been ratified by some 130 states**. One of the substantive rights recognized by the Covenant is **'the right of everyone to the enjoyment of the highest attainable standard of physical and mental health'**. **In particular, parties are obliged to take steps necessary for 'the prevention, treatment and control of epidemic, endemic, occupational and other diseases', and 'the creation of conditions which would assure to all medical service and medical attention in the event of sickness'**. The overarching obligation imposed by the Covenant is 'to take steps, individually and through international assistance and co-operation, especially economic and technical, to the maximum of its available resources, with a view to achieving progressively the full realization of the rights recognized in the present Covenant by all appropriate means, including particularly the adoption of legislative measures'."[540]
  - "…[T]he obligation on states is not absolute but qualified in two respects. In the first instance, **a state must take appropriate steps towards achieving progressively the full realization of the right.** The reference to progressive achievement does not hide the obligation that the state must take those steps that are within its power immediately and other steps as soon as possible… Secondly, **resource scarcity does not relieve a state of its 'core minimum obligation' – 'to ensure the satisfaction of, at the very least, minimum essential levels of each of the rights'**. Such core minimum obligation is lifted only when the state can show that its resources are 'demonstrably inadequate' to allow it to fulfill its duties. **And even when resources are demonstrably inadequate, the obligation remains on a state to strive to**

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[538] *Id*.

[539] *See* Conrad Visser, *Patent Exceptions and Limitations in the Health Context*, in *Exclusions from Patentability and Exceptions and Limitations to Patentees' Rights*, A Study Prepared for the World Intellectual Property Organization Standing Committee on the Law of Patents, at Introduction (SCP/15/3 Annex V), available at: http://www.wipo.int/edocs/mdocs/scp/en/scp_15/scp_15_3-annex5.pdf.

[540] *Id*., at p. 1.

ensure the widest possible enjoyment of the relevant rights under the prevailing circumstances."[541]

- "**<u>What is the significance of the human rights framework in the present context?</u>** In the first instance, **it provides an organisational matrix for the diverse pro-health provisions in patent laws**. In so doing, it also motivates the adoption of these provisions in countries where they do not exist in patent laws. Secondly, **<u>it brings to the fore the competing claims of patentees and consumers</u>**."[542]

▪ *See e.g.*, SCP/15/3 – Annex VI - *The Patent System and Research Freedom: A Comparative Study*[543]

- "One of the primary goals of the patent system is to encourage research of all kinds – basic, applied and translational – by both granting rights to inventors and by excluding or limiting those rights so as to enable others to use and improve existing inventions. As legislatures and courts around the world have recognized, the exclusions and exceptions placed on patent rights are far from an oversight: they are essential to achieving the appropriate set of policies that best foster research and development. **This chapter investigates patent exclusions and exceptions which affect research and development in science and technology**."[544]

o SCP/14/4 Rev.2 – *Transfer of Technology* (Jan. 2010; Oct. 2011)[545]

▪ "19. The term 'transfer of technology' may be understood in a narrow or broad sense when used in the context of intellectual property, in particular, patents. **Broadly stated, transfer of technology is a series of processes for sharing ideas, knowledge, technology and skills with another individual or institution** (e.g., a company, a university or a governmental body) **and of acquisition by the other of such ideas, knowledge, technologies and skills**. In the context of **<u>transferring technologies from the public sector and universities to the private sector</u>**, the term 'transfer of

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[541] *Id*., at pp. 2-3.
[542] *Id*., at p. 3.
[543] *See* Richard Gold & Yann Joly, *The Patent System and Research Freedom: A Comparative Study* in *Exclusions from Patentability and Exceptions and Limitations to Patentees' Rights*, A Study Prepared for the World Intellectual Property Organization Standing Committee on the Law of Patents, at Introduction (SCP/15/3 Annex VI), available at: http://www.wipo.int/edocs/mdocs/scp/en/scp_15/scp_15_3-annex6.pdf.
[544] *Id*., at p. 1.
[545] *See* World Intellectual Property Organization, Standing Committee on the Law of Patents, Jan. 25–29, 2010, *Transfer of Technology*, U.N. Doc. SCP/14/4, 14th Sess. (Dec. 11, 2009), available at: http://www.wipo.int/edocs/mdocs/scp/en/scp_17/scp_14_4_rev_2.pdf. "At its fifteenth session, held from October 11 to 15, 201[0], in Geneva, the SCP requested the Secretariat to update the preliminary study on transfer of technology (document SCP/14/4), taking into account the comments made by Member States. The revised preliminary study (document SCP/14/4 Rev.) was submitted to the sixteenth session of the SCP, held from May 16 to 20, 2011, in Geneva. The discussion led to the conclusion that the Secretariat would revise document SCP/14/4/Rev. based on Member States' inputs reflecting comments of delegations at the sessions of the SCP and addressing, in greater detail, the discussion on impediments and elaborating further on incentives to technology transfer, for submission to the next session of the SCP (see document SCP/16/8, paragraph 19(b)). The present document implements the above request and provides updates to issues which were raised by Member States at the fourteenth, and fifteenth and sixteenth sessions of the SCP." *Id*., at par. 16.

technology' is **sometimes used in a narrower sense:** as a synonym of **'technology commercialization' whereby basic scientific research outcomes from universities and public research institutions are applied to practical, commercial products for the market by private companies**."[546]

- "48…There is a general understanding that the determining factors of international technology transfer are complex, and that the dynamic interactions of various national factors, innovation system, market, human resources, etc. need to be taken into account as a whole."[547]
- "49. Furthermore, there appears to be **growing consciousness of the information asymmetry among various stakeholders involved in the process of technology transfer. A technology holder may not be able to determine easily whether any third party is interested in using his or her technology. A potential technology recipient may not be able to find out easily about available existing technologies**. **For a potential technology recipient, it is difficult to analyze correctly the 'value' of the technology before the technology is actually transferred**. With the right tool to bridge the needs of potential technology transferor and transferee, globalization could in fact be an opportunity, rather than an impediment for such a transfer to take place."[548]
- "51. One of the difficulties for policy makers in identifying an optimal policy for the transfer of technology in an objective manner is that **it is hard to quantify the flow of technology transfer, either within the territory or beyond it. This is because many forms of technology transfer, e.g., spill-over of knowledge or knowledge acquisition through imitation, are simply not measurable**. While it is possible to measure the amount of foreign direct investment, there is no guarantee that the quantity of foreign direct investment is in proportion to the amount of knowledge acquired by the recipient country…"[549]
- "52. Another significant challenge relating to the transfer of technology is that technology is not like any other commodity that can be bought and sold in the market without consideration of the need for capacity building on the recipient side and the tacit elements required for effective transactions…**The process of transferring technology**, which may involve the commercial transaction of blueprints and machines, transfer of both codified and non-codified knowledge, and adaptation and application of acquired knowledge for the purpose of innovation, **is a complex one**."[550]
- "53. Many scholars point out **the importance of the absorptive capacity of the recipient of the technology, that is, the ability of the recipient to evaluate and use the technology effectively**. As an example, even if the technology is within the public domain which can be 'accessed' by any party, the capacity to acknowledge, analyze and apply public domain technology is necessary in order to solve concrete problems encountered by the recipient party. **The absorptive capacity may include the ability of**

[546] *Id*., at par. 19.
[547] *Id*., at par. 48.
[548] *Id*., at par. 49.
[549] *Id*., at par. 51.
[550] *Id*., at par. 52.

the recipient party to conduct an effective negotiation with a technology holder, based on the clear understanding of the technology concerned and of legal terms and practical negotiation skills."[551]

- "61. **By granting limited exclusive rights, the patent system, in effect, creates property rights in the knowledge embedded in patented inventions**. **The patent system has transformed public goods knowledge into a tradable property with defined ownership and boundary of rights**. The exclusive right conferred by a patent can be used by a patentee to prevent others from using the patented invention. However, the same exclusive right can be used as a currency to promote an exchange of knowledge and collaboration by researchers through licensing agreements and assignment of rights. The patent system aims to improve the efficiency of the flow of knowledge and to facilitate the transfer of technology by setting up a legal framework that allows technology holders to disclose their inventions, license their patents or sell their patents without fear of free-riding. The possibility of defining ownership and a clear boundary of rights also facilitates packaging and trading technology under a 'patent'".[552]
- 62. **Another element of the patent system, the public disclosure of inventions, also plays an important role in the effective transfer of technology.** Published patent applications and patents are an enormous source of technological knowledge. In addition to the detailed description of inventions, such publication also contains claims which define the scope of patent protection and bibliographical data relating to inventors, patent applicants and patentees. Therefore, **patent information not only makes detailed technological knowledge available to others but also informs the public of the owner, extent and scope of patent (property) rights**. At the same time, patent information **indicates the extent to which third parties may exploit the technical knowledge contained in the patent document without infringing the patent**."[553]
- "63. **Without doubt, a patent system could make the above positive contributions to the efficient transfer of technology only where the system functions in a way for which it is intended**."[554]
- "64. In other words, patent laws provide requirements such as the conditions of patentability (patentable subject matter, novelty, inventive-step (non-obviousness), industrial applicability (utility)), sufficient disclosure of the claimed invention in the description and clarity of claims. **If those requirements are not properly stipulated in the patent law, or the patent law stipulating those requirements is not properly applied, the grant of the exclusive patent rights may not serve the public interest as intended through the patent system, and may increase the transaction cost for transfer of technology**. **Similarly, a proper and unambiguous scope of exceptions and limitations to the exclusive patent rights as well as enforcement and recourse**

[551] *Id*., at par. 53.
[552] *Id*., at par. 61.
[553] *Id*., at par. 62.
[554] *Id*., at par. 63.

measures accessible for all stakeholders **may be elements in the patent system that facilitate knowledge sharing**."[555]

- "68. Whether or not the patent system inhibits, rather than promotes, transfer of and access to technology is a recurring question. Most recently, in the context of the climate change debate, **it has been argued that patents on carbon abatement technology, mainly owned by patentees in developed countries, constitute a major barrier to developing countries' efforts to reduce greenhouse gases**…"[556]
- "72. International trade is one of the various channels through which technologies are disseminated internationally…On the one hand, strong IPR protection in the importing country may encourage foreign firms to export patented goods, while it may reduce the possibility of domestic firms imitating the patented technology and strengthen the market power of foreign firms…"[557]
- "73…[S]tudies may suggest that the level of IPR protection may have an impact on trade flows between countries in general, but it may also depend on the level of development, the market structure and the imitation capability."[558]
- "74…[F]oreign direct investment (FDI) is one of the channels for transferring technologies from one party to another. There is less conclusive evidence regarding the impact of patent protection on the level of FDI."[559]
- "77. In many cases of technology transfer, **patent licensing agreements** play an important role, as they allow access to the technology in question. The relationship between licensing, technology transfer and the strength of IPR protection can be highly complex due to the fact that technology licenses vary significantly from one agreement to the next."[560]
- "83…**[T]he crucial point in respect of IPR**s, and in particular patents, **is** not **whether they** promote trade or foreign investment, but how they **help or hinder access to the required technology by those who are in need of such technology**…"[561]
- "85…[T]here may be a number of common questions and challenges shared by many countries. Firstly, according to property rights theory, unclearly defined and/or insecure property rights (i.e., weak appropriability) are the sources of imperfections in the market.66 In the context of patents, this means that **clear rules are needed with respect to the ownership, including inventorship, of a patent and the boundary of protection, i.e., clear scope of claims**."[562]
- "86. Secondly, information asymmetry between the patent holder and a prospective licensee (or patent purchaser) is another problem. Certainly, **the publication of clear and complete disclosure of a patented invention narrows the information gap**. However, the availability of technical information as well as legal information relating to patents in

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[555] *Id*., at par. 64.
[556] *Id*., at par. 68. *See also* pars. 69-70.
[557] *Id*., at par. 72.
[558] *Id*., at par. 73.
[559] *Id*., at par. 74. *See also* pars. 75-76.
[560] *Id*., at par. 77. *See also* pars. 78-82.
[561] *Id*., at par. 83.
[562] *Id*., at par. 85.

the Registry of a patent office does not necessarily mean that they are **easily accessible to the public**."[563]

- "87. The third question relates to **how to reduce transaction costs**. Transparency of relevant information is of fundamental importance. **Clear licensing rules with *balanced rights* and *obligations* for licensees and licensors increase legal certainty and reduce costs**. In this context, an enabling environment that promotes licensing agreements supportive of competition in the market may play an important role…"[564]
- "88. The fourth question relates to **the *right balance* between the interests of the patent holder and third parties**, and the prevention of **abuse** or misuse of patent rights or market power…[**G]ranting full exclusive rights in all circumstances may not always contribute to the promotion of further innovation and to the transfer and dissemination of technology for the enhancement of public welfare and social benefits**. **Consequently, the scope of enforceable exclusive rights is carefully designed in order to *strike the right balance* with the interests of other parties, who may be prevented from using the patented invention for a limited period**. Those measures can be established within the patent system, e.g., certain limitations to patent rights such as a research exemption and compulsory licenses, and outside the patent system, e.g., competition law and policy."[565]
- "89. With the increase of globalization and transnational trade flows, the link between patents, trade and the transfer of technology has been increasingly recognized at the international level, as can be seen, for example in Articles 7, 8 and 66.2 of the… (TRIPS Agreement)…"[566]
- "93. **The Declaration on the TRIPS Agreement and Public Health** also reaffirmed the commitment of developed country members to provide incentives to their enterprises and institutions to promote and encourage technology transfer to least-developed country Members pursuant to Article 66.2. **The TRIPS Council, in 2003**, decided on the procedures for the submission and review of reports by developed country members and agreed on the list of issues to be reported."[567]
- "96. The TRIPS Agreement contains a number of substantive provisions, including enforcement provisions, with which the Members of the WTO must comply…For those who take the view that stronger IPR protection has a positive impact on trade, FDI and technology licensing…the TRIPS Agreement may be considered as an international instrument that is supportive of trade, FDI and technology licensing. However, **the implication of the TRIPS Agreement for developing countries is much disputed**."[568]
  - "**One scholar puts developing countries into three categories**, that is: (i) countries where the benefits of innovations outweigh the additional rent due to the TRIPS

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[563] *Id*., at par. 86.
[564] *Id*., at par. 87.
[565] *Id*., at par. 88.
[566] *Id*., at par. 89. *See also* pars. 90-92.
[567] *Id*., at par. 93. *See also* pars. 94-95.
[568] *Id*., at par. 96.

Agreement; (ii) countries where the additional rent due to the TRIPS Agreement outweighs the benefits of innovation; and (iii) the countries below a certain development threshold that cannot benefit from the TRIPS Agreement (and are now exempt from most TRIPS obligations). **In his view, for the LDCs, strong IPRs will probably not be appropriate in all situations, and policy goals should aim to move countries from group (ii) to group (i) through developing domestic industrial innovation potential**."[569]

- "97. **A provision that addresses the international transfer of relevant technologies is also found in many multilateral environment agreements (MEAs)**. The development, application and transfer of technology are core elements in the implementation of MEAs. **Intellectual property rights, in particular, patents, in the context of transfer of environment-related technologies are covered in different ways** in various MEAs. **Many agreements state that technology transfer should be provided to developing countries 'in fair and most favorable conditions or terms' including 'on concessional and preferential terms, as mutually agreed'**. The **Convention on Biological Diversity (CBD)** and the Convention to Combat Desertification (CCD) are two conventions that refer to intellectual property rights explicitly in conjunction with the transfer of technology."[570]
- "100. **Technology lies at the center of the climate change debate** as well. **International legal instruments and global policy debates place high emphasis on the role of technology in addressing the challenge of climate change**. For example, **Article 4.1 of the United Nations Framework Convention on Climate Change (UNFCCC)** states that all Parties to the Convention promote and cooperate in the development, application and diffusion, including transfer, of technologies, practices and processes that control, reduce or prevent anthropogenic emissions of greenhouse gases, and promote and cooperate in the full, open and prompt exchange of relevant scientific, technological, technical, socio-economic and legal information related to climate change. **The UNFCCC includes a specific commitment by developed countries regarding provisions of financial resources and technology transfer in Articles 4.3 and 4.5**, respectively…"[571]
- "102. While the text of the UNFCCC does not explicitly refer to intellectual property rights or patents, intellectual property issues have been raised in conjunction with the review of the implementation of commitments made by the Contracting Parties, in particular by developed country Parties, under Article 4. How intellectual property could be best addressed in the framework of the UNFCCC is part of the ongoing debate."[572]
- "108. **In relation to technology transfer, one of the major issues regarding…[bilateral and regional agreements containing IP provisions that have been signed in recent years between countries at different levels of**

[569] *Id*.
[570] *Id*., at par. 97. *See also* pars. 98-99.
[571] *Id*., at par. 100. *See also* par. 101.
[572] *Id*., at par. 102.

development[573]**]…as has been stated by some commentators, is the extent to which they set IP rights going beyond those agreed multilaterally**. Thus, some commentators refer to **FTA provisions** concerning, *inter alia*, compensatory extensions of the patent term in case of administrative delays and/or marketing approvals, limitation of the grounds for use of compulsory licensing, limitation on parallel importation, elimination of flexibility on the scope of patentable subject matter and strong enforcement rules. In addition, in the framework of access to pharmaceuticals, provisions on protection of pharmaceutical test data contained in some FTAs were intensively discussed as **going beyond the requirements set by the TRIPS Agreement**."[574]

