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Growing Foreign Investment and Regulatory/Policy Risks Facing High Technology Innovations

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High technology innovators and investors operating in the life sciences, clean energy, and information and communication technology (ICT) sectors face complex economic and legal uncertainties compounded by regulatory and policy risks during the course of guiding an innovative concept from its research and development through product testing and commercialization stages that will be indicative and determinative of economic value assigned to said technology in a given domestic or foreign marketplace. This assessment of value is directly dependent on local jurisdictions maintaining established rules of law and related standards that recognize and robustly enforce exclusive intellectual property rights without disruptive or excessive limitations and/or restrictions. An increasing number of developing countries aspire to become twenty-first century knowledge economies by seeking to recharacterize international law in a manner that enables the conversion of high technology patents and trade secrets from private to public goods. These countries have promoted the establishment of regimes to achieve this objective, principally compulsory licensing and interoperability frameworks that express or compel government procurement preferences for nonproprietary and/or royalty-free patented technologies emplaced within regional, national, and/or international technology standards. Beyond recourse to public international law remedies, companies and investors may also take private initiatives to mitigate the inherent regulatory and policy risks on company financial performance. Such initiatives include internal structural vigilance, wide external diligence, and carefully crafted communications with individuals and organizations, both public and private. This effort is predicated upon astute monitoring and analysis of relevant events in international and national fora discussing these issues.

1. Introduction: Historically, Capital-Intensive Technology Development and Commercialization Has Included Significant Economic and Legal Risks and Other Uncertainties

The pathways that lead to the success of cutting-edge technologies are often fraught with risk, difficulty, and uncertainty, and more so under a regime of lengthy time horizons for competent research and development and commercialization, which may require regulatory approvals. These challenges are known to be endemic to capital-intensive technology development that requires significant follow-on funding,[1] particularly in highly regulated industries such as life sciences

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1 See, e.g., National Venture Capital Association, "Impact of the Medical Device Safety Act on Venture Capital Investment in Medical Technology and Innovation," Statement for the Record, Health Subcommittee of the House Energy and Commerce Committee (hereinafter "National Venture Capital Association, 2009") (May 12, 2009), at 13, at <www.NVCA_Statement_to_EC_on_HR_1346-5-09.pdf>; Carmen Nobel, "Venture Capital's Disconnect With Clean Tech," Working Knowledge, Harvard Business School (Oct. 18, 2010), at <http://hbswk.hbs.edu/item/6499.html>; Stephen Lacey, "Can Cleantech Entrepreneurs Rely on Venture Capital?" RenewableEnergyWorld.com (Jul. 13, 2009), at <www.renewableenergyworld.com/rea/news/article/2009/07/should-entrepreneurs-rely-on-venture-capital>; Arleen Jacobius, "High Costs Taking Wind Out of Clean-tech Sails: Too Long a Wait for Too Small a Profit, VC Investors Complain," Investment News (Apr. 25, 2010), at <www.investmentnews.com/article/20100425/REG/304259991>.

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(e.g., pharmaceuticals/biotechnology,[2] and electronic medical devices[3]), and clean technology (which may be subdivided into clean or renewable energy generation[4] and clean or renewable energy efficiency technologies and/or services, the former having more direct exposure to the regulatory environment[5]). However, these conditions also loom large with respect to the development and introduction of new paradigm-setting information and communication technologies (ICTs),[6] categorized by reference to the economic activities generated by the application of ICT sector goods and services to *other* industry sectors,[7] including healthcare, energy and the environment, transportation, information and education, emergency and disaster management, and defense/national security.[8] According to one recent study, "the ICT sector undertakes large investments in R&D and is very innovative. In terms of R&D expenditures, patents, and venture capital investment, it exceeds other industries by a large margin."[9]

One of the most formidable obstacles faced by inventors and innovators of technologies engendering long gestation periods (e.g., development, testing, and scaling) and sustained high capital flows is the establishment of a technology's economic value determined in large part by management's ability to reduce associated economic and legal uncertainties that otherwise would impede technology development, commercialization, and market entry. And this assessment of value, which is sought increasingly through greater cooperation between financial and corporate investors,[10] is highly contingent on elements of certainty, principally robust enforcement of intellectual property (IP) right(s) (e.g., patents and trade secrets) that ensure market exclusivity.