- "149. **In any patent system**, with a view to contributing to the promotion of technological innovation and to the transfer and dissemination of technology, ***finding the right balance*** **between producers and users of technological knowledge is considered fundamental**. Since patents confer exclusive rights on patentees, national patent laws carefully exclude certain subject matter from patent protection and set a limit to exclusive patent rights in certain cases which otherwise would be considered as infringing a patent. This allows technology users to use inventions that fall under certain subject matter, or to use patented inventions in a certain manner or for a specific purpose, without fear of infringing a patent. In addition, measures have been taken in national laws, both within and outside the patent system, to prevent the **abuse or misuse of exclusive patent rights** that would impede, rather than promote, the dissemination and transfer of technology. **The need to embrace the mutual advantage of producers and users of technological knowledge in a manner beneficial to social and economic welfare and to take appropriate measures to prevent the abuse or practices that adversely affect the international transfer of technology is widely acknowledged at the international level.**"[575]
- "171. Among the various partnerships and networks that we have witnessed in the past, a considerable part consists of inter-firm relationships, but collaborative innovation networks are gaining popularity among players from the private sector and government-funded agencies (so-called **public-private partnerships**). To a certain extent, almost all these collaboration models rely on patent strategies and contain provisions on the management and use of patent rights."[576]
- "172…Many private companies are successfully committed to the above three stages, i.e., from the R&D to the commercialization and dissemination of products. On the other hand, it has been widely recognized that, **in many countries, a substantive amount of R&D, particularly basic research, is financed by the government and conducted by public research institutions including universities, while the commercialization of new products is essentially conducted by the private sector**. Furthermore, as the

[573] *See*, *Id*. par. 107.
[574] *Id*., at par. 108.
[575] *Id*., at par. 149. *See also* pars. 150-161.
[576] *Id*., at par. 171.

technology becomes increasingly complex, the private sector is seeking collaboration with public sector research institutions that possess a high level of research expertise."[577]

- "173. Generally speaking, there used to be a clear division between the activities of firms and those of the academic sector. The academic sector, including the public research institutions, previously concentrated more on the basic science. **However, there has been an erosion of the division between basic science and applied science, in particular, in the field of biotechnology <u>where basic science, such as genomics, is perceived as having potentially significant commercial value</u>**…"[578]
- "178. Taking into account the various interests involved, it appears that **the policy choices of many governments are to allow universities and public research institutions to claim ownership of intellectual property based on public-funded research with the aim of maximizing the public benefits of such research. Consequently, universities and public research institutions can, to a large extent, set up IP and licensing policies, and decide on the distribution of royalty incomes among the stakeholders**. One of the first countries that established a legal framework to implement such a policy was the United States of America: the so-called **Bayh-Dole Act of 1980**…"[579]
- "182…Nevertheless, [one German] study concludes that the hope for revenues from commercialization as a new source of funding for universities could be misguided."[580]
- "183. In order to facilitate collaboration between the public sector and the private sector, **<u>some countries</u> provide standard model agreements, such as model research collaboration agreements and consortium agreements**, for a variety of circumstances…"[581]
- "184. **It has been observed that the amount of knowledge and technology transferred from university to industry (and/or which is the result of collaboration between these two types of institutions) depends on**: (i) the amount of knowledge generated within universities and public research institutions; (ii) the type of knowledge disclosure; (iii) the nature and type of their research; and (iv) the absorptive capacity and demand for new knowledge by companies. Since public-private partnerships are one form of technology transfer from one party to another, **intellectual property rights are relevant, but represent just one element for successfully transferring knowledge from the public sector to the private sector**. Needless to say, in addition to the legal and institutional framework of the knowledge production system, **the capacity of the business sector to absorb the research results and other enabling environments are essential for effective public-private partnerships**."[582]
- "190. In order to facilitate the sharing of knowledge and the adaptation, transfer and diffusion of technologies, WIPO has been developing platforms that build on partnerships

[577] *Id*., at par. 172.
[578] *Id*., at par. 173. *See also* pars. 174-177.
[579] *Id*., at par. 178. *See also* pars. 179-181.
[580] *Id*., at par. 182.
[581] *Id*., at par. 183.
[582] *Id*., at par. 184. *See also* par. 185.

and collaborations between technology holders and technology users. There are at present two such collaborative platforms developed or being developed by WIPO: WIPO Re:Search in the field of health and WIPO Green relating to environmental technology…"[583]

- 193. **Access to new technologies is considered crucial in effectively responding to global challenges, such as development, climate change, health and food security**. Indeed, new technologies can be a solution to a number of, if not all, challenges **prescribed in the United Nations Millennium Development Goals (MDGs).**[584] **In particular, Goal 8 of the MDGs states that UN Member States are committed to developing a global partnership, and Target 8f** [585] **indicates: "in cooperation with the private sector, make available the benefits of new technologies, especially information and communications**".[586]
- "195. As a specialized agency of the United Nations, the effective use of intellectual property for economic, social and cultural development has been a key concern to WIPO…**[T]he WIPO Development Agenda**[587] **has been aiming to ensure that development considerations form an integral part of WIPO's work**. **The forty-five recommendations adopted by the WIPO General Assembly in October 2007 contain a number of recommendations that relate to the transfer of technology**. Specifically, Cluster C 'Technology Transfer, Information and Communication Technologies and Access to Knowledge'…highlights the concerns of WIPO Member States and recommends actions in this area…"[588]
- "197. **The Committee on Development and Intellectual Property (CDIP) was established by the WIPO General Assembly in 2007 to** (i) develop a work program for implementation of the 45 adopted recommendations; (ii) to monitor, assess, discuss and report on the implementation of all recommendations adopted, and for that purpose it shall coordinate with relevant WIPO bodies; and (iii) **discuss IP and development-related issues as agreed by the Committee, as well as those decided by the [WIPO]**

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[583] *Id*., at par. 190. *See also* pars. 191-192.

[584] *See* World Intellectual Property Organization, *Millennium Development Goals (MDGs) and WIPO - Intellectual Property for Development*, available at: http://www.wipo.int/ip-development/en/agenda/millennium_goals/.

[585] *See* World Intellectual Property Organization, *Millennium Development Goal 8 - Develop a Global Partnership for Development, What WIPO is Doing on MDG 8*, available at: http://www.wipo.int/ip-development/en/agenda/millennium_goals/millennium_goal_8.html.

[586] *See* SCP/14/4 Rev.2d., *supra* at par. 193.

[587] "[T]he Development Agenda…was formally established by WIPO's member states in 2007, in a decision which included the adoption of 45 Development Agenda recommendations, grouped into six clusters, and the establishment of a Committee on Development and Intellectual Property (CDIP)." *See* World Intellectual Property Organization, *Development Agenda for WIPO*, available at: http://www.wipo.int/ip-development/en/agenda/. See also World Intellectual Property Organization, *The 45 Adopted Recommendations under the WIPO Development Agenda*, available at: http://www.wipo.int/ip-development/en/agenda/recommendations.html; http://www.wipo.int/export/sites/www/ip-development/en/agenda/recommendations.pdf.

[588] *See* SCP/14/4, *supra* at par. 195. *See also* par. 196.

General Assembly.[589] Consequently, implementation of the above recommendations has been monitored, assessed, discussed and reported at the CDIP…"[590]

- "Two projects for the implementation of the WIPO Development Agenda are directly relevant to the transfer of technology. They are the '**Project on Innovation and Technology Transfer Support Structure for National Institutions**' and the '**Project on Intellectual Property and Technology Transfer: Common Challenges – Building Solutions**'.[591]
- In addition, the project entitled '**Capacity-building in the use of appropriate technology-specific technical and scientific information as a solution for identified development challenges**' aims to strengthen the capacity of LDCs to improve the management, administration and utilization of technical and scientific information with a view to building an appropriate technology base. Further, the **Project on Intellectual Property and the Public Domain** reviews the role of the patent system in the identification, access and use of technology that is in the public domain."[592]
- **WIPO CDIP has prepared interesting reports concerning the interrelationship between patents, competition and technology transfer**.[593]

- WIPO Secretariat Report – *Refusals to License IP Rights – A Comparative Note on Possible Approaches* (Aug. 2013)[594]

  - "1. **The WIPO Secretariat has been mandated by WIPO Member States to work on the interface between Intellectual Property (IP) and Competition Policy with a view to ensuring that IP be used as a tool for the promotion of economic and social development**. For that purpose, the Committee on Development and Intellectual Property (CDIP) asked the WIPO Secretariat to implement a two-year project that reflected the thrust of three of the forty-five recommendations, the implementation of which the CDIP supervises."[595]
  - "3. An introductory analysis of the potential competitive implications of refusals to license is one of the components of the work plan for the current biennium. Its spirit corresponds to recommendation 7, which calls for the promotion of a better

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[589] See World Intellectual Property Organization, *Committee on Development and Intellectual Property (CDIP)*, available at: http://www.wipo.int/policy/en/cdip/.
[590] *See* SCP/14/4, *supra* at par. 197.
[591] *Id*.
[592] *Id*., at par. 198.
[593] *See, e.g.*, World Intellectual Property Organization, Committee on Development and Intellectual Property 8th Sess., *Report on an Analysis of the Economic/Legal Literature on Intellectual Property (IP) Rights: A Barrier to Entry?*, CDIP/8/INF/6 CORR. (Jan. 16, 2012), available at: http://www.wipo.int/edocs/mdocs/mdocs/en/cdip_8/cdip_8_inf_6_corr.pdf.
[594] *See* World Intellectual Property Organization, *Refusals to License IP Rights – A Comparative Note on Possible Approaches*, Report of the Secretariat (Aug. 2013), available at: http://www.wipo.int/export/sites/www/ip-competition/en/studies/refusals_license_IPRs.pdf.
[595] *Id*., at par. 1.

understanding of the interface between IPRs and competition policies, so that those Members with less experience in the pro-development management of IP can benefit from the experience of other Member States."[596]

- "6. **Intellectual property rights (IPRs) are fundamentally the right to say 'no,' or, in other words, the right to exclude**. Almost invariably, they are defined by international agreements and national statutes in a negative way, thereby expressing their essentially exclusive nature. For example, most of the provisions of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement), of 1994, which define the rights granted to IP owners, do so by providing for the right to prevent others from copying or using the subject matter of protection."[597]
- "8. **But in spite of this, it is not uncommon that the exercise by IPR owners of their primary right be seen with suspicion, if not with outright condemnation**. **This widespread attitude results from the misguided notion that IPRs are monopolies and that, therefore, their ownership invariably confers dominant market power – hence, their exclusionary exercise is considered socially reproachable in itself**. It is important, therefore, to have a bird's eye view on how far WIPO Member States go in ensuring that their national laws and practices protect the right of IPR owners to say 'no,' especially given the international standards set by the TRIPS Agreement."[598]
- "9. **IPR owners' rights to exclude others from using their protected intangible assets are at the heart of the IP system**. **However, the legal implications of this core right have led to different approaches and treatments in WIPO Member States' national statutes as well as in their construction by courts and agencies in charge of enforcing IP and antitrust law**."[599]
- "10. This Note aims to provide a brief overview of the various approaches found in a number of jurisdictions that are committed to applying internationally harmonized IP standards, such as those set in the Paris and Berne Conventions, as well as in the TRIPS Agreement…[T]he intention of this Note is just to sample national statutes and practices, not to undertake an exhaustive exercise of analysis of principles. Basically, **this Note tries to answer a question: how do WIPO Member States apply the principles and rules of competition law to refusals to license IPRs?**"[600]

b. Initiatives of Economic Intergovernmental[601] Organizations

i. World Trade Organization (WTO)[602]

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[596] *Id*., at par. 3.
[597] *Id*., at par. 6.
[598] *Id*., at par. 8.
[599] *Id*., at par. 9.
[600] *Id*., at par. 10. *See also* Lawrence A. Kogan, *Commercial High Technology Innovations Face Uncertain Future Amid Emerging 'BRICs' Compulsory Licensing and IT Interoperability Frameworks*, 13 San Diego Intl. L.J. 201, supra at pp. 243-246.
[601] *See* Thomas J. Volgy, Elizabeth Fausett, Keith A. Grant and Stuart Rodgers, *Identifying Formal Intergovernmental Organizations*, 45 Journal of Peace Research 849, 2008, available at: http://www.u.arizona.edu/~volgy/Page_proofs.pdf.

- Declaration on the TRIPS Agreement and Public Health (Doha Declaration) (Nov. 14, 2001)[603]

  - "**We agree that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health**. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that **the Agreement can and should be interpreted and implemented in a manner supportive of WTO members' <u>right to protect public *health*</u> <u>and, in particular, to promote access to medicines for all</u>**."[604] Accordingly and in the light of paragraph 4 above, while maintaining our commitments in the TRIPS Agreement, **<u>we recognize that these flexibilities include</u>**:

    - In applying the customary rules of interpretation of public international law, each provision of **<u>the TRIPS Agreement shall be read in the light of the object and purpose of the Agreement</u>** as expressed, in particular, in its objectives and principles.
    - **<u>Each member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted</u>**.
    - **<u>Each member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency</u>**, it being understood that **<u>public health crises</u>**, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, ***<u>can</u>*** **represent a national emergency or other circumstances of extreme urgency**.
    - The effect of the provisions in the TRIPS Agreement that are relevant to the exhaustion of intellectual property rights is to leave **<u>each member free to establish its own regime for such exhaustion without challenge</u>**, subject to the MFN and national treatment provisions of Articles 3 and 4."[605]
    - "**We recognize that WTO members with insufficient or no manufacturing capacities in the pharmaceutical sector** could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement. We instruct the Council for TRIPS to find an expeditious solution to this problem…"[606]

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[602] "The World Trade Organization (WTO) is the only global international organization dealing with the rules of trade between nations." *See* World Trade Organization, *What is the WTO?*, available at: http://www.wto.org/english/thewto_e/whatis_e/whatis_e.htm. "The WTO provides a forum for negotiating agreements aimed at reducing obstacles to international trade and ensuring a level playing field for all, thus contributing to economic growth and development. The WTO also provides a legal and institutional framework for the implementation and monitoring of…16 different multilateral agreements (to which all WTO members are parties) and two different plurilateral agreements (to which only some WTO members are parties)…as well as for settling disputes arising from their interpretation and application." *See* World Trade Organization, *About the WTO — A Statement by former Director-General Pascal Lamy*, available at: http://www.wto.org/english/thewto_e/whatis_e/wto_dg_stat_e.htm.

[603] *See* World Trade Organization, *Declaration On the TRIPS Agreement and Public Health*, DOHA WTO MINISTERIAL 2001: TRIPS (WT/MIN(01)/DEC/2) (adopted Nov. 14, 2001), available at http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm.

[604] *Id*., at par. 4.

[605] *Id*, at par. 5(a)-(d).

[606] *Id*., at par. 6.

- WTO General Council[607] Decision on the Implementation of Doha Declaration Par. 6 (2003)[608]

  - "**Recognizing**, where **eligible importing Members** seek to obtain supplies under the system set out in this Decision…[An eligible importing Member includes "**any least-developed country Member, and any other Member that has made a notification** (2) to the Council for TRIPS of its intention to use the system as an importer…]"[609]

  - "**Noting** that…**exceptional circumstances exist justifying waivers from the obligations set out in paragraphs (f) and (h) of Article 31 of the TRIPS Agreement with respect to pharmaceutical products** [including patented products and "processes", and "active ingredients necessary for its manufacture and diagnostic kits needed for its use";[610]

  - "The obligations of an **exporting Member** under **[TRIPS] Article 31(f) ["any such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use"**]…**shall be waived** with respect to the grant by it of a compulsory licence to the extent necessary for the purposes of production of a pharmaceutical product(s) and its export to an eligible importing Member(s) in accordance with the terms set out below…"[611]

  - An **exporting Member's notification** must specify:

    - Names and quantities of products needed;
    - In case of non-LDCs, the lack of or insufficient manufacturing capacities in the pharmaceutical sector for the product(s) in question; and
    - Its intention to grant a TRIPS Article 31-compliant compulsory license with respect to a pharmaceutical product patented in said Member.[612]

  - The **compulsory license** must provide:

    - For the manufacture of "only the amount necessary to meet the needs of the eligible importing Member…"

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[607] "The General Council is the WTO's highest-level decision-making body in Geneva, meeting regularly to carry out the functions of the WTO. It has representatives (usually ambassadors or equivalent) from all member governments and has the authority to act on behalf of the ministerial conference which only meets about every two years…The General Council also meets, under different rules, as the Dispute Settlement Body and as the Trade Policy Review Body." *See* World Trade Organization, *The WTO General Council*, available at: http://www.wto.org/english/thewto_e/gcounc_e/gcounc_e.htm.

[608] See World Trade Organization General Council, *Decision on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health* (WT/L/540 and Corr.1) (Aug. 30, 2003; Sept. 1, 2003), available at: http://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm.

[609] *Id*., at Preamble par. 4 and Decision par. 1(b).

[610] *Id*., at Preamble, par. 5 and Decision, par. 1(a).

[611] *Id*., at par. 2.

[612] *Id*., at par. 2(a)(i)-(iii).