This is especially the case in the life sciences sector.[11] According to one well-known venture capitalist, the expectation of substantial revenue losses resulting from a large number of drug patents expiring within the next few years and the reality of reduced R&D productivity (i.e., the lower rate of new drug product regulatory approvals notwithstanding increased R&D investments) "is creating an incentive for pharmaceutical companies to pay a lot of money for early-stage program[s] ... [and to] ... look[] to create partnerships externally to reduce R&D expenditure."[12] Yet, patent protection also has become an important element in the valuation of computer software companies. For example, the recently released Berkeley patent study clearly reveals that 60% of venture capitalists negotiating with software firms "indicated that patents were an important factor in their investment decision ... [compared with] ... 73 % for biotech and 85% for

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2 See Scott Gottlieb, "Medical Innovation in Peril," in *Reforming America's Health Care System: The Flawed Vision of ObamaCare*, ed. Scott W. Atlas, M.D. (Hoover Institution Press, 2010), at 56–57, accessible online at <www.aei.org/docLib/Reforming-Americas-Health-Care-System-Gottlieb-101810.pdf> and <www.hooverpress.org/productdetails.cfm?PC=1430>, citing C. Johnston, *Annals of Neurology* 62, no. 6 (2007): A6–A7, and J.A. DiMasi, R.W. Hansen & H.G. Gradbowski, "The Price of Innovation: New Estimates of Drug Development Costs," *Journal of Health Economics* 22 (2003): 151–185. See also "Fight or Flight?: Diversification vs. Rx-focus in Big Pharma's Quest for Sustained Growth," Short Report Version, Roland Berger Strategy Consultants (October 2010), at <www.rolandberger.com/media/pdf/Roland_Berger_Fight_or_flight_Shortversion_20101025.pdf>; " 'Fight or flight?': Roland Berger Study Identifies Diversification as One of the Most Prominent Trends in the Pharmaceutical Industry, " Roland Berger Press Release (Oct. 25, 2010), at <www.rolandberger.com/company/press/releases/Diversification_in_the_pharmaceutical_industry.html>; Ben Adams, "Two Thirds of Pharma Companies Face 'Strategic Crisis'," InPharm (Oct. 25, 2010), at <www.inpharm.com/news/101025/two-thirds-pharma-companies-face-strategic-crisis>; Andrew Jack, "Drugs Groups Diversify Away from Patents," Financial Times (Oct. 21, 2010), at <www.ft.com/cms/s/0/d6fb3f60-dc9d-11df-84f5-00144feabdc0.html>; Kenneth Getz & Rachael Zuckerman, "Anticipating Structural Change in the CRO Market – Sponsor Crises Lead to an Unstable Landscape," Tufts Center for the Study of Drug Development, ContractPharma (October 2010), at <www.contractpharma.com/articles/2010/10/anticipating-structural-change-in-the-cro-market>.

3 See National Venture Capital Association, 2009, *supra* at 2–3.

4 See "Cleantech Investment and Private Equity: An Industry Survey," a Norton Rose, LLP Survey (July 2010), 5, at <www.nortonrose.com/knowledge/publications/pdf/file30016.pdf?lang=en-gb>.

5 See "Cleantech and Renewables Update," SJ Berwin, LLP (Jul. 14, 2010), 1, at <www.sjberwin.com/Contents/Publications/pdf/210/e421e383_70c2_4d12_8caf_b54b582b4fc6.pdf>.

6 See Joseph Galante & Amy Thomson, "Cisco Shortfall Shows Wider Risks in Government Cuts," BloombergBusinessweek (Nov. 11, 2010), accessible online at <www.businessweek.com/news/2010-11-11/cisco-shortfall-shows-wider-risks-in-government-cuts.html>.

7 See International Standard Industrial Classification of All Economic Activities (ISIC), Revision 4 (ISIC Rev. 4) United Nations Department of Economic and Social Affairs Statistics Division (ST/ESA/STAT/SER.M/4/Rev.4) (Aug. 11, 2008), at 278–78 at paras. 218–220 and Table 4.3, accessible online at <http://unstats.un.org/unsd/cr/registry/isic-4.asp>.

8 See Graham Vickery & Sacha Wunsch-Vincent, "R&D and Innovation in the ICT Sector: Toward Globalization and Collaboration," Ch. 1.8 in *The Global Information Technology Report* 2008–2009 (World Economic Forum, 2009), at 95–97, accessible online at <www.tubisad.org.tr/Tr/Library/Analizler/Toward%20Globalization%20and%20Collaboration.pdf>.

9 *Ibid.*, at 97.

10 See "UPDATE 3-GE, Partners to Invest $55 Mln in Power-Grid Tech," Reuters (Nov. 16, 2010), at <http://finance.yahoo.com/news/UPDATE-3-GE-partners-invest-rc-2858014743.html?x=0&.v=4>; "GE Energy Financial Services Joins North Bridge Venture Partners in Investment in CoolPlanetBiofuels," Wall Street Journal.com (Nov. 17, 2010), at <http://online.wsj.com/article/PR-CO-20101117-905018.html?mod=wsjcrmain>. See James Harris, "A design for Life Sciences: Q&A Stephen Bunting," Real Deals Europe (May 20, 2010), at 24, accessible online at <www.abingworth.com/images/RealDeals2010.pdf>.

11 See *Fight or Flight?: Diversification v. Rx-focus in Big Pharma's Quest for Sustained Growth*, Short Report Version, Roland Berger Strategy Consultants, *supra*; Gottlieb, *supra*, at 60.

12 See Harris, at 24–25, *supra*.

medical devices … [and that] … substantial percentages of other types of investors, such as angels, investment banks, and other companies found patents important to their investment decisions."[13]

At least one other study suggests that "the economic and strategic value of patents is subject to a very high degree of uncertainty. Patents vary widely in their value, and much of the value associated with IP depends on endogenous outcomes in technology and product markets" (i.e., commercialization efforts).[14] However, this study also clearly shows how certain exogenous (i.e., formal institutional or systemic) factors can be quite determinative of the commercial success of patented technologies. Indeed, the economic and legal uncertainties surrounding the patenting of technologies are many—they include (1) patent allowance, (2) patent scope, (3) patent grant delay, (4) patent enforceability, and (5) patent value.[15] In particular, the study's findings show that delays surrounding the issuance of a Notice of Patent Allowance by the U.S. Patent and Trademark Office patent will effectively delay cooperative commercialization efforts vis-à-vis technology contracting/licensing,[16] especially in the case of technologies requiring long development (gestational) periods and incurring longer patent allowance lags (the time between patent application and patent allowance)[17] where alternative forms of IP protection are not available.[18] In other words, reduced patent allowance uncertainty can result in reduced patent scope uncertainty, which, in turn, can significantly increase both the probability (likelihood) (between 70% and 80%) and the frequency (overall rate) of securing (post-allowance) patent cooperation/licensing agreements within a relatively shorter period of time.[19] These findings arguably have important implications for start-up[20] and repeat innovators, many of whom are likely to increase their rate of licensing absent "significant [lingering] uncertainty … [about] … their ability to enforce those claims through the applicable legal system"—that is, in a court of law.[21]

It is precisely for these reasons that law and policy proposals, enactments, or implementations potentially impacting the strength, scope, and duration of patents can and often do alter the course of investment, innovation, and market presence and increase the economic and legal uncertainties affecting the measurement of value.

2. Domestic and Foreign Regulatory and Policy Risks Associated with High Technology Development, Commercialization, and Market Behavior

2.1. Domestic Risks

Technology innovators, financial and corporate investors (despite their different return expectations, capital structures, and levels of day-to-day involvement),[22] and commercialization partners also must overcome challenges posed by those entities charged with regulatory authority at the national and/or regional levels where greater innovation may be seen as capable of significantly disrupting the marketplace status quo ante and transcending the definitions, rules, and principles of extant law. To the extent that overly intrusive or otherwise ill-conceived or inadequate government policy and legal promulgations including those relating to IP rights[23] associated with novel and/or emerging technologies either create[24] or are themselves a symptom of[25] legal and economic uncertainties, it may be expected that actual and intended capital availability may be placed at risk and/or withdrawn prematurely as measured by the recipient's economic model.[26]

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13 See Robert Merges & Pamela Samuelson, "Patenting by Entrepreneurs: The Berkeley Patent Survey (Part III of III)," PatentlyO Blog (Jul. 21, 2010), accessible online at <www.patentlyo.com/patent/2010/07/patenting-by-entrepreneurs-the-berkeley-patent-survey-part-iii-of-iii.html>.