- That "products produced under the licence shall be clearly identified as being produced under the system set out in this Decision through specific labelling or marking…"
- That the licensee, prior to shipment, must post on the web the quantities for each product shipment destination, and each product's distinguishing features (labeling and marking).[613]
- The exporting Member must notify the TRIPS Council of the grant and duration of the compulsory license, and provide licensee, shipment and website information.[614]

- Where an **exporting Member grants a compulsory license**, TRIPS Article 31(h) requires that Member **to pay "'adequate remuneration'**…taking into account the economic value to the importing Member of the use that has been authorized in the exporting Member."[615]

- "Where an eligible **importing Member grants a compulsory license** for the same products, the **importing Member's TRIPS Article 31(h) obligation is waived** with respect to those products for which the exporting Member has **already paid remuneration** consistent with Article 31(h).[616]

- "[E]ligible **importing Members** shall take reasonable measures within their means, proportionate to their administrative capacities and to the risk of trade diversion, to **prevent re-exportation** of the products that have actually been imported into their territories under the system, using the means already required to be available under the TRIPS Agreement."[617]

- "[ALL] Members shall ensure the availability of effective legal means to prevent the importation into, and sale in, their territories of products produced under the system set out in this Decision and diverted to their markets inconsistently with its provisions, using the means already required to be available under the TRIPS Agreement."[618]

- "[E]ligible importing Members and exporting Members are encouraged to use the system set out in this Decision in a way which would promote this objective. Members undertake to cooperate in paying special attention to the transfer of technology and capacity building in the pharmaceutical sector in the work to be undertaken pursuant to Article 66.2 of the TRIPS Agreement."[619]

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[613] *Id*., at par. 2(b)(i)-(iii).
[614] *Id*., at par. 2(c).
[615] *Id*., at par. 3.
[616] *Id*.
[617] *Id*., at par. 4.
[618] *Id*., at par. 5.
[619] *Id*., at par. 7. TRIPS Article 66.2 provides that, "Developed country Members shall provide incentives to enterprises and institutions in their territories for the purpose of promoting and encouraging technology transfer to least-developed country Members in order to enable them to create a sound and viable technological base." Doha Declaration par. 7 "reaffirms…developed-country…commitment…to provide incentives to their enterprises and institutions to promote and encourage technology transfer to least-developed country members pursuant to Article 66.2", and not to "oblige[]…the least-developed country members…with respect to pharmaceutical products, to implement or apply Sections 5 and 7 of Part II of the TRIPS Agreement or to enforce rights provided for under these Sections until 1 January 2016, without prejudice to the

- "**This Decision is without prejudice to the rights, obligations and flexibilities that Members have under [TRIPS Articles 31(f) and (h)]…including those reaffirmed by the Declaration**, and to their interpretation…[and] to the extent to which pharmaceutical products produced under a compulsory licence can be exported under the present provisions of Article 31(f)…"[620]

- "**Members shall not challenge** any measures taken in conformity with the provisions of the waivers contained in this Decision under subparagraphs 1(b) and 1(c) of Article XXIII of GATT 1994." [AS 'NON-VIOLATIONS' – i.e., as prosecutable violations of overall expected benefits from trade, rather than violations of specific obligations under a WTO Agreement][621]

- "This Decision, including the waivers granted in it, shall terminate for each Member on the date on which **an amendment to the TRIPS Agreement** replacing its provisions takes effect for that Member."[622]

  - On December 6, 2005, WTO Members approved changes to the TRIPS Agreement to reflect this Decision,[623] **which amendment shall take effect "[o]nce two thirds of members have formally accepted" them**.[624] As of the date of this writing, the requisite 2/3 Member voting acceptance has not yet been secured despite multiple extensions having been granted.[625]

ii. World Bank[626]

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right of least-developed country members to seek other extensions of the transition periods as provided for in Article 66.1 of the TRIPS Agreement." See *Declaration On the TRIPS Agreement and Public Health*, supra at par. 7.

[620] See *Decision on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health*, supra at par. 9.

[621] *Id*., at par. 10.

[622] *Id*., at par. 11.

[623] *See* World Trade Organization, *Members OK Amendment to Make Health Flexibility Permanent*, Press Release (Press/426) (Dec. 6, 2005), available at: http://www.wto.org/english/news_e/pres05_e/pr426_e.htm. "The decision directly transforms the 30 August 2003 'waiver' into a permanent amendment of the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)." *Id*.

[624] *See* World Trade Organization, *Members Accepting Amendment of the TRIPS Agreement*, available at: http://www.wto.org/english/tratop_e/trips_e/amendment_e.htm. "Once two thirds of members have formally accepted it, the amendment will take effect in those members and will replace the 2003 waiver for them. For each of the remaining members: the waiver will continue to apply until that member accepts the amendment and it takes effect." *Id*. Although the United States approved the TRIPS amendment on December 17, 2005, the amendment has not yet taken effect, and thus, the US may not rely upon it unilaterally, because 2/3 of the WTO Membership has still not approved it. Consequently, the waiver provision still governs all Members.

[625] *Id*.

[626] Initially "[c]onceived during World War II…[to] help[] rebuild Europe after the war…[t]oday's Bank…has sharpened its focus on poverty reduction as the overarching goal of all its work… It has become a Group, encompassing five closely associated development institutions: the International Bank for Reconstruction and Development (IBRD), the International Development Association (IDA), the International Finance Corporation (IFC), the Multilateral Investment Guarantee Agency

- World Bank Report – *Inclusive Green Growth: The Pathway to Sustainable Development* (May 2012)[627]

  - "The best way to facilitate access to green technologies is through openness to international trade, foreign direct investment, technology licensing, worker migration, and other forms of global connectedness."[628]

  - "**Other underused policies to boost access** to existing technologies include patent buyouts, **compulsory licenses**, patent pools, and **open source approaches**."[629]

    - "**Making it easier for countries to issue *compulsory licenses* under appropriate circumstances can help ensure more affordable access to patented green innovations by poorer households in low-income countries**."[630]
    - "**In open source development, a body of original information is made available for anyone to use**. Usually, any party using the original material must agree to make its enhancements publicly available. **Open source projects are inherently royalty free**. Both of these approaches could be used for neglected seeds for drought-prone, saline environments, or other green solutions for lower-income countries."[631]

iii. BRICS Forum[632]

(MIGA), and the International Centre for Settlement of Investment Disputes (ICSID)." *See* The World Bank, *World Bank History*, available at: http://web.worldbank.org/WBSITE/EXTERNAL/EXTABOUTUS/EXTARCHIVES/0,,contentMDK:20053333~menuPK:63762~pagePK:36726~piPK:36092~theSitePK:29506,00.html. "The World Bank Group has set two goals for the world to achieve by 2030: End extreme poverty by decreasing the percentage of people living on less than $1.25 a day to no more than 3%; Promote shared prosperity by fostering the income growth of the bottom 40% for every country." *See* The World Bank, *About-What We Do*, available at: http://www.worldbank.org/en/about/what-we-do.

[627] *See* World Bank, *Inclusive Green Growth: The Pathway to Sustainable Development* (2012), available at: http://siteresources.worldbank.org/EXTSDNET/Resources/Inclusive_Green_Growth_May_2012.pdf.

[628] *Id*., at p. 78. Many green technologies are embodied in technology licensing agreements and in equipment machinery, and imported capital goods. Some are knowledge-based processes or business models that diffuse through movements of people attached to multinational corporations or from the diaspora. Some can be recreated by emulating imported final goods, copying lapsed patents, or studying and inventing around patents that are still in effect. Technology and skill transfer also occur through the purchase of manufacturing equipment on global markets, because suppliers usually provide worker training with their equipment." *Id*.

[629] *Id*.

[630] *Id*.

[631] *Id*.

[632] "[T]he BRICS — with Brazil, Russia, India, China and, later, South Africa — *initiated in 2006 by Russia* has become one of the most significant geopolitical events of the new century. This institution has become a powerful factor in world politics in a short time. Informal global institutions such as the G7 and the G77 existed before the BRICS. However, the BRICS differs from them in a variety of ways that allow it to be defined as a global forum for a new generation. This group of five major economies reflects an objective trend of global governance towards a multipolar international relations system and the strengthening of economic interdependence. Within the framework of this system, non-institutional structures of global governance and network diplomacy are resorted to more and more widely. The basis of BRICS influence in the international arena is the growing economic power of its member states, their important (and in some cases irreplaceable) role

- First BRICS Summit, BRICS Joint Communique (June 2009)[633]

  - "5. We recognize the important role played by international trade and foreign direct investments in the world economic recovery. We call upon all parties to work together to improve the international trade and investment environment. We urge the international community to keep the multilateral trading system stable, curb trade protectionism, and **push for comprehensive and balanced results of the WTO's Doha Development Agenda**."[634]

  - "6. The poorest countries have been hit hardest by the financial crisis. The international community needs to step up efforts to provide liquidity for these countries. **The international community should also strive to minimize the impact of the crisis on development and ensure the achievement of the Millennium Development Goals**. Developed countries should fulfill their commitment of 0.7% of Gross National Income for the Official Development Assistance and **make further efforts in increasing assistance, debt relief, market access and technology transfer for developing countries**."[635]

  - "7. **The implementation of the concept of sustainable development, comprising, inter alia, the Rio Declaration, Agenda for the 21st Century and multilateral environmental agreements**, **should be a major vector in the change of paradigm of economic development**."[636]

  - "11. We reaffirm to advance **cooperation** among our countries in science and education with the aim, inter alia, **to engage in fundamental research and development of advanced technologies**."[637]

- Third BRICS Summit, Sanya Declaration (April 2011)[638]

  - "6. **In the economic, financial and development fields, BRICS serves as a major platform for dialogue and cooperation**. We are determined to continue strengthening the

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demographically and their natural resources. *In 2011 the BRICS's share of global gross domestic product (GDP) based on purchasing power parity amounted to about 25%; they occupy 30% of the global territory; and they are home to 45% of the world's population. The contribution of the BRICS countries to global economic growth over the last decade has reached 50%*, which makes this group of states the leading power in global economic development" (emphasis added). See Vadim Lukov, *A Global Forum for the New Generation: The Role of the BRICS and the Prospects for the Future*, BRICS Information Centre, University of Toronto (Jan. 24, 2012), available at: http://www.brics.utoronto.ca/analysis/Lukov-Global-Forum.html.

[633] *See* First BRIC Summit, *Joint Statement of the BRIC Countries Leaders* (Yekaterinburg, Russia, June 16, 2009), available at: http://www.brics5.co.za/about-brics/summit-declaration/first-summit/.

[634] *Id*., at par. 5.

[635] *Id*., at par. 6.

[636] *Id*., at par. 7.

[637] *Id*., at par. 11.

[638] *See* Third BRICS Summit, *Sanya Declaration*, (Sanya, Hainan, China, April 14, 2011), available at: http://www.brics5.co.za/about-brics/summit-declaration/third-summit/.

BRICS partnership for common development and advance BRICS cooperation in a gradual and pragmatic manner, reflecting the principles of openness, solidarity and mutual assistance."[639]

- "…8. **We express our strong commitment to multilateral diplomacy with the United Nations playing the central role in dealing with global challenges and threats**. In this respect, we reaffirm the need for a comprehensive reform of the UN, including its Security Council, with a view to making it more effective, efficient and representative, so that it can deal with today's global challenges more successfully. **China and Russia reiterate the importance they attach to the status of India, Brazil and South Africa in international affairs, and understand and support their aspiration to play a greater role in the UN**."[640]

- "…18. We support the development and use of renewable energy resources. We recognize the important role of renewable energy as a means to address climate change. **We are convinced of the importance of cooperation and information exchange in the field of development of renewable energy resources**."[641]

- "…20. Accelerating sustainable growth of developing countries is one of the major challenges for the world. **We believe that growth and development are central to addressing poverty and to achieving the MDG goals**. **Eradication of extreme poverty and hunger is a moral, social, political and economic imperative of humankind** and one of the greatest global challenges facing the world today, particularly in Least Developed Countries in Africa and elsewhere."[642]

- "21. We call on the international community to actively implement the outcome document adopted by the High-level Plenary Meeting of the United Nations General Assembly on the Millennium Development Goals held in September 2010 and **achieve the objectives of the MDGs by 2015** as scheduled."[643]

- "…23. **Sustainable development, as illustrated by the Rio Declaration on Environment and Development, Agenda 21, the Johannesburg Plan of Implementation and multilateral environmental treaties, should be an important vehicle to advance economic growth**…"[644]

- Fourth BRICS Summit, Delhi Declaration (March 2012)[645]

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[639] *Id*., at par. 6.
[640] *Id*., at par. 8.
[641] *Id*., at par. 18.
[642] *Id*., at par. 20.
[643] *Id*., at par. 21.
[644] *Id*., at par. 23.
[645] *See* Fourth BRICS Summit, *Delhi Declaration* (March 29, 2012), available at: http://www.brics5.co.za/about-brics/summit-declaration/fourth-summit/.

- "3. **BRICS is a platform for dialogue and cooperation amongst countries that represent 43% of the world's population**…"[646]

- "…16. **We will continue our efforts for the successful conclusion of the Doha Round, based on the progress made and in keeping with its mandate**. Towards this end, we will explore outcomes in specific areas where progress is possible while preserving the centrality of development and within the overall framework of the single undertaking. **We do not support plurilateral initiatives that go against the fundamental principles of transparency, inclusiveness and multilateralism**…"[647]

- "17. **Considering UNCTAD to be the focal point in the UN system for the treatment of trade and development issues, we intend to invest in improving its traditional activities of consensus-building, technical cooperation and research on issues of economic development and trade**. We reiterate our willingness to actively contribute to the achievement of a successful UNCTAD XIII, in April 2012."[648]

- "…30. We are fully committed to playing our part in the global fight against climate change and will contribute to the global effort in dealing with climate change issues through sustainable and inclusive growth and not by capping development. **We emphasize that developed country Parties to the UNFCCC shall provide enhanced financial, technology and capacity building support for the preparation and implementation of nationally appropriate mitigation actions of developing countries**."[649]

- "31. **We believe that the UN Conference on Sustainable Development (Rio+20) is a unique opportunity for the international community to renew its high-level political commitment to supporting the overarching sustainable development framework** encompassing inclusive economic growth and development, social progress and environment protection **in accordance with the principles and provisions of the Rio Declaration on Environment and Development, including the principle of common but differentiated responsibilities, Agenda 21 and the Johannesburg Plan of Implementation**."[650]

- "32. **We consider that sustainable development should be the main paradigm in environmental issues, as well as for economic and social strategies**. We acknowledge the relevance and focus of the main themes for the Conference namely, Green Economy in the context of Sustainable Development and Poverty Eradication (GESDPE) as well as Institutional Framework for Sustainable Development (IFSD)."[651]

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[646] *Id*, at par. 3.
[647] *Id*., at par. 16.
[648] *Id*., at par. 17.
[649] *Id*., at par. 30.
[650] *Id*., at par. 31.
[651] *Id*., at par. 32.

- Fifth BRICS Summit, eThekwini Declaration (March 2013)[652]

  - "1…The Fifth BRICS Summit concluded the first cycle of BRICS Summits and we reaffirmed our commitment to the promotion of international law, multilateralism and **the central role of the United Nations (UN)**…"[653]

  - "…2…**We aim at progressively developing BRICS into a full-fledged mechanism of current and long-term coordination on a wide range of key issues of the world economy and politics**. The prevailing global governance architecture is regulated by institutions which were conceived in circumstances when the international landscape in all its aspects was characterised by very different challenges and opportunities. **As the global economy is being reshaped, we are committed to exploring new models and approaches towards more equitable development and inclusive global growth** by emphasising complementarities and building on our respective economic strengths."[654]

  - "…15. We reaffirm our support for an open, transparent and rules-based multilateral trading system. **We will continue in our efforts for the successful conclusion of the Doha Round, based on the progress made and in keeping with its mandate**, while upholding the principles of transparency, inclusiveness and multilateralism. **We are committed to ensure that new proposals and approaches to the Doha Round negotiations will reinforce the core principles and the developmental mandate of the Doha Round**. **We look forward to significant and meaningful deliverables that are *balanced* and address key development concerns** of the poorest and most vulnerable WTO members, at the ninth Ministerial Conference of the WTO in Bali."[655]

  - "16. We note that the process is underway for the selection of a new WTO Director-General in 2013. We concur that the WTO requires a new leader who demonstrates a commitment to multilateralism and to enhancing the effectiveness of the WTO including through a commitment to support efforts that will lead to an expeditious conclusion of the DDA. **We consider that the next Director-General of the WTO should be a representative of a developing country**."[656]

  - "17. We reaffirm the United Nations Conference on Trade and Development's (UNCTAD) mandate as the focal point in the UN system dedicated to consider the interrelated issues of trade, investment, finance and technology from a development

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[652] *See* Fifth BRICS Summit - BRICS and Africa: Partnership for Development, Integration and Industrialisation, *eThekwini Declaration*, (Durban, South Africa March 26-27, 2013), available at: http://www.brics5.co.za/about-brics/summit-declaration/fifth-summit/.
[653] *Id*., at par. 1.
[654] *Id*., at par. 2.
[655] *Id*., at par. 15.
[656] *Id*., at par. 16.

perspective. UNCTAD's mandate and work are unique and necessary to deal with the challenges of development and growth in the increasingly interdependent global economy. **We also reaffirm the importance of strengthening UNCTAD's capacity to deliver on its programmes of consensus building, policy dialogue, research, technical cooperation and capacity building, so that it is better equipped to deliver on its development mandate**."[657]

- "…34. **We recognize the critical positive role the Internet plays globally in promoting economic, social and cultural development**. We believe it's important to contribute to and participate in a peaceful, secure, and open cyberspace and **we emphasise that security in the use of Information and Communication Technologies (ICTs) through universally accepted norms, standards and practices is of paramount importance**."[658]

- "35. We congratulate Brazil on hosting the UN Conference on Sustainable Development (Rio+20) in June 2012 and welcome the outcome as reflected in "The Future we Want", in particular, **the reaffirmation of the Rio Principles and political commitment made towards sustainable development and poverty eradication** while creating opportunities for BRICS partners to engage and cooperate in the development of the future Sustainable Development Goals."[659]

- "36. We congratulate India on the outcome of the 11th Conference of the Parties to the **United Nations Conference on Biological Diversity (CBD COP11)** and the sixth meeting of the Conference of the Parties serving as the Meeting of the Parties to the **Cartagena Protocol on Biosafety**."[660]

- "37. While acknowledging that climate change is one of the greatest challenges and threats towards achieving sustainable development, we call on all parties to build on the decisions adopted in **COP18/CMP8 in Doha**, with a view to reaching a successful conclusion by 2015, of negotiations on the **development of a protocol, another legal instrument or an agreed outcome with legal force under the [Uniform Framework on Climate Change] Convention** applicable to all Parties, guided by its principles and provisions."[661]

- "38. We believe that the internationally agreed development goals including **the Millennium Development Goals (MDGs) address the needs of developing countries**, many of which continue to face developmental challenges, including widespread poverty and inequality…We reiterate that individual countries, especially in Africa and other

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[657] *Id*., at par. 17.
[658] *Id*., at par. 34.
[659] *Id*., at par. 35.
[660] *Id*., at par. 36.
[661] *Id*., at par. 37.

developing countries of the South, cannot achieve the MDGs on their own and therefore **the centrality of Goal 8 on Global Partnerships for Development to achieve the MDGs should remain at the core of the global development discourse for the UN System**. Furthermore, this requires the honouring of all commitments made in the outcome documents of previous major international conferences."[662]

- "39. **We reiterate our commitment to work together for accelerated progress in attaining the Millennium Development Goals (MDGs) by the target date of 2015**, and we call upon other members of the international community to work towards the same objective…It is important to ensure that any discussion on the UN development agenda, including **the "Post 2015 Development Agenda**" is an inclusive and transparent inter-Governmental process under a UN-wide process which is universal and broad based."[663]

- Fifth BRICS Summit, BRICS Joint Trade Minister Communique (March 2013)[664]

  - "[I]nsisted on **preserving the centrality of the Doha development mandate and the principle of the single undertaking**[;]

  - …[E]xpressed concern at initiatives that may undermine the coherence of the Doha Development Agenda and that deviate from the principles of multilateralism[;]

  - …[**A]greed to strengthen their collaboration to ensure that any meaningful deliverables reached by the Ninth WTO Ministerial Conference** in December 2013 **are *balanced* and addresse[d] key developmental concerns of the poorest and most vulnerable WTO members**[;]

  - …[P]roposed that **the [WTO] Ministerial Conference should re-affirm Members' commitment to conclude the Doha Development Agenda on the basis of its development mandate and the single undertaking**[;]

  - …[R]eaffirmed their **commitment to cooperate in other multilateral fora where trade and investment issues arise, such as the G20, UNCTAD, UNDP, UNIDO and WIPO, amongst others**.