14 See Joshua S. Gans, David H. Hsu & Scott Stern, "The Impact of Uncertain Intellectual Property Rights on the Market for Ideas: Evidence from Patent Grant Delays," Management Science 54, 982–997 (May 2008); April 2007 version at 7, at <http://works.bepress.com/cgi/viewcontent.cgi?article=1008&context=joshuagans>.

15 *Ibid.*, at 4.

16 *Ibid.*, at 29.

17 *Ibid.*, at 21.

18 *Ibid.*, at 1, 29. See also W.T. Lina & B.B.M. Shao, "Assessing the Input Effect on Productive Efficiency in Production Systems: The Value of Information Technology Capital," *International Journal of Production Research* 44, 1799–1819, at Abstract (May 2006), accessible online at <www.informaworld.com/smpp/content~db=all~content=a746060327~frm=abslink>. See also "Productive Efficiency", Encyclo Online Encyclopedia, at <www.encyclo.co.uk/define/Productive%20efficiency>.

19 See Gans, Hsu & Stern, *supra*, at 2–3, and 21, Table 1B at 37.

20 *Ibid.*, at 29–30.

21 *Ibid.*, at 6.

22 See *Cleantech and Renewables Update*, SJ Berwin, LLP, *supra*.

23 See, e.g., Ben Depoorter, "Technology and Uncertainty: The Shaping Effect on Copyright Law," *University of Pennsylvania Law Review* 157 (2009): 1831, 1861–1862.

24 *Ibid.*, at 1836.

25 *Ibid.*, at 1853.

26 See Jacobius, *supra*.

Financial and corporate investors are well aware how U.S. domestic regulatory policy changes can increase economic and legal risks that can impair the market introduction and subsequent economic success of pharmaceutical, medical device, and clean technologies. For example, during June 2009, the National Venture Capital Association and the Medical Device Manufacturers Association together and individually implored the U.S. Congress to consider the likely adverse economic impacts[27] that the Medical Device Safety Act of 2009,[28] if enacted, would have had upon venture capital flows to the medical device sector and its ability to innovate.

> [P]olicymakers must evaluate the potential impacts and consequences of new rules and regulations with great care. They must also weigh the benefits of such policies against the possibility of hampering future innovation . . . Even minute changes in the number of length of required clinical trials or steps for reimbursement approval can significantly alter risk profile and projected cost of a given product.[29]

Similarly, at least one Washington think-tank that evaluated the recently enacted Patient Protection and Affordable Care Act[30] expressed deep concerns about how the law's restrictions on drug and medical device insurance expense reimbursement create legal and economic uncertainties that "will inevitably weigh on entrepreneurship, investment, and innovation . . . could diminish the capital formation that underpins the riskiest endeavors . . . [and are] already chasing investment capital into other endeavors that are more lucrative when adjusted for their risk," with the net result being the shrinkage of "the industry's total R&D effort."[31]

It is also widely recognized within the venture capital and academic communities that "any industry that revolves around energy is heavily dependent on public policy at both the federal and the local level, and much more so than the general high-tech sector . . . [which] . . . is a big problem when product development cycles and election cycles don't mesh."[32] Nuclear energy technology is especially prone to public perceptions, policy influences, and related regulatory risk.[33] Some believe also that "too many clean tech investments feature significant regulatory risk" because their success is dependent upon whether they are the ultimate recipients of government subsidies or grants.[34]According to one recently released Harvard Business School study, the extent to which a startup company's product (e.g., biofuels), and thus its profitability, is contingent on whether it is included in a given subsidy or credit, subject to a carbon tax, or eligible for a government price premium, and is consequently susceptible to policy changes and uncertainty are AQ3

> *major factors hindering the potential investment by private sector players across the clean energy investment landscape* . . . particularly . . . when the periodicity of the regulatory cycle is smaller than the investment cycle required for demonstrating commercial viability . . . *[N]o one is willing to invest in the first commercial plant if they do not know what the regulatory environment is going to be by the time success has been demonstrated* (emphasis added).[35]