  - …[**O]bserved that in the current global context of economic difficulty and the impasse in the Doha Development Agenda negotiations, UNCTAD could play a vital role in promoting cooperation among Governments and relevant stakeholders in a range of**

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[662] *Id*., at par. 38.
[663] *Id*., at par. 39.
[664] See *Joint Communique*, The Third Meeting of the BRICS Trade Ministers (Durban 26 MARCH 2013), available at: http://english.mofcom.gov.cn/article/newsrelease/significantnews/201303/20130300070292.shtml 13.pdf.

areas relevant to trade and investment from a development perspective...[and]…agreed to support UNCTAD in this role.

- …[A]greed that current circumstances required new principles, concepts, models and mechanisms to strengthen intra-BRICS cooperation[; and]

- …[**C]ommitted to support Africa's development agenda** by strengthening their cooperation in the search for synergies for investment in Africa's infrastructure, agriculture and manufacturing sectors."[665]

2. **Copyrights**

a. Initiatives of the United Nations Secretariat, Agencies, Offices, and Instrumentalities

i. United Nations Educational, Scientific and Cultural Organization (UNESCO)[666]

- Copyright Protection Policy

  - Generally:

    - "Committed to promoting copyright protection since its early days (the Universal Copyright Convention was adopted under UNESCO's aegis in 1952), **UNESCO has over time grown concerned with ensuring general respect for copyright in all fields of creation and cultural industries**. It conducts, in the framework of the Global Alliance for Cultural Diversity, awareness-raising and capacity-building projects, in addition to information, training and research in the field of copyright law. It is particularly involved in developing new initiatives to fight against piracy. **The digital revolution has not left copyright protection unaffected. UNESCO endeavours to make a contribution to the international debate on this issue, taking into account the development perspective** and paying particular attention to the **need of maintaining the *fair balance* between the interests of authors and the interest of the general public of access to knowledge and information**."[667]

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[665] *Id*., at pp. 2-4.

[666] "UNESCO's mission is to contribute to the building of peace, the eradication of poverty, sustainable development and intercultural dialogue through education, the sciences, culture, communication and information. The Organization focuses, in particular, on two global priorities: Africa [and] Gender equality." *See* United Nations Educational, Scientific and Cultural Organization, *About Us- Introducing UNESCO: What we are*, available at: http://www.unesco.org/new/en/unesco/about-us/who-we-are/introducing-unesco/.

[667] *See* United Nations Educational, Scientific and Cultural Organization, Creativity, *Creative Industries – Copyright*, available at: http://www.unesco.org/new/en/culture/themes/creativity/creative-industries/copyright/.

- UNESCO Report – Basic Notions About Copyright and Neighbouring Rights[668]
  - "…6) **When can a protected work be used without having to seek permission? In order to find a *fair balance* between the public's interest in access to information and knowledge, on the one hand, and the exclusive position of rights owners, on the other, copyright protection is subject to a number of exceptions and limitations**. In certain situations, a protected work may be used without the copyright owner's consent for the benefit of the society as a whole. The relevant provisions vary from one country to another: while some countries (mainly those adhering to the civil law tradition), have adopted a very restrictive set of limitations on copyright protection, **others include in their legislation comparatively extensive provisions allowing acts to take place without the prior authorisation of the rights owner. The open- ended 'fair use' concept in the USA and the more restrictive 'fair dealing' one in the UK, Canada or Australia** are examples of the latter approach."[669]
  - "8) **How does copyright function in the digital environment?** Copyright protection of computer software is today established in most countries and harmonized by international treaties. Moreover, **recent legislation in many countries, backed by international law, has clarified that existing rights continue to apply when works are disseminated through new technologies and communication systems such as the Internet**. In order **to ensure that right holders can effectively use technology to protect their rights and license their works in a digital environment, certain technological adjuncts to copyright law have emerged:** many countries have introduced the so-called **'anti-circumvention' provisions** that aim at **prohibiting the circumvention of technological measures**, introduced by right owners in order **to prevent copying of the works (such as encryption), as well as alteration of electronic 'rights management information'**, which identifies the work, its creators, performer or owner, and the terms and conditions of its use."[670]
  - "**The current debate relates to the need to adapt the limitations and exceptions to copyright protection to new technologies, in an aim to maintain a *fair balance* between the interests of the rightholders and those of the public**, without violating the obligations established by international law."[671]
    - "For example, the copying of a page from a textbook, the duplication of a CD or an Internet download may all constitute relevant reproductions under copyright law. Similarly, the music we hear in publicly accessible places, such as bars or shops, is normally communicated to the public under the terms of copyright."[672]

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[668] *See* United Nations Education, Scientific and Cultural Organization, *Basic Notions About Copyright and Neighbouring Rights*, available at: http://www.unesco.org/fileadmin/MULTIMEDIA/HQ/CLT/creativity/pdf/copyright/basic_notions_en.pdf.
[669] *Id*., at pp. 5-6.
[670] *Id*., at pp. 6-7.
[671] *Id*., at p. 7.
[672] *Id*.

- "**Exclusive rights, on the one hand, and *fairly balanced* exceptions/limitations, on the other, are therefore both designed to foster creativity**. Their interplay is of vital importance for the creative development of any society."[673]
- "**Cultural diversity is strengthened by the free flow of ideas**, and that it is nurtured by constant exchanges and interaction between cultures (**Convention on the protection and promotion of the diversity of cultural expressions**).[674] Books, films, CDs and other products that embody copyright-protected works of the mind play a central role in this context since they are vehicles for ideas, traditions and values of the regional and national culture from which they originate."[675]

- UNESCO Report – The ABC's of Copyright (2010)[676]

  - "**Copyright laws must take into consideration the interests of authors and creators and the needs of society for access to knowledge and information**. In order **to *strike a balance*** between the two, copyright is subjected to two sorts of limitations…[D]uring the term of protection, **the rights of authors to control the economic exploitation (use) of their works may be restricted by exceptions and limitations laid down by national laws: they allow for certain free uses, for purposes described by the legislators, which could be made, generally, without a financial compensation**. Permitted free use of works is sometimes confused with the so-called system of 'non-voluntary licences'. In some cases, **national laws may, in accordance with the international standard, replace certain exclusive rights of the authors with such a system of non-voluntary licences**: in practical terms, this means that **right owners cannot refuse to grant authorization for the use of the work by third parties, but they retain the right to receive a remuneration and to negotiate its amount**. Typical examples of non-voluntary licences can be found in the field of broadcasting."[677]
  - "All copyright laws grant exceptions and limitations in favour of certain groups of users or the public at large. The legitimate interests recognized by **domestic legislations and case law that would justify the existence of exceptions may be divided into four main categories: promotion of freedom of expression, access to knowledge, the purposes of justice and the public, and finally private or personal use**. Yet it must not be overlooked that the notion of **'legitimate interest'** may vary significantly from one

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[673] *Id*., at p. 10.
[674] See *Convention on the Protection and Promotion of the Diversity of Cultural Expressions*, U.N. Educational, Scientific and Cultural Organization [UNESCO], 33d Sess., 20th Plenary Meeting (Oct. 20, 2005), available at http://unesdoc.unesco.org/images/0022/002253/225383E.pdf (emphasizing "the importance of cultural diversity for the full realization of human rights and fundamental freedoms proclaimed in the Universal Declaration of Human Rights and other universally recognized legal instruments", and that "cultural activities, goods and services have both an economic and a cultural nature, because they convey identities, values and meanings, and must therefore not be treated as solely having commercial value.") *Id*., at Preamble, par. 18.
[675] *Id*., at pp. 10-11.
[676] *See* United Nations Educational, Scientific and Cultural Organization, *The ABC's of Copyright* (2010), available at: http://www.unesco.org/fileadmin/MULTIMEDIA/HQ/CLT/diversity/pdf/WAPO/ABC_Copyright_en.pdf.
[677] *Id*., at p. 45.

jurisdiction to another. What may be allowed as an exception in one country is therefore not necessarily allowed in another."[678]

- *Freedom of Expression*: "[**T]he right to quote** is the only mandatory exception provided for by the **Berne Convention**,[679] which allows quoting from already published works under the condition that this is compatible with fair practice and to the extent justified by the specific purpose…[A]s a rule, the name of the author and the source of the quoted work must be indicated in the quotation or reproduction in an appropriate manner."[680]
- *Access to Knowledge*: "Typically, these limitations cover acts such as **reproduction for the purposes of preservation and replacement** of lost or damaged copies of works (in the case of libraries), as well as reproduction of copies of protected works **for teaching purposes**. The 'utilisation of works by way of illustration' (this is the formulation used in the Berne Convention) may include the use not only of printed material, but also of broadcasts or sound and audiovisual recordings…[T]o encourage the dissemination of knowledge and information, many countries have in recent years started to adopt specific provisions in favour of handicapped persons."[681]
- *For Private Use*: "A number of laws provide that a work may be **reproduced** by the user **for personal use or for a limited circle of family members and friends**. To qualify for this exception, **the copied work must**, as a rule, **have already been made public and there should be no profit-making purpose**. In order to compensate right owners, private copying provisions are usually (but not always) accompanied by levy-based remuneration schemes: they aim to compensate, at least partially, the right owners, whose rights may be prejudiced by private copying on a large scale through, for example, photocopying of printed works or home recording of films and music. Levies are usually imposed on the sale of reproduction equipment, such as photocopying machines or recording devices, as well as on blank sound or video supports, and administered by collective management bodies, often on a mandatory basis. **With the emergence of digital technologies the reproduction of protected content is becoming increasingly easy and inexpensive. This has provoked rather vigorous debates on the issue of private copying in recent years**."[682]

▪ "[W]hile some countries (mainly those adhering to the civil law tradition) have adopted a very restrictive set of limitations on copyright protection, others include in their legislation comparatively **extensive provisions allowing acts to take place without the prior authorization of the right owner. The open-ended 'fair use' concept in the United States and the more restrictive 'fair dealing' one in the United Kingdom, Canada or Australia, are examples** of the latter approach. It is worth noting here that

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[678] *Id*., at p. 46.
[679] See *Berne Convention for the Protection of Literary and Artistic Works*, Sept. 9, 1886, as revised at Paris on July 24, 1971 and amended in 1979, S. Treaty Doc. No. 99-27 (1986), available at: http://www.wipo.int/treaties/en/ip/berne/trtdocs_wo001.html.
[680] *Id*., at p. 48.
[681] *Id*., at pp. 48-49.
[682] *Id*., at pp. 49-50.

the exceptions and limitations have not been harmonized at the international level and that all but one of the exceptions provided for by the Berne Convention are optional: in other words, national legislators may decide whether to adopt them or leave them out."[683]

- "Nonetheless, the so called **'three-step test'** has come to be regarded as the **international yardstick for exceptions to exclusive rights**. Initially **introduced by the Berne Convention as a set of criteria against which any exception to the right of reproduction were to be assessed**, nowadays it has been **adopted by** the most recent international instruments **(the TRIPs Agreement and the WIPO 1996 Treaties)** and **serves as a basis for assessment of all exceptions to exclusive authors' rights**."[684]
- "According to the [three-step] test, limitations or exceptions to exclusive rights should be confined to 1) certain special cases which 2) do not conflict with a normal exploitation of the work and 3) do not unreasonably prejudice the legitimate interests of the right owner."[685]

▪ "**The digital environment, the ever more increasing use of works over digital networks and the use of technological protection measures (TPM) and digital rights management systems, which aim to prevent illegal copying of protected works, have provoked a heated discussion as to whether or not these measures limit the possibility of exercising legitimate free uses allowed by national copyright laws, as well as to the possible solutions that may reconcile these tensions**. Case law varies from country to country and the debate is ongoing: there is no universally accepted solution and it is for the national lawmakers and courts to determine on a case-by-case basis whether the general criteria of the three-step test are met."[686]

o UNESCO's Contribution to Post-2015 – The Power of Culture for Development

▪ "**Culture is a key resource to address both the economic and social dimensions of poverty and to provide innovative and cross-cutting solutions to complex issues -- such as health and the environment, gender equality and promoting quality education for all**. Cultural and creative industries are some of the most rapidly growing sectors in the world, representing an estimated global value of US$ 1.3 trillion. At the same time, **culture is a source of wealth in ways that do not have price tags**. Culture can help promote social cohesion and youth engagement, and it is a wellspring for social resilience. Culture is a source of identity and cohesion for societies at a time of bewildering change. No development can be sustainable without it. **At this moment of change, when we are rethinking strategies for development** and seeking to identify

[683] *Id*., at p. 47.
[684] *Id*.
[685] *Id*.
[686] *Id*., at p. 50.

new sources of dynamism, let's put culture on the agenda as a force for **sustainability in development**."[687]

ii. United Nations Conference on Trade and Development (UNCTAD)[688]

- UNCTAD/International Centre for Trade and Sustainable Development Project on Intellectual Property Rights and Sustainable Development[689]
  - Report – *The International Copyright System: Limitations, Exceptions and Public Interest Considerations for Developing Countries* (2006)[690]
    - "Examining the limitations of Article 40 of the TRIPS Agreement and the new realities of copyright in the digital age, Professor Okediji **argues for a reform of the Appendix to the Berne Convention and for a global approach to limitations and exceptions that *better balances* the exclusive rights conferred through copyrights with public interest considerations for developing countries**."[691]
      - "Crafting the ***appropriate balance*** between rights and limitations/exceptions in domestic copyright is a dynamic experiment, not easily subject to formulaic approaches, particularly in light of ongoing technological developments and shifting social and economic expectations by users and authors respectively. **In the global**

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[687] *See* United Nations Educational, Scientific and Cultural Organization, *UNESCO's Contribution to Post-2015 - The Power of Culture for Development*, available at: http://en.unesco.org/post2015/power-culture-development. *See also* United Nations Educational, Scientific and Cultural Organization, *Culture for Sustainable Development*, available at: https://en.unesco.org/themes/culture-sustainable-development; United Nations Educational, Scientific and Cultural Organization, The International Congress, *Culture: Key to Sustainable Development*, (Hangzhou, China (May 15-17 2013), available at: http://www.unesco.org/new/en/culture/themes/culture-and-development/hangzhou-congress/; United Nations Educational, Scientific and Cultural Organization and Ministry of Foreign Affairs Republic of Indonesia, World Culture Forum - *The Power of Culture in Sustainable Development* (Nov. 24-27, 2013) available at: http://wcfina.org/.

[688] *See* United Nations Conference on Trade and Development, *A Brief History of UNCTAD*, available at: http://unctad.org/en/Pages/About%20UNCTAD/A-Brief-History-of-UNCTAD.aspx. See also, United Nations Conference on Trade and Development, *About UNCTAD*, available at: http://unctad.org/en/Pages/AboutUs.aspx ("UNCTAD, which is governed by its 194 member States, is the United Nations body responsible for dealing with development issues, particularly international trade – the main driver of development…UNCTAD is also a forum where representatives of all countries can freely engage in dialogue and discuss ways to establish *a better balance* in the global economy. In addition, UNCTAD offers direct technical assistance to developing countries and countries with economies in transition, helping them to build the capacities they need to become equitably integrated into the global economy and improve the well-being of their populations" (emphasis added). *Id*.

[689] *See* United Nations Conference on Trade and Development, *UNCTAD-ICTSD Project on Intellectual Property Rights and Sustainable Development*, available at: http://unctad.org/en/Pages/DIAE/Intellectual%20Property/IPRs-and-Sustainable-Development.aspx.

[690] *See* Ruth L. Okediji for United Nations Conference on Trade and Development and International Centre for Trade and Sustainable Development, *The International Copyright System: Limitations, Exceptions and Public Interest Considerations for Developing Countries*, Issue Paper No. 15 (2006), available at: http://unctad.org/en/docs/iteipc200610_en.pdf. *See also* P. Bernt Hugenholtz & Ruth L. Okediji, *Conceiving an International Instrument on Limitations and Exceptions to Copyright*, Amsterdam Law School Research Paper No. 2012-43, Institute for Information Law Research Paper No. 2012-37 (March 2012), available at: http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2017629.

[691] *Id*., at Executive Summary, p. viii.

> **context, determining the *appropriate balance* is understandably more complex**…[T]he ***relevant balance* for international law purposes** is between the mandatory standards of protection established in treaties and the scope of discretion reserved to states to establish limitations and exceptions specifically directed at domestic concerns. This can be called the '***domestic/international balance***.' A second ***balance* is *between authors and users***—a relationship which has historically been reserved mainly to the sphere of domestic regulation."[692]

- "[**T]he concept of the public interest in international intellectual property regulation** [has] focused disproportionately on just one aspect of the public interest, namely securing the optimal provision of knowledge goods by granting exclusive rights to authors and inventors. **The other aspect of the public interest consists of mechanisms to ensure that the public has optimal access to the rich store of knowledge products. Such access is important to facilitate the dissemination of knowledge, thus generating social welfare gains, and for the benefit of downstream creators who rely on the availability of a robust public domain** from which to draw resources for productive ends."[693]
- "…**As digitization and new communication technologies have largely eroded the importance and effect of territorial boundaries, so have owners of knowledge goods asserted increasing rights over such goods, often seeking and receiving at the domestic and international spheres unprecedented levels of control over these otherwise public goods**. In effect, **while the digital era has created remarkable opportunities for greater access to information and knowledge goods by developing countries and consumers more broadly speaking, it has also spurred new forms of private rights**, negotiated multilaterally, to effectuate absolute control over access, use, and distribution of information and knowledge. The **efforts to control the dissemination of digitized knowledge goods have been largely technological, and reinforced by the emergence of international laws to protect these technologies of control as part of the international copyright system under the auspices of the World Intellectual Property Organization (WIPO)**."[694]
  - "The deep commitment to transform the essential characteristics and objectives of international copyright is best reflected in the integration of para-copyright rules concerning digital works through the legal protection of technological protection measures (TPMs)—the currency of the digital knowledge economy. **The embrace of TPMs in the international copyright system** via the WCT [WIPO Copyright Treaty]/WPPT [WIPO Performances and Phonograms Treaty] **consolidated the importance of authorial control over creative expression** in the *droit d'auteur* systems of continental Europe and the utilitarian models associated with the common law regions. **By transferring the power to regulate access and use of creative works from policymakers to the private realm of the owner, the unrestrained**

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[692] *Id*., at p. 3.
[693] *Id*., at Executive Summary, p. ix.
[694] *Id*., at Executive Summary, pp. ix-x.

application of TPMs coupled with an under-developed theory and application of public interest norms will effectively privatize copyright law on a global scale. The prevailing intensity of copyright harmonization and privatization suggests that **unless the public interest principles articulated in the TRIPS Agreement are effectively translated into meaningful normative principles and practical opportunities for the exercise of sovereign discretion, the welfare interests that justify the proprietary model for protecting creative expression will remain largely unrealized**."[695]

- "**The welfare concern is particularly significant with respect to developing and least-developed countries**, whose capacity to access knowledge goods on reasonable terms is defined primarily by the limitations and exceptions to the copyright owner's proprietary interest. **In copyright parlance, limitations and exceptions are coextensive with promoting public welfare**."[696]

- "Widespread concern by activists, scholars, non-governmental organizations, and institutions such as libraries, educational facilities, information providers, and policymakers has impelled the important need to consider the access/use and dissemination aspect of the public interest vision that justifies proprietary regimes for creative works. **The primary legal instrument deployed for this purpose has been the reconsideration, activation, and operation of limitations and exceptions to proprietary rights**."[697]
- "**At the international level, limitations and exceptions must be**: i) **more carefully considered** for their efficacy in promoting access, use, and dissemination of copyrighted goods; ii) **more consistently emphasized** as an important feature of the copyright system; iii) **more explicitly integrated** into the fabric of the international copyright regime; and iv) **more rigorously enforced** as a requisite for follow-on innovation and economic development."[698]
  - "**There is an important and urgent need** to develop doctrinally coherent and sensibly pragmatic strategies **to reform the international copyright system**, **both by infusing the relevant institutions with a mandate for articulating, defending and preserving an international public policy for international copyright regulation, and identifying core state practices that constitute the basis for a global approach to limitations and exceptions**."[699]
  - "Such a reform is vital for reasons that extend beyond the requirement to ensure that the pro-welfare concepts that pervade the free trade system are not eroded by a restricted vision of intellectual property rights. **Constructive reform also ensures that weak states that lack effective bargaining power in multilateral fora, but whose development priorities often compel them to bargain for market access (among other things) in exchange for adopting tough intellectual property rights,**

[695] *Id*., at pp. 1-2.
[696] *Id*., at p. 2.
[697] *Id*., at Executive Summary, p. x.
[698] *Id*., at Executive Summary, p. xi.
[699] *Id*., at p. 6.

have a strong and legitimate justification for reserving and exercising state power in the interest of domestic public goals."[700]

- "**In a digital era, the interests of developing countries ironically overlap with those of consumers in developed countries**. Consequently, **one of the notable paradigm shifts in the negotiation of international copyright agreements has been the tremendous rise in non-governmental organizations, private corporations and other non-state entities which have participated in alliance-building with developing countries to curtail the aggressive expansion of proprietary interests in information works and other copyrighted objects**."[701]

- UNCTAD/ICTSD Sidebar Event at WIPO/SCCR (May 2009)[702] Explaining the *Munich Declaration on a Balanced Interpretation of the 'Three-Step Test' in Copyright Law* (2008)[703]

  - "The benefits of copyright protection can be served well, if the rights of all parties are ***balanced*** in copyright laws, as declared under Article 7 of the TRIPS Agreement and the preamble to the WIPO Copyright Treaty (WCT)…Exceptions and limitations under the three-step test can provide an effective mechanism to ***balancing interests in copyright***. The narrow interpretation of the three-step test is, however, a problem, and is by no means compelling."[704]
  - "**Unlike the TRIPS provisions on patents, trademarks and industrial designs, the three-step test in copyright law does not mention the interests of other ("third") parties involved**. This, however, may not be understood as an intended void, but as an omission, to be filled. It must be filled in view of the overall aim as contained under Article 7 and 8 of the TRIPS Agreement and the preamble to the WIPO copyright Treaty. The aim of the three-step test is to balance all interests involved. As a result, **the three-step test in copyright has to be read by analogy to other three-step tests provided by the TRIPS Agreement (i.e. articles 17, 26 and 30) by *taking account of the legitimate interests of third parties***."[705]

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[700] *Id*.
[701] *Id*.
[702] *See* United Nations Conference on Trade and Development and International Centre for Trade and Sustainable Development, *Limitations and Exceptions to Copyright: Recent Developments and the Way Forward*, Side-event during the meeting of the WIPO Standing Committee on Copyright and Related Rights (SCCR) (May 29, 2009), available at: http://unctad.org/sections/dite_totip/docs/tot_ip_0011_en.pdf.
[703] See *Declaration: A Balanced Interpretation of the 'Three-Step Test in Copyright Law*, available at: http://www.ip.mpg.de/files/pdf2/declaration_three_step_test_final_english1.pdf. "The Three-Step Test has already established an effective means of preventing the excessive application of limitations and exceptions. However, there is no complementary mechanism prohibiting an unduly narrow or restrictive approach. For this reason, the Three-Step Test should be interpreted so as to ensure a proper and balanced application of limitations and exceptions. This is essential if an *effective balance* of interests is to be achieved" (emphasis added). *Id*., at Preface.
[704] *See* Reto M. Hilty, *The Munich Declaration on a Balanced Interpretation of the 'Three-Step Test' in Copyright Law*, in United Nations Conference on Trade and Development and International Centre for Trade and Sustainable Development, *Limitations and Exceptions to Copyright: Recent Developments and the Way Forward*, supra at p. 1.
[705] *Id*., at p. 2.

Exceptions and Limitations to the Patent Right	Exceptions and Limitations to the Copyright
TRIPS Article 30*	**TRIPS Article 13**
Allowed, provided:	Allowed, provided:
1. "are limited";	1. "confined…to certain special cases";
2. "do not unreasonably conflict with a normal exploitation of the patent";	2. "do not conflict with a normal exploitation of the work";
3. "do not unreasonably prejudice the legitimate interests of the patent owner";	3. "do not unreasonably prejudice the legitimate interests of the right holder."
4. "taking account of the legitimate interests of third parties."	

See also virtually identical TRIPS Article 26.2 (applicable to industrial designs)[706] and TRIPS Article 17 (applicable to trademarks).[707]

- "The second point of the Declaration states that **the three step test does not require countries to interpret limitations and exceptions narrowly**…All legal provisions – including exceptions and limitations – always must be interpreted according to their objectives and purposes…The third point of the Declaration addresses the gap in civil law and common law approaches, and differences in legal systems…The fourth point…clarifies that **the requirement of 'normal exploitation' may not be read in such a way as to confine the test to the right holder's view and to disregard general interests**…The fifth clarifications is based on the civil law system, where the original right holder necessarily is the creator (the natural person), and any producer may only be a subsequent right holder…**If the test has to balance all interests*, it must consider the interests of the creators***."[708]
- "Automated knowledge techniques generated new models of creating, disseminating, and reworking the products of both science and culture. Such techniques have further potential when they can be readily applied to the relevant scientific literature, creating opportunities for enhanced speed of dissemination of publicly funded research, for the

[706] TRIPS Article 26.2 provides that, "Members may provide *limited exceptions* to the protection of industrial designs, provided that such exceptions do not unreasonably conflict with the normal exploitation of protected industrial designs and do not unreasonably prejudice the legitimate interests of the owner of the protected design, *taking account of the legitimate interests of third parties*" (emphasis added).

[707] TRIPS Article 17 provides that, "Members may provide *limited exceptions* to the rights conferred by a trademark, such as fair use of descriptive terms, *provided that such exceptions take account of the legitimate interests of the owner of the trademark and of third parties*" (emphasis added).

[708] *See* Reto M. Hilty, *The Munich Declaration on a Balanced Interpretation of the 'Three-Step Test' in Copyright Law*, in United Nations Conference on Trade and Development and International Centre for Trade and Sustainable Development, *Limitations and Exceptions to Copyright: Recent Developments and the Way Forward*, supra at p. 2.

development of high performing research engines and for automated cross-linking and text mining…Many **modern ways of exploiting digital technology, however, violate copyright protection**. The use of automated knowledge techniques requires scientists to extract data and scientific articles into their own database. In order to correct errors during automation, scientists have to reuse the material they extracted. In the EC Database Directive, there is no mandatory exception for scientific research…"[709]

- "…**On top of the narrow exceptions, the publishers of scientific articles impose technological protection measures (TPMs).** The scientific publications are surrounded by electronic fences. **Even the most fundamental principles, such as the idea-expression dichotomy or fair use in the US, may be entirely overridden by a combination of TPMs and contractually imposed restrictions**. The US Digital Millennium Copyright Act of 1998 conditioned the ability of users to invoke the idea-expression dichotomy or fair use, on their having first gained lawful access to the work being transmitted online. **Moreover, when the user attempts to access work, he will encounter a technological fence that forces the user to go through an electronic gateway. The electronic gateway leads to a one-sided electronic contract of adhesion that restricts all or most user rights and privileges that copyright law might have permitted**. When these technological fences and electronic contracts are supported by the EC database right—and by anti-circumvention measures, the publisher's power becomes virtually absolute…**These publishers tend to impose greater restrictions on access and use than authors or the scientific community** who would have preferred to increase dissemination of their work for reputation and peer-review."[710]
- "…[T]here should be legislative reform enabling limitations and exceptions. In this regard **WTO Members need to codify the idea-expression dichotomy in addition to relying on the 'fair use' exception, as in the United States**. The doctrine has proved more dispositive in the judicial treatment of copyright infringement cases in the US. In Europe there is no mention of the doctrine in the Infosoc Directive, and the Green Paper, despite its embodiment at the multilateral level under Article 9.2 of the TRIPS Agreement and Article 10 of the WCT. Any serious reform effort should accordingly start with a codification of the idea-expression dichotomy as a central subject matter exception. Such codification should be accompanied by detailed provisions specifically directed at scientific and educational literature."[711]
- "[**A]lthough national level reforms are important, the full implementation of the permissive rules of the TRIPS Agreement and the Bern Convention can be supported at multilateral level** where countries develop normative guidelines in the form of soft-law approaches such as declarations at the WIPO on the general framework of limitations and exceptions."[712]

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[709] *See* Jerome Reichman, *Empowering Digitally Integrated Scientific Research: The Pivotal Role of Copyright Law's Limitations and* Exceptions, in United Nations Conference on Trade and Development and International Centre for Trade and Sustainable Development, *Limitations and Exceptions to Copyright: Recent Developments and the Way Forward*, supra at p. 3.
[710] *Id*., at p. 4.
[711] *Id*., at p. 5.
[712] *Id*.

- ***Cf.*** Former WIPO Assistant Director General Presentation at Fordham Intellectual Property Conference, Cambridge University, UK (April 15-16, 2009)[713]

  - "Recently it has become fashionable in certain academic circles to raise doubts about the "three-step-test" for the application of exceptions of and limitations on IP rights. It is either alleged that the test is badly construed and, therefore, should be 'fixed,' or that during its more than 40-year-long carrier it has not been applied adequately by legislators, governments, courts, dispute-settlement bodies, etc., and thus a completely ***new, 'more balanced'*** interpretation should be adopted."[714]
  - "…The paper, by applying Articles 31 and 32 of the Vienna Convention on the Law of Treaties, proves that, although as a result of the application of the test, legislators and courts may reach an overall assessment about the applicability of an exception or limitation, *de lege lata* it is inevitable to apply the three-step test truly step by step, and that it is only justified to proceed to a next step if an exception or limitation has successfully passed the previous one. **Therefore, what the Declaration suggests is not a new interpretation; it is rather a *de lege ferenda* proposal to change the test**."[715]
  - "…The Munich Declaration refers to three decisions which, according to, it have 'overlooked' what is suggested in the Declaration as a ***new 'balanced interpretation***;' namely, the WTO panel report WT/DS114/R of 17 March 2000 (*Canada – Patents*) the WTO panel report WT/DS160/R, 15 June 2000 (*USA – Copyright*) and the decision of the French Supreme Court, 28 February 2006 in the *Mulhollad Drive* case."[716]
  - "…The paper presents the following interpretation of the three steps:
    - *First step:* '*in certain special cases*.' It is a both quantitative and qualitative-normative condition…
    - …*Second step:* '*[no] conflict with a normal exploitation*.' It is a both descriptive and normative condition…
    - …*Third step: '[no] unreasonable prejudice to the legitimate interests of authors/owners of copyright.'* The term 'legitimate interest' has a legal positivist basis, but it has also a normative connotation…**It is this third step where a *balance* between the public interest to protect copyright as an indispensable incentive for creativity, on the one hand, and other public interests along, on the other hand, along with the related legitimate interests of authors, other owners of copyright, users and the general public** may and should be duly established."[717]

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[713] *See* Mihály Ficsor, *The "Three-Step Test" De Lege Lata – De Lege Ferenda*, presented at Fordham Intellectual Property Conference, Cambridge University, UK (April 15-16, 2009), available at: http://fordhamipconference.com/wp-content/uploads/2010/08/MihalyFicsor_Three-step_Test.pdf.
[714] *Id.*, at p. 1.
[715] *Id.*
[716] *Id.*
[717] *Id.*, at pp. 1-2.