In addition, at least one commentator has opined how the U.S. government's piecemeal rather than comprehensive approach to energy policy has unexpectedly created regulatory risks that have inadvertently triggered a *reduction* in clean tech investment. "It's not just regulation that is important, it's [also the] certainty around regulation—whether it happens or not—that makes the wheels move."[36]

ICT investors in the course of undertaking their due diligence similarly consider the level of regulatory risk of potential investment opportunities. For example, they "focus on the independence of the regulator . . . , the transparency of the regulatory process, the legal processes for regulation," and the overall impact of the proposed regulatory framework on competition and investment. If the perceived regulatory risk is too high

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27 See National Venture Capital Association, 2009, *supra* at 2–3.

28 See H.R. 1346: *Medical Device Safety Act of 2009* (111th Cong.), accessible online at <http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=111_cong_bills&docid=f:h1346ih.txt.pdf>.

29 See "Medical Technology and Venture Capital: A Fruitful yet Fragile Ecosystem," Medical Device Manufacturers Association and National Venture Capital Association (June 2009), 13, at <www.medicaldevices.org/sites/default/files/MDMA%20NVCA%20Final.June2009.pdf>.

30 See P.L. 111–148 (Mar. 23, 2010, 111th Cong.), otherwise known as "Patient Protection and Affordable Care Act."

31 See Gottlieb, *supra* at 54, 62, 67–68.

32 See Nobel, *supra*, paraphrasing Harvard Business School professor Joseph Lassiter.

33 See Eric Wesoff, "Is There a Role for Venture Capital in Nuclear Power?: A Survey of VC Attitudes Towards Investing in Nuclear Power," Interviews with Peter Wagner of Accel Partners, Raj Atlaru of Draper Fisher Jurvetson, Ullas Naik of Globespan Capital, and Peter Nieh of Lightspeed Venture Partners, Greentech Media (GTM) Research (Dec. 14, 2009), at <www.greentechmedia.com/research-blog/post/is-there-a-role-for-venture-capital-in-nuclear-power/>.

34 See Jacobius, *supra*.

35 See Shikhar Ghosh & Ramana Nanda, "Venture Capital Investment in the Clean Energy Sector," Harvard Business School Working Paper 11-020 (Aug. 1, 2010), at 16, accessible online at <www.hbs.edu/research/pdf/11-020.pdf>.

36 See Michael Meehan, *Uncertainty in US Energy Policy is Cleantech's Real Challenge*, GreenBeat (Nov. 1, 2010), at <http://venturebeat.com/2010/11/01/uncertainty-in-us-energy-policy-is-cleantech%E2%80%99s-real-challenge/>.

and cannot be appropriately mitigated, the greater the likelihood that their appetite for investment will be dampened and the financial viability of an ICT investment will be harmed.[37]

In the end, "government can make a significant contribution . . . through stable, predictable and long-term policy measures . . . Removing uncertainty around policies reduces policy risk dramatically and makes it easier for the private capital markets to plan their investments accordingly."[38] Government can also provide a market-friendly environment by selecting the least costly regulatory alternative available to reduce investors' operational and capital expenditure costs, which, in turn, can improve companies' ability to secure necessary investor funding.[39]

Failing this, institutional and corporate investors in life science, clean energy, and ICTs are likely to endeavor to influence ("capture") regulatory policy[40] to the extent necessary to mitigate risks that would otherwise prevent them from emerging from the "valley of death"[41] and realizing a reasonable economic rate of return or, perhaps, even a return of their original capital.[42] It must be kept in mind, however, that regulatory and policy risks faced by institutional and corporate investors do not arise in a vacuum. Governments are also susceptible to "capture" by *other than* economic entities. For example, civil society pressure groups may seek to embed their own economic, legal, and/or political positions and preferences at the expense of competing interests, including economic interests, through the enactment, repeal, or maintenance of a given regulation—a phenomenon known as "interest group regulatory capture."[43]

2.2. Foreign Risks

The phenomenon of regulatory and policy risk has also assumed an international dimension in the current era of globalization and growing interconnectedness, especially concerning high technologies in the life science, clean energy, and ICT sectors. Increasingly, foreign governments and international policymakers have deemed these technologies as "public goods" necessary to establish a twenty-first century domestic knowledge economy capable of competing effectively in the international trading system. At least one study has noted how "[t]he global exposure of [clean energy] markets implies that changes in the regulatory regime in one country can affect the investment landscape across the entire sector." For example, it found that Spain's inability to honor its subsidy commitments to the domestic solar sector not only damaged the credibility of the Spanish government but also created policy uncertainties in other countries, that is, suspicions that other governments would be unable to meet their obligations to that sector, which effectively dampened investor enthusiasm for solar industry portfolios.[44] In addition, another very recent study reveals how the French government has finally come to recognize that *anti*-science regulatory policies and promulgations such as those dependent on a broad and extensive application of the precautionary principle incorporated within the laws of the Member States of the European Union and the European Community itself[45] can adversely impact entrepreneurial, innovative, and investment behavior, ultimately contributing to risk aversion and diminished national economic growth, and retardation of scientific knowledge.[46]

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37 See Lynne Dorward & Hal Peters, "Impact of Effective Regulation on Investment: an Investor's Perspective," GSR Discussion Paper 2009, presented at the 9th Global Symposia for Regulators (GSR), "Hands-on or Hands-off? Stimulating Growth through Effective ICT Regulation" (November 2009), at 5 and 7, accessible online at <www.itu.int/ITU-D/treg/Events/Seminars/GSR/GSR09/doc/GSR09_Regulation-Investment_Dorward.pdf>.

38 See Ghosh & Nanda, *supra* at 18.

39 See Mandla Msimang, "Effective Regulation: The 'Stimulus Plan' for the ICT Sector," GSR Discussion Paper 2009, presented at the 9th Global Symposia for Regulators (GSR), "Hands-on or Hands-off? Stimulating Growth through Effective ICT Regulation" (November 2009) at 14–15, accessible online at <www.itu.int/ITU-D/treg/Events/Seminars/GSR/GSR09/doc/GSR09_Regulation-Investment_Msimang.pdf>.

40 See Frédéric Boehm, "Regulatory Capture Revisited – Lessons from Economics of Corruption," Internet Center for Corruption Research Working Paper (July 2007) at 3–6, accessible online at <www.icgg.org/downloads/Boehm%20-%20Regulatory%20Capture%20Revisited.pdf>.

41 The "valley of death" is "that precarious stage between researching and developing a product and actually going to market with it." See Lacey, *supra*; "The valley of death refers to the difficult period between proof-of-concept for a technology and large-scale deployment." See Jacobius, *supra*.

42 See, e.g., Ghosh & Nanda, *supra* at 18–19.

43 See Boehm, *supra* at 3–6.

44 See Ghosh & Nanda, *supra* at 16–17.

45 See Jerzy Sommer, "The Organizational and Legal Instruments Available for Harmonizing Polish Environmental Law With EC Environmental Law," in *Reform in CEE-Countries With Regard to European Enlargement*, ed. Michael Schmidt and Lothar Knopp (Springer-Verlag, 2004), 29–30, accessible online at <http://books.google.com/books?id=qiSz1LaYzaoC&pg=PA30&lpg=PA30&dq=acquis+communautaire+%2B+precautionary+principle&source=bl&ots=rmZ0uU550K&sig=AQSaDsJUbaYMstJbTwzZJSaRxWo&hl=en&ei=V7jzTKaiLYX7lwfP99jmDA&sa=X&oi=book_result&ct=result&resnum=1&ved=0CBMQ6AEwAA#v=onepage&q=acquis%20communautaire%20%2B%20precautionary%20principle&f=false>.

46 See "An Ambition for Ten Years," Report of the Committee for the Liberation of Growth (October 2010), at 34–35, 149–150, at <http://lesrapports.ladocumentationfrancaise.fr/BRP/104000541/0000.pdf>, English translation available at <http://itssdeconomicfreedom.blogspot.com/2010/10/attali-commission-france-must-strictly.html>.