- "…It is pointed out that **the test is sufficiently flexible without being vague. It offers broad latitude to national legislators and jurisprudence, but also determines the conditions and limits thereof**. If the potentials of the test is duly taken into account and exploited, **it is equally suitable to determine the desirable scope and reasonable application of exceptions and limitations in the digital environment**. For this reason, **the mainly *de lege ferenda* suggestions of the Munich Declaration are not necessary for a 'balanced interpretation' of the test**, for establishing adequate balance of interests in respect of copyright and related rights…**The test is not broken; it should not be fixed**…"[718]

iii. World Intellectual Property Organization

- Standing Committee on the Copyright and Related Rights[719]
  - SCCR/9/7 - *WIPO Study on Limitations and Exceptions of Copyright and Related Rights in the Digital Environment* (2003)[720]
    - "THE ROLE OF LIMITATIONS AND EXCEPTIONS…[T]he present international conventions on authors' and related rights contain a mixture of limitations and exceptions on protection that may be adopted under national laws. These can be grouped, very roughly, under the following headings"[721] and "[t]he juridical and policy basis for each kind of provision is different":[722]
      - "1. **Provisions that exclude, or allow for the exclusion of, protection for particular categories of works or material**."[723]
        - "The first proceeds on the assumption that there are **clear public policy grounds** that copyright protection should not exist in the works in question, for example,

[718] *Id*., at p. 2.
[719] "The Standing Committee on Copyright and Related Rights (SCCR) was set up in the 1998-1999 biennium to examine matters of substantive law or harmonization in the field of copyright and related rights. The Committee is composed of all member states of WIPO and/or of the Berne Union; and, as observers, certain member states of the United Nations (UN) which are non-members of WIPO and/or the Berne Union, as well as a number of intergovernmental and non-governmental organizations. The Standing Committee formulates recommendations for consideration by the WIPO General Assembly or a Diplomatic Conference. The Committee is currently engaged in discussing: *Limitations and exceptions* [and] Broadcasting organizations" (emphasis added). *See* World Intellectual Property Organization, Standing Committee on Copyright and Related Rights (SCCR), available at: http://www.wipo.int/policy/en/sccr/."
[720] *See* Sam Ricketson, *WIPO Study on Limitations and Exceptions of Copyright and Related Rights in the Digital Environment*, prepared for the World Intellectual Property Organization Standing Committee on Copyright and Related Rights, 9th Sess. (June 23 to 27, 2003), SCCR/9/7 (April 5, 2003), available at: http://www.wipo.int/edocs/mdocs/copyright/en/sccr_9/sccr_9_7.pdf.
[721] *Id*., at p. 3.
[722] *Id*., at p. 4.
[723] *Id.*, at p. 3.

because of the importance of the need for ready availability of such works from the point of view of the general public."[724]

- "…2. **Provisions that allow for the giving of immunity (usually on a permissive, rather than mandatory, basis) from infringement proceedings for particular kinds of use**…"[725]
  - "The second represents a more limited concession that **certain kinds of uses of works that are otherwise protected should be allowed**: there is **a public interest present here** that justifies overriding the private rights of authors in their works in these particular circumstances."[726]
- "…3. [**P]rovisions that allow a particular use of copyright material, subject to the payment of compensation to the copyright owner**. These are usually described as **'compulsory'** or 'obligatory **licenses**…'"[727]
  - "In the third category of cases, the author's rights continue to be protected but are significantly abridged: **public interest still justifies** the continuance of the use, regardless of the author's consent, but subject to the payment of appropriate remuneration**.**"[728]

▪ "LIMITATIONS AND EXCEPTIONS UNDER THE BERNE CONVENTION

- "…(b) Exceptions to Protection
  - "…***General Exception Concerning Reproduction Rights–the 'Three-Step Test'***…[T]he Stockholm Conference opted for the general formula approach, which is now embodied in Article 9(2) of the Paris Act. Commonly referred to as the **'three-step test,'** this has now come to enjoy something of the status of holy writ, providing as follows: [**Article 9(2)]** 'It shall be a matter for legislation in the countries of the Union **to permit the reproduction of such works in certain special cases, provided that such reproduction does not conflict with a normal exploitation of the work and does not unreasonably prejudice the legitimate interests of the author.'**"[729]
    - "…Certain Special Cases **The adjectives 'certain' and 'special' suggest that there must be limits to any exception to the reproduction right that is made under Article 9(2)**…[T]hese two adjectives require that a proposed exception ('case') should be both clearly defined and narrow in its scope and reach…[**T]he phrase 'certain special cases' should not be interpreted as requiring that there should also be some 'special purpose' underlying it**."[730]

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[724] *Id*., at p. 4.
[725] *Id*., at p. 3.
[726] *Id*., at p. 4.
[727] *Id*.
[728] *Id*.
[729] *Id*., at pp. 20-21.
[730] *Id*., at pp. 21-22, *referencing* Panel Report, *United States — Section 110(5) of US Copyright Act*, WT/DS160R, adopted July 27, 2000, at pars. 6.108-6.109, available at: https://docs.wto.org/dol2fe/Pages/FE_Search/FE_S_S006.aspx?Query=(@Symbol=%20wt/ds160/r*%20not%20rw*)&Language=ENGLISH&Context=FomerScriptedSearch&languageUIChanged=true#.

- "…**'<u>*Conflict with the Normal Exploitation of the Work*</u>'**…In the view of the WTO Panel[731], [there are]…two possible connotations of the phrase 'normal exploitation': the first of an empirical nature, i.e., what is regular, usual, typical or ordinary in a factual sense, and the second reflecting a 'somewhat more normative, if not dynamic, approach, i.e., conforming to a type or standard'…**Under <u>the empirical approach</u>**, the question to ask would be **whether the exempted use would otherwise fall within the range of activities from which the copyright owner would usually expect to receive compensation**…This would involve looking at what presently is the case, and would disregard potential modes of exploitation that might arise in the future. **<u>The 'normative' or dynamic approach</u>, on the other hand**, would look beyond this purely quantitative assessment and would seek to take into account technological and market developments that might occur, although these might not presently be in contemplation…On this more qualitative or dynamic approach, **'normal exploitation' will therefore require consideration of potential, as well as current and actual, uses or modes of extracting value from a work.**"[732] "Accordingly, the phrase 'normal exploitation' should be interpreted as including 'in addition to **<u>those forms of exploitation that *currently* generate significant or tangible revenue</u>**, those forms of exploitation which, with a certain degree of likelihood **<u>and</u>** plausibility, ***<u>could</u>* <u>acquire considerable economic or practical importance</u>**.'"[733]
  - "…There is another aspect of the adjective **'normal'** that is not considered [by the WTO Panel]…namely **the extent to which this term embraces** normative considerations of the true type, i.e., **considerations as to what the copyright owner's market *should* cover, as well as the more empirical inquiries into what is presently, and may be, the case**…**If one has regard only to the object and purposes of the Berne Convention** ('...a Union…to protect, in as effective and uniform manner as possible, the rights of authors in their literary and artistic works'), **there is little, if any, support to be found for such a *balancing* approach**. **<u>Interpretation of treaty provisions</u>, <u>however</u>, under both customary international law and the Vienna Convention, requires that this <u>should be done in the 'context' of the treaty as well as its</u>**

[731] *See* Panel Report, *United States — Section 110(5) of US Copyright Act*, supra.
[732] *See* SCCR/9/7, *supra* at p. 23, referencing Panel Report, *United States — Section 110(5) of US Copyright Act*, supra at pars. 6.180 and 6.182.
[733] *Id*., at p. 24, *quoting* Panel Report, *United States — Section 110(5) of US Copyright Act*, supra at par. 6.180. According to the Panel, "We believe that an exception or limitation to an exclusive right in domestic legislation rises to the level of a conflict with a normal exploitation of the work (i.e., the copyright or rather the whole bundle of exclusive rights conferred by the ownership of the copyright), if uses, that in principle are covered by that right but exempted under the exception or limitation, enter into economic competition with the ways that right-holders normally extract economic value from that right to the work (i.e., the copyright) and thereby deprive them of significant or tangible commercial gains." *See* Panel Report, *United States — Section 110(5) of US Copyright Act*, supra at par. 6.183.

objects and purposes, and this involves consideration of the text of the treaty as a whole…**Viewed against this wider context of the treaty, it therefore seems logical to conclude that the scope of the inquiry required under the second step of Article 9(2), does include consideration of non-economic normative considerations, i.e., whether this particular kind of use is one that the copyright owner *should* control**. This interpretation furthermore is consistent with what is to be found in the preparatory work for the Stockholm Conference, a legitimate supplementary aid to treaty interpretation. "[734]

- "While the foregoing has the semblance of coherence, it nonetheless leaves the application of the second step of Article 9(2) more open-ended and uncertain. **The words 'normal exploitation' give no guidance as to the kinds of non-economic normative considerations that may be relevant here, and the extent to which they may limit uses that would otherwise be within the scope of normal exploitation by the copyright owner**. **Striking this *balance* is left as a matter for national legislation. Value judgments will need to be made, and these will clearly vary according to the society and culture concerned**."[735]

- "…***'Does Not Unreasonably Prejudice the Legitimate Interests of the Author'***…[S]ome **further *balancing* of interests** is required by the third step of Article 9(2), and this is confirmed by a consideration of the meanings of the key words used in its formulation. Thus, in the present context, **the 'interests' in question are those of the 'author,' not those of the 'right-holder' as in Article 13 of the TRIPS Agreement.** As **the rights of authors** that are protected under Berne **include both economic and non-economic (moral) rights** (under Article 6bis), it is clear **'interests' in Article 9(2) covers both pecuniary and non-pecuniary interests**. As for the term 'legitimate'…the WTO Panel also noted that this has the connotation of legitimacy from a more normative perspective. **It therefore seems reasonable to conclude that, while the phrase 'legitimate interests' covers all the interests (economic and noneconomic) of authors that are to be protected under the Stockholm/Paris Acts, this is not an unqualified or absolute conception: there must be some normative justification underpinning these interests**. In other words, there is a "proper" sphere of application for authors' interests that is not to be pursued regardless of other considerations. "[736]

- "…The words **'not unreasonably prejudice'** therefore allow the making of exceptions that may cause prejudice of a significant or substantial kind to the author's legitimate interests, provided that (a) the exception otherwise satisfies the first and second conditions stipulated in Article 9(2), and (b) it is

[734] *See* SCCR/9/7, *supra* at pp. 24-25.
[735] *Id*., at p. 25.
[736] *Id*., at pp. 26-27.

proportionate or within the limits of reason, i.e., if it is not unreasonable. The requirement of proportionality clearly **implies that there may be conditions placed on the usage that will make any prejudice that is caused 'reasonable'**…"[737]

- "…**It is therefore clear that exceptions under Article 9(2) may take the form of either free uses or compulsory licenses**, depending essentially on the number of reproductions made."[738]

- "…(c) Compulsory Licenses Allowed Under the Berne Convention
  - …[**A] number of the exceptions provided for under the Paris Act of Berne allow member countries to impose compulsory licenses in certain circumstances**. However, it is also relevant to note that there are several provisions of the Convention that acknowledge this specifically. These apply to the recording of musical works… [Article 13(1)]…and with respect to the exclusive rights recognized under Article 11*bis*."[739]
  - "…***Compulsory Licenses in Respect of the Broadcasting of Works*** From its inception, many governments have shown a strong interest in broadcasting because of its powerful informatory, educational and entertainment role. Article 11*bis(2)* therefore provides for the possibility of compulsory licenses…"[740]
  - "…***Ephemeral Recordings of Broadcast Works*** Article 11*bis(3)* allows national laws to make exceptions where ephemeral or transitory recordings of works are made for the purposes of exercising one of the rights listed in Article 11*bis(1)*."[741]
  - "…***Compulsory Licenses in Relation to Developing Countries*** **The Appendix to the Paris Act contains a series of compulsory licenses with respect to the translation and reproduction of works protected under the Convention that may be invoked under certain limited conditions by developing countries, notably for educational and developmental purposes**…[T]he history leading up to their addition to the Convention in the Paris Act was a complex and controversial one and the present provisions of the Appendix represent a hard-fought compromise between developing and developed countries…"[742]
    - "(1) **Any country regarded as a developing country** in conformity with the established practice of the General Assembly of the United Nations

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[737] *Id*., at p. 27.
[738] *Id*.
[739] *Id*., at p. 28. *See also* pp. 29-30.
[740] *Id*., at p. 30. *See also* pp. 31-32.
[741] *Id*., at p. 32. *See also* pp. 32-33.
[742] *Id*., at p. 33. For a more in-depth discussion regarding how the Berne Convention Annex underserves developing countries and should be replaced with a new instrument to achieve that objective, *See* Alberto J. Cerda Silva, *Beyond the Unrealistic Solution for Development Provided by the Appendix of the Berne Convention on Copyright*, PIJIP Research Paper No. 2012-08, American University Washington College of Law, Washington, D.C. (2012), available at: http://digitalcommons.wcl.american.edu/research/30/.

which ratifies or accedes to this Act, of which this Appendix forms an integral part…**may, by a notification…declare that it will avail itself of the faculty provided for in Article II, or of the faculty provided for in Article III, or of both of those faculties**…".[743]

- ***Article II*** - "**Non-Exclusive, Non-Transferrable Compulsory Licenses for *Translation***:[744]
  - Re: **granting of compulsory licenses, "only for the purpose of teaching, scholarship or research"**[745] to "**any national of such country**",[746] in the event of failure to make available "in a language in general use in that country translations of copyrighted works after the expiration of a period of three years, or of any longer period determined by the national legislation of the said country[747]…, [except]…when the author has withdrawn from circulation all copies of his work…"[748]
  - Re: **grant of compulsory licenses** "**to any broadcasting organization having its headquarters in [said developing] country**…**to make a translation of a work** which has been published in printed or analogous forms of reproduction…[and] **[s]ound or visual recordings of [such] a translation**…a license **for use in broadcasts intended exclusively for teaching or for the dissemination of the results of specialized technical or scientific research to experts in a particular profession**…"[749]
- "***Article III* - Non-Exclusive, Non-Transferrable Compulsory Licenses for *Reproduction***:[750]
  - Re: **granting of compulsory licenses "to any national of such country…to reproduce and publish…works published in printed or analogous forms** of reproduction…[**and** to **reproduce and translate any]…audio-visual form of lawfully made audiovisual fixations including any protected works incorporated therein**…into a language in general use in the country at a price reasonably related to that normally charged in [that] country…or a lower price **for use in connection with systematic instructional activities", if** "after the expiration of…three years…five years…[or] seven years…**copies of such edition have not been distributed** in

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[743] See *Berne Convention for the Protection of Literary and Artistic Works (Paris Text 1971)*, at APPENDIX [SPECIAL PROVISIONS REGARDING DEVELOPING COUNTRIES], at Appendix, Article I, available at: http://www.wipo.int/export/sites/www/treaties/en/ip/berne/pdf/trtdocs_wo001.pdf.
[744] *Id*., at Appendix, Article II(a).
[745] *Id*., at Appendix, Article II(5).
[746] *Id*., at Appendix, Article II(2)(a).
[747] *Id*., at Appendix, Article II(2)-(4).
[748] *Id*., at Appendix, Article II(8).
[749] *Id*., at Appendix, Article II(9)(a)-(b). *See also* Article II(9)(c).
[750] *Id*., at Appendix, Article III(1).

that country to the general public or in connection with systematic instructional activities, by the owner of the right of reproduction or with his authorization" [or] "**no authorized copies of that edition have been on sale…to the general public or in connection with systematic instructional activities**…for a period of six months" at such price.[751]

- "LIMITATIONS AND EXCEPTIONS UNDER THE WCT
  - **Limitations and exceptions under the WCT [WIPO Copyright Treaty[752]] are dealt with in two ways, both of which incorporate the three-step test**. The first occurs indirectly under Article 1(4), while the second is done explicitly under Article 10. These provisions need to be considered separately.
    - ***Under Article 1.4*** [753]
      - …[A]n 'agreed statement' to Article 1(4) of the WCT…was adopted by the 1996 Diplomatic Conference at the time of adopting the text of the WCT itself. This provides for a possible extension of the operation of Article 9(1) and (2) through the adoption of the following interpretation:
        - 'The reproduction right, as set out in Article 9 of the Berne Convention, and the exceptions permitted thereunder, apply fully **in the digital environment**, **in particular to the use of works in digital form**. **It is understood that the storage of a protected work in digital form in an electronic medium constitutes a reproduction within the meaning of Article 9 of the Berne Convention**.'"[754]
        - "…**The significance of the statement, in terms of international law, needs to be considered in three contexts**: first, as a possible agreement between the parties at the Diplomatic Conference with respect to the interpretation and application of a provision of the WCT (Article 1(4)); secondly, as a possible subsequent agreement between Berne Convention members as to the interpretation and application of a provision of that Convention (Article 9); and thirdly, as a possible subsequent agreement between TRIPS members as to the interpretation and application of an incorporated provision of that agreement (Article 9 of Berne)…"[755]
    - "…***Under Article 10***
      - Unlike Article 1(4), the three-step test appears directly in the text of Article 10, and has a much wider potential application than just to the reproduction right (an obvious model in this regard being Article 13 of TRIPS).

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[751] *Id*., at Appendix Article III(2)-(7).
[752] *See* World Intellectual Property Organization, *Copyright Treaty*, Apr. 12, 1997, S. Treaty Doc. No. 105-17 (1997), available at: http://www.wipo.int/treaties/en/ip/wct/trtdocs_wo033.html.
[753] WIPO Copyright Treaty Article 1.4 provides that, "Contracting Parties shall comply with Articles 1 to 21 and the Appendix of the Berne Convention."[fn2] Footnote #2 contains the 'agreed statement' reproduced above, which explains Member States' understanding of Article 1.4.
[754] *See* SCCR/9/7, *supra* at p. 56.
[755] *Id*., at p. 57.

- '10(1) Contracting Parties **may**, in their national legislation, **provide for limitations of or exceptions** to the rights granted to authors of literary and artistic works under this Treaty in certain special cases that do not conflict with a normal exploitation of the work and do not unreasonably prejudice the legitimate interests of the author.'
- (2) Contracting Parties **shall**, **when applying the Berne Convention**, **confine any limitations of or exceptions** to rights provided therein to certain special cases that do not conflict with a normal exploitation of the work and do not unreasonably prejudice the legitimate interests of the author.'"[756]

  - "Both paragraphs have a different sphere of operation. The less problematical is Article 10(1) which applies only to the rights to be accorded under the WCT, namely the new rights of distribution (Article 6), rental (Article 7) and communication to the public (Article 8)."[757]
  - "…Article 10(2), on the other hand, is more problematic in that, like Article 13 of TRIPS, it purports to apply to all the rights protected under Berne and does so in far more explicit terms: 'Contracting Parties ***shall***, when applying the Berne Convention,…'"[758]

- "LIMITATIONS AND EXCEPTIONS UNDER THE TRIPS AGREEMENT
  - (a) TRIPS and Berne Convention…
    - *Compliance with **Article 9(1) of TRIPS***
      - …**members can apply the specific limitations and exceptions that are contained in Articles 1-21 of Berne**…[While] under Article 9(1), it will be obligatory for members to provide for exceptions for quotations under Article 10(1)…there is no compulsion for any of…the other…limitations or exceptions to be recognized…"[759]
    - "…*As Part of the National Treatment Requirement Under **Article 3(1) of TRIPS***
      - A further reference to 'exceptions' appears in Article 3(1) of TRIPS which is the national treatment provision of that instrument… This **confirms more explicitly that members can apply those exceptions allowed for under the**

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[756] *Id*., at p. 60.
[757] *Id*.
[758] *Id*., at p. 61. *See also* Sam Ricketson, *WIPO Study on Limitations and Exceptions of Copyright and Related Rights in the Digital Environment*, WIPO Information Session on Limitations and Exceptions, Standing Committee on Copyright and Related Works (Nov. 3-4, 2008), available at: http://www.wipo.int/edocs/mdocs/copyright/en/sccr_17/sccr_17_www_111472.pdf ("[WCT] Art 1(4): requires compliance with arts 1-21 and Appendix of Berne: Includes art 9(1) and (2), Berne, Agreed statement to art 1(4)… Direct application of 3 step test to WCT rights - Article 10(1)…") *Id*., at pp. 49-50. *See also* Jeffrey P. Cunard and Keith Hill, *Study on Current Developments in the Field of Digital Rights Management (DRM)*, prepared for the World Intellectual Property Organization Standing Committee on Copyright and Related Works, 10th Sess. (Nov. 3-5, 2003), SCCR/10/2 Rev. (May 4, 2004), available at: http://www.wipo.int/edocs/mdocs/copyright/en/sccr_10/sccr_10_2_rev.pdf. "This study of digital rights management ("DRM") with respect to the technologies upon which it is based and the legal instruments that govern the technologies and processes in Australia, Europe, Japan and the United States of America (U.S.A.), is intended for anyone with an interest in the subject, especially those whose familiarity with digital rights management may be limited." *Id*., at p. 2.
[759] *See* SCCR/9/7, *supra* at p. 46.

Berne Convention, so far as foreigners claiming protection under TRIPS are concerned."[760]

- "…*As a Specific TRIPS Obligation Under* ***Article 13 of TRIPS***
  - …Article 13 of TRIPS contains a free standing TRIPS obligation with relation to limitations and exceptions that purports to apply a general formula or template. This **adopts the language, slightly modified, of the three-step test in Article 9(2) of Berne…[that] has to be interpreted as part of the TRIPS Agreement, rather than as part of Berne**…
    - "Members **shall confine limitations and exceptions** to exclusive rights to certain special cases which do not conflict with a normal exploitation of the work and do not unreasonably prejudice the legitimate interests of the right-holder."[761]
      - "…The interpretations of the three-step test in Article 9(2) of Berne are clearly relevant to Article 13, if only because of the close identity of language and subject-matter. At the same time, **there are specific features of the TRIPS Agreement that suggest that the individual components of the three-step test in Article 13 should bear a different nuance or emphasis**…
      - [Although] as with Berne, TRIPS is concerned with maximizing the protection of IPRs and that a **'maximalist' pro-rights interpretation** should be taken, wherever necessary…[t]he **TRIPS preamble…is broader than this, and contains other objectives that need to be taken into account**. Among other things, these include recognition of 'the underlying public policy objectives of national systems for the protection of intellectual property, including developmental and technological objectives.' More specifically, Articles 7 and 8 point to other factors that member states are to take into account in implementing their TRIPS obligations."[762]
        - "Thus, **Article 7**…provides: 'The **protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology** to the mutual advantage of producers and users of technological knowledge, and **in a manner conducive to social and economic welfare, and to a balance of rights and obligations**.'"[763]
        - "**Article 8(1)** then provides that **member states may**, in formulating or amending their laws and regulations, **adopt 'measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to**

[760] *Id*.
[761] *Id*.
[762] *Id*., at p. 47.
[763] *Id*.

their socio-economic and technological development, ***provided*** **that such measures are consistent with the provisions of this Agreement**.'"[764]

- "**Article 8(2)** allows further for 'appropriate **measures**…consistent with the provisions of this Agreement' that may be **needed to prevent the abuse of IPRs or "practices which unreasonably restrain trade or adversely affect the international transfer of technology**."[765]
- "…[Although] **Article 13 of TRIPS might permit further limitations or exceptions to the exclusive rights protected under Berne than are presently allowed under that text**, **Article 2(2) of TRIPS** ["nothing in Parts I-IV of this Agreement shall derogate from existing obligations that Members may have towards each other under…the Berne Convention"] **would require that Article 13 should not be applied in this way**, as that would represent a derogation from these rights. This would be so, even though application of Article 13 might otherwise permit a more generous range of exceptions because of the balancing process."[766]
- "…**Article 2(2) only operates as between Berne members, but given the near universal membership of Berne this will cover virtually all states that are also parties to TRIPS**."[767]
  - ***This "Berne Gap" in TRIPS was addressed in the recently adopted Marrakesh Treaty*** (*see below)

- *WIPO Intellectual Property Handbook: Policy, Law and Use* – Chap. 7, *Technological and Legal Developments in Intellectual Property* (2004)[768]

  - "7.17 It is a clear trend today that **national laws expressly include computer programs as protected works of a kind, more precisely as writings**, and thus there is no doubt that copyright protection applies to such programs, provided that they are original."[769]
  - "7.18 The significance of this categorization of computer programs as literary works (writings), depends on other relevant provisions of the respective laws and on the practice adopted in subsequent court decisions."[770]

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[764] *Id*., at p. 48.
[765] *Id*.
[766] *Id*.
[767] *Id*.
[768] *See* World Intellectual Property Organization, *WIPO Intellectual Property Handbook: Policy, Law and Use* (2004), available at: http://www.wipo.int/about-ip/en/iprm/; http://www.wipo.int/export/sites/www/freepublications/en/intproperty/489/wipo_pub_489.pdf; http://www.wipo.int/export/sites/www/about-ip/en/iprm/pdf/ch7.pdf.
[769] *Id*., at par. 7.17.
[770] *Id*., at par. 7.18.

- "7.19 The protection of computer programs as writings entails, furthermore, that the rights pertaining to copyright protection also apply to such programs. **In particular, the right of reproduction, the right of distribution of copies and the right of communication to the public should be applicable**."[771]
- "7.20 **The most important issue concerning the right of reproduction in copyright laws is the question of in which cases it is justified to permit reproduction without the authorization of the right-owner**. The international norm which is applicable is **Article 9(2) of the Berne Convention**. According to this provision, national laws may permit reproduction of literary and artistic works in certain special cases, provided that such reproduction does not conflict with a normal exploitation of the work and does not unreasonably prejudice the legitimate interests of the author. **The views of professional circles concerning this provision, when applied to computer programs, are ambiguous, and governments having legislated or planning to legislate in this field do not always agree**."[772]
- "7.21 The question is: **in which special cases does the free reproduction of computer programs not conflict with normal exploitation or unreasonably prejudice the legitimate interests of copyright owners**, and in which special cases can it therefore be allowed?"[773]
- "7.22 Although differing views still exist, **there seems to be growing agreement concerning free copying for private purposes,** taking into account the purpose and value of computer programs — **except for cases covered by the points below — should not be allowed**;
  - **free copying by lawful owners**, that is, persons who have acquired ownership of copies of (not of the copyright in) computer programs should be **allowed in certain circumstances**;
  - **free decompilation of computer programs** (see discussion of this issue, below) may also be **allowed under certain conditions**. It should be added, however, that in the latter aspect, there is less than general agreement."[774]
- "7.23 **It is obvious that copying should be allowed if it is indispensable for the use of a program in conjunction with a machine for the purpose, and to the extent of use for which the program has been lawfully obtained**. Furthermore, **it also seems justified to allow making a "back-up copy" for archival purposes, as a security measure**, for cases where the replacement of the program may become necessary. In addition to clarifying the extent to which a lawful owner of a computer program may make a copy, it also seems necessary to make it clear that **the right of adaptation under Article 12 of the Berne Convention does not include the right to prevent an adaptation that is indispensable for using the computer program in conjunction**

[771] *Id*., at par. 7.19.
[772] *Id*., at par. 7.20.
[773] *Id*., at par. 7.21.
[774] *Id*., at par. 7.22.

with a machine for the purpose, and to the extent of use, for which the program has been lawfully obtained."[775]

- "7.24 **Decompilation of computer programs** means **reproduction and adaptation ("translation") of computer programs into a form in which the coding and structure of the program can be examined and analyzed**."[776]
  - "According to certain views, such **decompilation by lawful owners of computer programs should be allowed, since it would not conflict with any normal exploitation of the program and would not cause any unreasonable prejudice to the legitimate interests of copyright owners, in cases where decompilation is needed to obtain information necessary to achieve interoperability of independently created programs with the original programs concerned**."[777]
  - "However, to avoid any conflict and prejudice referred to above, **the information thus obtained should not be used for the development, production or distribution of a program substantially similar in its expression to the original program, or for any other act infringing copyright**. It is a difficult task to formulate legal provisions in respect of decompilation, because of the very strong interests involved."[778]

- SCCR/15/7 - *WIPO Study on Copyright Limitations and Exceptions for the Visually Impaired* (Sept. 2006; Feb. 2007)[779]

  - "In particular, the Study looks at what might be ***the appropriate balance*** **between the interests of right holders on the one hand, and visually impaired users of copyright works and those assisting them on the other hand** where exceptions to rights are provided, but it also looks at other possible solutions to the copyright problems that have been identified…**The framework in international treaties and conventions relating to intellectual property seems to permit exceptions for the benefit of visually impaired people**. Indeed, exceptions seem possible with respect to a wide range of acts restricted by copyright that might be undertaken by those making and supplying accessible copies to visually impaired people. **However, the possibility of such provision is not specifically addressed and is not mandatory under these treaties and conventions**, although it is widely accepted that copyright laws should provide a balance between the interests of different stakeholders."[780]
  - "…In examining exceptions for the benefit of visually impaired people in national laws, **57 countries have been found that have specific provisions that would permit**

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[775] *Id*., at par. 7.23.
[776] *Id*., at par. 7.24.
[777] *Id*.
[778] *Id*.
[779] *See* Judith Sullivan, *Study on Copyright Limitations and Exceptions for the Visually Impaired*, prepared for the World Intellectual Property Organization Standing Committee on Copyright and Related Works, 15th Sess. (September 11 to 13, 2006), SCCR/15/7 (Feb. 20, 2007), available at: http://www.wipo.int/edocs/mdocs/copyright/en/sccr_15/sccr_15_7.pdf.
[780] *Id*., at p. 9.

activity to assist visually impaired people unable to access the written word, or to assist people with a print disability more generally, by making a copyright work available to them in an accessible form. Some of the exceptions found in these countries would also permit other types of assistance for handicapped people, and two further countries have been found that have exceptions that would permit, amongst other things, audio description of broadcasts."[781]

- "…The specific exceptions found in national laws have been analysed in some detail, for example looking at how the end beneficiary is defined, what type of copyright works can be copied or otherwise used and by what type of organisation, whether or not activity must be of a non-commercial nature and what type of accessible copies can be made…**A number of exceptions are specifically qualified by a requirement to comply with a test the same as or similar to the 3-step test found in the Berne Convention**. **The majority of exceptions do not provide for any remuneration to be paid to right holders for activity under the exception**…"[782]
- "…International treaties and conventions relating to intellectual property generally permit countries to decide for themselves what provision to make on cross-border movement of copies of copyright works made under exceptions. **The laws of both the exporting and importing country do, however, need to be considered regarding cross-border movement of accessible copies**. One of the difficulties in deciding whether accessible copies made under an exception in one country may be exported to another country is **the lack of clarity about what types of distribution of accessible copies are within the scope of many of the specific exceptions to copyright for the benefit of visually impaired people**. However, **other aspects of the scope of the exceptions are also likely to be relevant**, such as **who may act under the exception, how to determine whether or not the requirements about the end beneficiary of the exception are met, whether requirements that a work must have been published are met, whether or not only copies made under the exception may be distributed in the country and whether the same type of accessible copies in both importing and exporting countries are permitted**. In a number of countries, the interaction with more general provisions relating to import and/or export of copies that have been made without the authorisation of the right holder also seems to be relevant."[783]

- SCCR/14/5 - *WIPO Study on Automated Rights Management Systems and Copyright Limitations and Exceptions* (2006)[784]

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[781] *Id*.
[782] *Id*.
[783] *Id*., at p. 10.
[784] *See* Nic Garnett, *Automated Rights Management Systems and Copyright Limitations and Exceptions*, prepared for the World Intellectual Property Organization Standing Committee on Copyright and Related Works, 14th Sess. (May 1-5, 2006), SCCR/14/5 (April 27, 2006), available at: http://www.wipo.int/meetings/en/doc_details.jsp?doc_id=59952; http://www.wipo.int/edocs/mdocs/copyright/en/sccr_14/sccr_14_5.doc. *See also* Nic Garnett, *Presentation of the study entitled 'Automated Rights Management Systems and Copyright Limitations and Exceptions'*, Informative Session on Limitations and Exceptions Geneva at the World Intellectual Property Organization Standing Committee on Copyright and

- "The 1996 WIPO Internet Treaties have rapidly become the international standard for the development of copyright in the digital environment. The Internet Treaties contain the basic rules for technological adjuncts to copyright protection, composed of technological protection measures and rights management information…**The compatibility between limitations and exceptions, on the one hand, and technological protection measures, on the other, has proven to be one of the more complex areas in the implementation of the Internet Treaties**."[785]
- "…The present Study…focus[es] on certain limitations and specific countries. In fact, **two groups of beneficiaries are considered: <u>the subset of the educational community involved in distance learning</u>, on the one hand, and <u>visually impaired persons</u>, on the other. To illustrate the state-of-the-art in the relevant fields, the law and practice in five countries is described, namely, Australia, the Republic of Korea, Spain, the United Kingdom, and the United States of America**. These countries were selected based on criteria which included the presence in national legislation of relevant exceptions in the two subject areas; the existence of statutory and/or voluntary licensing practices, including private-sector initiatives, in the two subject areas; and the state of their national technological infrastructure for digital content delivery."[786]
- "…**Copyright, especially as reinforced by the application of technical protection measures, is seen by many as exclusionary, denying access unless the price of admission is paid in full**. Hemmed in on the one side by the general application of the so-called three-step test and on the other by the process of digital lock-up, exceptions long established in the public interest seem to many to be under increasing threat."[787]
- "…Two other considerations are worthy of reference at the start of this study[:]
  - The first of these is the realization that **<u>the use of technology not only in the protection of content, but also in the management of rights, introduces a profound change in the way that copyright works</u>**. **<u>Traditionally, a considerable use of copyright works has occurred without direct authorisation of the copyright owner or pursuant to a privilege granted by law</u>**. This occurs where for example the medium of delivery of a work facilitates a use which is either impliedly licensed or in respect of which the copyright owner is, in practice, unable to exercise a right to control the use. We argue later in this study that **<u>to a certain extent this marginal activity is an important part of the *traditional* copyright *balance*</u>**. **The binary nature of digital technology effectively negates the possibility of such marginal activity**. When content is made available exclusively in a technically protected form, it can only be accessed and used where explicit machine-executable

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Related Works (Nov. 3rd 2008), available at: http://www.wipo.int/edocs/mdocs/copyright/en/sccr_17/sccr_17_www_111452.pdf.

[785] *Id*., at p. iv.

[786] *Id*., at p. v.

[787] *Id*., at p. vi.

instructions are constructed and delivered for that purpose. Take away the traditional marginal use, however, and many users denounce the denial of privileges."[788]

- "…The second consideration is the relationship between technology and the market for copyright works. This has at least two dimensions.
  - **First, the natural fears of copyright owners which lead them to maximise protection of their works in the face of digital technology would seem to be reinforced by the uncertain state of the new markets into which they are required to launch their works**.
  - **Secondly, as digital formats and systems dramatically reduce both marginal and transaction costs, so renewed attention has to be paid by both copyright owners and regulators as to where potential markets may exist**. And that means identifying the normal field of exploitation of a particular work could become a much more complex process with significant potential to impact on the scope, if not the very nature, of particular limitations and exceptions."[789]
- "…**The principal exceptions and limitations relevant to this study are those relating to the use of protected works and other subject matter in education, and use by persons with visual and print disabilities**. In both these areas, technology is playing an increasing part in the way protected materials are used.
  - **Virtual learning environments employ sophisticated combinations of learning tools and content to advance the educational process**, increasingly outside the traditional classroom context.
  - **Visual and print disabled persons make extensive and increasing use of advanced technologies such as electronic braille, computer screen readers and text-to-speech synthesisers**."[790]

- SCCR/24/8/PROV. - WIPO Secretariat - *Provisional Working Document Towards an Appropriate International Legal Instrument (In Whatever Form) on Limitations and Exceptions for Educational, Teaching and Research Institutions and Persons With Other Disabilities Containing Comments and Textual Suggestions* (July 2012)[791] – **Based on proposals from the African Group**,[792] **Brazil** [793] and **Ecuador, Peru & Uruguay** [794]

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[788] *Id*., at p. vii.
[789] *Id*.
[790] *Id*.
[791] See World Intellectual Property Organization Secretariat, *Provisional Working Document Towards an Appropriate International Legal Instrument (In Whatever Form) on Limitations and Exceptions for Educational, Teaching and Research Institutions and Persons With Other Disabilities Containing Comments and Textual Suggestions*, Standing Committee on Copyright and Related Works 24th Sess. (July 16-25, 2012), SCCR/24/8 PROV. (July 31, 2012), available at: http://www.wipo.int/edocs/mdocs/copyright/en/sccr_24/sccr_24_8_prov.pdf.
[792] *See* World Intellectual Property Organization, Standing Committee on Copyright and Related Works, 22nd Sess. (June 15-24, 2011), *Draft WIPO Treaty on Exceptions and Limitations for the Persons with Disabilities, Educational and Research Institutions, Libraries and Archives – Proposal by the African Group*, SCCR/22/12 (June 3, 2011), available at: http://www.wipo.int/edocs/mdocs/copyright/en/sccr_22/sccr_22_12.pdf.
[793] *See* World Intellectual Property Organization, Standing Committee on Copyright and Related Works, 24th Sess. (July 16-25, 2012), *Draft Articles and Thematic Clusters on Limitations and Exceptions to Copyright for the Benefit of Educational,*

- "…3. GENERALLY APPLICABLE CONSIDERATIONS
  - Comment(s): *from the European Union*
    - "3. Copyright protection is required in order to foster the creation of not only educational contents but also works in general which are at the very heart of the functioning of teaching activities. Thus, copyright protection is required so that educational establishments in the EU have access to top-quality works such as teaching material. **It is therefore vital that *a fair and sustainable balance* is achieved between copyright protection, on the one hand, and the achievement of public interest objectives, on the other**."[795]
  - "*from the United States of America*
    - 4. **Like the EU**, we would like to emphasize that our educational system in the United States is supported by a vibrant commercial market for education and research materials, as well as a set of exceptions and limitations in our copyright law, including the doctrine of fair use and specific provisions for teachers and students. Together, the commercial market (through licensing and voluntary agreements) and the exceptions and limitations in our copyright law (through, for example, 17 USC 110 and 107) provide the critical access to information, research, and creative expression needed to enable full participation in our information society…At the same time, **there is no question that exceptions and limitations are an important part of the copyright *balance worldwide* and at the national level**. **In our experience, *appropriate and balanced exceptions* that satisfy the three-step test require careful study and consideration of all circumstances, but we must recognize that such circumstances may differ from country to country**."[796]
- "…3.1. Flexibilities Comment(s):
  - *from the European Union*
    - 7. The Berne Convention provides for specific exceptions to allow uses of copyrighted works for the purpose of quotation and teaching. The same types of exceptions are permitted under the WIPO Copyright Treaty and, as far as related rights are concerned, under the Rome Convention and the WIPO Performances and Phonograms Treaty. **These exceptions leave a significant margin of manoeuvre to members of these Conventions and Treaties in their implementation (for instance, in the case of education they make no distinction between the level of education or its nature). It is for individual countries to apply the framework provided at international level, to put it**

Teaching and Research Institutions – Proposal by the Delegation of Brazil, SCCR/24/7 (July 16, 2012), available at: http://www.wipo.int/edocs/mdocs/copyright/en/sccr_24/sccr_24_7.pdf.

[794] *See* World Intellectual Property Organization, Standing Committee on Copyright and Related Works, 24th Sess. (July 16-25, 2012), *Limitations and Exceptions Regarding Education - Proposal by the Delegations by Ecuador, Peru and Uruguay*, SCCR/24/6 (July 16, 2012), available at: http://www.wipo.int/edocs/mdocs/copyright/en/sccr_24/sccr_24_6.pdf.

[795] *Id*., at p. 5.

[796] *Id*.

into practice via their national legislation and adapt it to their local conditions while respecting the three-step test as provided for in the Conventions and Treaties."[797]

- "…3.2. Three-step test - Text proposal(s) **[Ecuador, Peru & Uruguay]**:
  - …When applying either Article 9.2 Berne, 13 TRIPS, 10 WCT, or similar provisions in any other multilateral treaty, **nothing prevents contracting parties to interpret the three-step test in a manner that respects the legitimate interests, including of third parties**, deriving from:
    - **educational and research needs, and other human rights and fundamental freedoms**; and
    - **other public interests**, such as the need to achieve scientific progress and cultural, educational, social, or economic development, and protection of competition and secondary markets."[798]
- "…3.4. Obligations/Proposals to update exceptions - Text proposal(s) **[Ecuador, Peru & Uruguay]**:
  - … **Obligation to update and expand exceptions for educational purposes, in particular in the digital environment**…
    - Contracting Parties **shall update, carry forward and appropriately extend into the digital environment limitations and exceptions** in their national laws which have been considered acceptable under the Berne Convention, especially under article 10.1 and 10.2, **and devise new exceptions and limitations that are appropriate in the digital network environment to protect educational and research activities**."[799]
- "4. USES
  - 4.1. **Educational, Teaching and Research Institutions** - Text Proposals [predominantly from the African Group[800] and Brazil]…Comments…"[801]
  - "…4.2. **In-class room** - Text Proposals [predominantly from the African Group and Brazil]…Comments…"[802]
  - "…4.3. **Outside class room** - Text Proposals [predominantly from the African Group and Brazil]…"[803]

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[797] *Id*., at p. 6.
[798] *Id*., at p. 7.
[799] *Id*., at p. 9.
[800] "[I]n WIPO there is the standing arrangement of regional groups-geographical groups-of which there are seven: the African group; Asian group; Latin American and Caribbean group; and then what we call the Group B countries, which are the developed countries, not just those based in Europe or North America, but also Japan, Australia, New Zealand; then you have the countries of eastern Europe and Baltic countries; you have the central Asian and caucus countries; and China, because of its size, is considered a group by itself, although it is only one country." *See* Geoffrey Yu, *The Structure and Process of Negotiations at the World Intellectual Property Organization*, 82 Chicago-Kent Law Review 1445, 1451 (2007), available at: http://scholarship.kentlaw.iit.edu/cgi/viewcontent.cgi?article=3625&context=cklawreview.
[801] *Id*., at pp. 11-17.
[802] *Id*., at pp. 18-20.
[803] *Id*., at pp. 21-24.

- "…4.6. **Distance Learning** – Text Proposals [predominantly from the African Group]…Comments…"[804]
- "…4.7. **Research** – Text Proposals [predominantly from the African Group]…Comments…"[805]

- "…5. PERSONS WITH DISABILITIES – Text Proposals [predominantly from the African Group]…Comments…"[806]
- "…7. BROADER TOPICS WITH IMPLICATIONS FOR EDUCATION
  - 7.1. Technology – Text Proposals [predominantly from the African Group]]…Comments…"[807]
  - "…7.2 **Orphan Works and Withdrawn or Out of Print Works** – Text Proposals [predominantly from the African Group]…Comments"[808]
  - "…7.5 **ISP Liability** – Text Proposals [predominantly from the African Group]"[809]
  - "…7.6 **Importation and Exportation** – Text Proposals [predominantly from the African Group]"[810]

- SCCR/23/8 – *Working Document Containing Comments on and Textual Suggestions Towards an Appropriate International Legal Instrument (In Whatever Form) on Exceptions and Limitations for Libraries and Archives* (Aug. 2012) [811] - **Based largely on a Proposal from the African Group**[812]

  - "Topic 1: PRESERVATION – Proposed Texts [predominantly from the African Group]…Comments…"[813]
  - "…Topic 2: RIGHT OF REPRODUCTION AND SAFEGUARDING COPIES – Proposed Texts [predominantly from the African Group]…Comments…"[814]
  - "…Topic 3: LEGAL DEPOSIT – Proposed Texts [predominantly from the African Group]…Comments…"[815]
  - "…Topic 4: LIBRARY LENDING – Proposed Texts [predominantly from the African Group]…Comments…"[816]

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[804] *Id*., at pp. 27-30.
[805] *Id*., at pp. 31-35.
[806] *Id*., at pp. 37-50.
[807] *Id*, at pp. 51-53.
[808] *Id*., at p. 54.
[809] *Id*., at pp. 57-58.
[810] *Id*., at p. 59.
[811] *See* World Intellectual Property Organization, Standing Committee on Copyright and Related Works, 24th Sess. (July 16-25, 2012), *Working Document Containing Comments on and Textual Suggestions Towards an Appropriate International Legal Instrument (In Whatever Form) on Exceptions and Limitations for Libraries and Archives*, adopted by the Committee SCCR/23/8 (Aug. 8, 2012), available at: http://www.wipo.int/edocs/mdocs/copyright/en/sccr_23/sccr_23_8.pdf.
[812] See *Draft WIPO Treaty on Exceptions and Limitations for the Persons with Disabilities, Educational and Research Institutions, Libraries and Archives – Proposal by the African Group*, SCCR/22/12 (June 3, 2011), supra.
[813] See *Working Document Containing Comments on and Textual Suggestions Towards an Appropriate International Legal Instrument (In Whatever Form) on Exceptions and Limitations for Libraries and Archives*, SCCR/23/8, supra at pp. 2-8.
[814] *Id*., at pp. 9-18.
[815] *Id*., at pp. 19-25.

- "…Topic 5: PARALLEL IMPORTATIONS – Proposed Texts [predominantly from the African Group]…Comments…"[817]
- "…Topic 6: CROSS-BORDER USES – Proposed Texts [predominantly from the African Group]…Comments…"[818]
- "…Topic 7: ORPHAN WORKS, RETRACTED AND WITHDRAWN WORKS, AND WORKS OUT OF COMMERCE – Proposed Texts [predominantly from the African Group]…Comments…"[819]
- "…Topic 8: LIMITATIONS ON LIABILITY OF LIBRARIES AND ARCHIVES – Proposed Texts [predominantly from the African Group]…Comments…"[820]
- "…Topic 9: TECHNOLOGICAL MEASURES OF PROTECTION – Proposed Texts [predominantly from the African Group]…Comments…"[821]

- SCCR/24/9 - *Revised Working Document on an International Instrument on Limitations and Exceptions for Visually Impaired Persons/Persons with Print Disabilities* (July 2012)[822]

- VIP/DC/8 - WIPO – Adoption by Diplomatic Conference of: *Marrakesh Treaty to Facilitate Access to Published Works for Persons Who are Blind, Visually Impaired, or Otherwise Print Disabled* (July 2013)[823]

  - **(The scope of this treaty is narrower than that envisioned by the African Group, Brazil and Ecuador, Peru and Uruguay [EPU] proposals (see above). While it could potentially be utilized for the benefit of unintended 'beneficiaries', its lack of any 'technical assistance' provisions will pose a considerable impediment to certain countries' 'authorized entities'.[824])**

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[816] *Id*., at pp. 26-33.
[817] *Id*., at pp. 33-36.
[818] *Id*., at p. 37.
[819] *Id*., at pp. 38-45.
[820] *Id*., at pp. 46-48.
[821] *Id*., at pp. 49-52.
[822] *See* World Intellectual Property Organization, *Revised Working Document on an International Instrument on Limitations and Exceptions for Visually Impaired Persons/Persons with Print Disabilities – Adopted by the Committee*, 24th Sess. (July 16-25, 2012), SCCR/24/9 (July 26, 2012), available at: http://www.wipo.int/edocs/mdocs/copyright/en/sccr_24/sccr_24_9.pdf.
[823] *See* World Intellectual Property Organization, Diplomatic Conference to Conclude a Treaty to Facilitate Access to Published Works by Visually Impaired Persons and Persons with Print Disabilities (Marrakesh, June 17-28, 2013), *Marrakesh Treaty to Facilitate Access to Published Works for Persons Who are Blind, Visually Impaired, or Otherwise Print Disabled – Adopted by the Diplomatic Conference*, VIP/DC/8 REV. (July 31, 2013), available at: http://www.wipo.int/dc2013/en/; http://www.wipo.int/edocs/mdocs/copyright/en/vip_dc/vip_dc_8_rev.pdf.
[824] *See* Catherine Saez, *Over 50 Countries Sign Marrakesh Treaty On Copyright Exceptions And Limitations For The Blind*, Intellectual Property Watch (July 1, 2013), available at: http://www.ip-watch.org/2013/07/01/over-50-countries-sign-marrakesh-treaty-on-copyright-exceptions-and-limitations-for-the-blind/. "According to sources from developing and developed countries, the lack of a clause on technical assistance in the treaty can be detrimental to its implementation since a number of authorised entities will need capacity building." *Id.*

- **According to one report, a representative of the Chinese government had stated that, "'The Treaty has far-reaching impact since it is the first treaty on limitations and exceptions in the field of intellectual property'…"**[825]
- **Relevant Articles**:
  - "Article 2 – Definitions - For the purposes of this Treaty…(c) **'authorized entity'** means an entity that is **authorized or recognized by the government [including those receiving financial support from the government**[826]**]…to provide education, instructional training, adaptive reading or information access to beneficiary persons on a non-profit basis**…[and]…**a government institution or non-profit organization that provides the same services to beneficiary persons as one of its primary activities or institutional obligations**."[827]
  - **Article 4** –National Law Limitations and Exceptions Regarding Accessible Format Copies
    - Article 4.1(a) requires "copyright laws [to provide] for a **limitation or exception to the right of reproduction, the right of distribution, and the right of making available to the public** as provided by the WIPO Copyright Treaty (WCT) to facilitate the availability of works in accessible format copies for beneficiary persons."[828]
    - Article 4.4 states that "**limitations or exceptions** under this Article…***may*** **[be] confine[d]…to works which, in the particular accessible format, cannot be obtained commercially under reasonable terms for beneficiary persons in that market**."[829] Apparently, "negotiators decided to drop the commercial availability test requirement in the importing country for the cross-border exchange of an accessible format copy of the work."[830]

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[825] *Id*.
[826] *See* Marrakesh Treaty VIP/DC/8 REV., *supra* at fn# 2.
[827] "For the purposes of this Treaty, it is understood that 'entities recognized by the government' may include entities receiving financial support from the government to provide education, instructional training, adaptive reading or information access to beneficiary persons on a non-profit basis." *Id*., at Article 2(c).
[828] *Id*., at Article 4.1(a).
[829] *Id*., at Article 4.4.
[830] *See* KM Gopakumar, *WIPO: Treaty Concluded for Visually Impaired to Access Published Works*, Infojustice.org (June 27, 2013), available at: http://infojustice.org/archives/30032. "Dropping of the commercial availability test is expected to facilitate the transfer of accessible format copies from developed countries to developing countries and to fill a knowledge gap that exists among the blind, visually impaired and persons living with print disability…During the negotiations, *it became untenable for the European Union (EU) to continue its demand on the insertion of commercial availability*. One observer cited two reasons for the EU's late flexibility, which resulted in the dropping of the commercial availability. *First, globally, the commercial availability requirement is mentioned in the national laws of around six countries including the United Kingdom and Canada*. According to this observer, *except for the UK, no other EU Member State has a commercial availability requirement in their national law. Secondly, the European Parliament resolution, which provides the negotiating mandate for the European Commission to negotiate the treaty, does not mention the commercial availability requirement*" (emphasis added). *Id*.

- If a Party chooses this option, it "shall so declare in a notification deposited with the Director General of WIPO at the time of ratification of, acceptance of or accession to this Treaty or at any time thereafter."[831]
- "**It is understood that a commercial availability requirement does not prejudge whether or not a limitation or exception under this Article is consistent with the three-step test**."[832]

- "**Article 5 – Cross-Border Exchanges of Accessible Formats** –
  - Articles 5.1 and 5.2 **permit the distribution or making available of "an accessible format copy**…made under a limitation or exception or pursuant to operation of law…**by an authorized entity to a beneficiary person or an authorized entity in another Contracting Party**…**without the authorization of the rightholder**…***provided*** **that prior to the distribution or making available the originating authorized entity did not know or have reasonable grounds to know that the accessible format copy would be used for other than beneficiary persons**."[833]
  - ***Article 5.3 addresses the "Berne Gap"*** (**countries that are not Parties to the Berne Declaration for the Protection of Literary and Artistic Works**) – "A Contracting Party may fulfill Article 5(1) by providing other limitations or exceptions in its national copyright law **pursuant to Articles 5(4), 10 and 11**."[834]
  - **Article 5.4(a) – A Contracting Party that does not have obligations under Article 9 of the Berne Convention must "ensure**, consistent with its own legal system and practices, that the **accessible format copies it receives are only reproduced, distributed or made available for the benefit of beneficiary persons in that Contracting Party's jurisdiction**."[835]
  - **Article 5.4(b)** – "The **distribution and making available of accessible format copies** by an authorized entity pursuant to Article 5(1) **shall be limited to that jurisdiction *unless* the Contracting Party is a Party to the WIPO Copyright Treaty [WCT] or otherwise limits limitations and exceptions** implementing this Treaty to the right of distribution and the right of making available to the public **to certain special cases which do not conflict with a normal exploitation of the work and do not unreasonably prejudice the legitimate interests of the rightholder**."[836]
    - This language reflects the language of the "three-part test" contained in the WCT, but does not oblige Parties to become a member of the WCT and, thus,

[831] *See* "Marrakesh Treaty" VIP/DC/8 REV. *supra* at Article 4(4).
[832] *Id*., at fn# 5 – "***Agreed statement concerning Article 4(4)***."
[833] *Id*., at Articles 5.1-5.2.
[834] *Id*., at Article 5.3.
[835] *Id*., at Article 5.4(a).
[836] *Id*., at Article 5.4(b).

subject to such test under said Treaty.[837] Arguably, it nevertheless remains subject to such test under the TRIPS Agreement.[838]

- **Article 10** – General Principles of Implementation – "Contracting Parties may fulfill their rights and obligations under this Treaty through limitations or exceptions specifically for the benefit of beneficiary persons, other limitations or exceptions, or a combination thereof, within their national legal system and practice."[839]
- **Article 11** – General Obligations on Limitations and Exceptions
  - "In adopting measures necessary to ensure the application of this Treaty, a Contracting Party may exercise the rights and shall comply with the obligations that that Contracting Party has under the Berne Convention, the Agreement on Trade-Related Aspects of Intellectual Property Rights and the WIPO Copyright Treaty, including their interpretative agreements…**in accordance with**:
    - (a)…Article 9(2) of the Berne Convention…
    - (b)…Article 13 of the Agreement on Trade-Related Aspects of Intellectual Property Rights…
    - (c)…Article 10(1) of the WIPO Copyright Treaty…[and/or]
    - (d)…Article 10(2) of the WIPO Copyright Treaty…"[840]

[837] "It is understood that nothing in this Treaty creates any obligations for a Contracting Party to ratify or accede to the WCT or to comply with any of its provisions and nothing in this Treaty prejudices any rights, limitations and exceptions contained in the WCT." Id., at fn#8 *"**Agreed statement concerning Article 5(4)(b)**"*.

[838] "It is understood that nothing in this Treaty requires or implies that a Contracting Party adopt or apply the three-step test beyond its obligations under this instrument or under other international treaties. *Id*., at fn#9 – *"**Agreed statement concerning Article 5(4)(b)**"*. *See also* Sam Ricketson, *WIPO Study on Limitations and Exceptions of Copyright and Related Rights in the Digital Environment*, supra at pp. 46-48 et seq.

[839] *Id*., at Article 10(3).

[840] *Id*., at Article 11.