Given the indispensability of private investment and innovation to the creation of a knowledge economy, it would behoove developing country governments seeking to establish successful industrial and economic growth policies to avoid the enactment of laws and regulations such as compulsory licensing that can increase regulatory risks for high technology companies and correspondingly reduce the flow of knowledge-based foreign direct investment (FDI).[47] While government patent (IP) policy by itself is an incomplete measurement of a country's market and investment-friendliness, it is generally agreed that it is reflective as well as indicative of a country's law-enabling environment. Through effective deterrence of imitation, "patents reduce the costs of enforcing contracts and at the same time increase the expected returns on FDI and licensing, which will have a positive effect on technology transfer. *Patent rights encourage technology transfer by providing owners with legal certainty*."[48] Consequently, the passage of IP laws that do not include a provision for compulsory licensing, for example, may favorably signal to foreign investors concerned about "the security of property rights" that a government is willing to let them make strategic business decisions without undue interference and to ensure more transparent and unbiased application of commercial laws with the prospect of reduced government corruption.[49] "There is little doubt that developing countries who issue compulsory licenses also face additional risks in attracting global capital. Particularly, for MDC's [middle developing countries], a compulsory license can trigger the loss of significant FDI."[50]

It is commonly believed that patent ownership rights indicate to prospective investors a firm's proper regard for its IP security, its innovative (R&D) capabilities, and its market potential, and thereby a firm's increased ability to secure requisite financing made available by angel investors, venture capitalists, secondary markets or others,[51] as well as signals overall that the firm is well managed,[52] If this is true, then surely a company's willingness to engage in a foreign market where the government has decided to adopt and/or enforce *anti*-patent measures that would undermine valuable company patent rights (e.g., compulsory licensing or express government procurement preferences for patent-free or royalty-free technology standards) can readily convey *negative* signals to the investment community about the company and the strength and economic value (or lack thereof) of its patents and associated projected revenue streams:

> Just as the sale of a product through a low-status selling channel of a product can signal a diminution in brand status to the consumer, exposure of a patent to an uncertain legal environment can signal that the firm may not consider the patent to be as valuable as others believe. Even the threat of an 'anti-patent' such as a compulsory license can impair firm equity, thereby reducing the attractiveness of a country as an investment partner. Any firm calculating its returns from FDI will have to account for the possibility of these signaling-based losses.[53]

Therefore, financial and corporate investors would surely be remiss if they did not carefully scrutinize a company's business plan and financial statements to ascertain management's strategy for and its actual success or failure in mitigating foreign regulatory and policy risks to secure a reasonable rate of return on investment (ROI).

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47 See Robert Bird & Daniel R. Cahoy, "The Impact of Compulsory Licensing on Foreign Direct Investment: A Collective Bargaining Approach," *American Business Law Journal* 45, 1 (Issue 2, 2008), at 1–2, accessible online at <www.personal.psu.edu/faculty/d/r/drc13/Index_files/CL_and_FDI.pdf>. ("There is little doubt that developing countries who issue compulsory licenses also face additional risks in attracting global capital. Particularly for MDCs [middle developed countries], a compulsory license can trigger the loss of significant FDI. Thus, each nation has to weigh the benefits as well as the disadvantages of issuing such a license for the benefit of its citizens.") *Ibid.*, at 47.

48 See "Report on the International Patent System," World Intellectual Property Organization (SCP/12/3), at para. 41, 11–12, accessible online at <www.wipo.int/edocs/mdocs/scp/en/scp_12/scp_12_3.pdf>.

49 See Bird & Cahoy, *supra*, at 1 and 16.

50 *Ibid.*, at 47. See also "ITSSD Response to Annex III – Comments on the Report on the International Patent System Received from Members and Observers of the SCP" (SCP/12/3 Rev.2) (Feb. 24, 2009) and sources cited therein, at 10–22, accessible online at <www.wipo.int/scp/en/meetings/session_13/pdf/itssd_annex3.pdf> ("Knowledge-based Foreign Direct Investment (FDI) is Important to Emerging and Developing Country National Governments and is Related to Intellectual Property Right Protection . . . Host Countries May Derive National, Regional and Local Socio-Economic Spillover Benefits from Knowledge-based Foreign Direct Investment (FDI)"); Lawrence A. Kogan, "Promoting International Development, not Welfare Dependence: Benefiting From Intellectual Property," presentation at the Harvard Kennedy School of Government's 15th Annual Harvard International Development Conference IMPACT Turning Global Challenges into Opportunities (Apr. 4, 2009) and sources cited at 8–15 and 31–32, at <www.itssd.org/Intellectual%20Property%20Promotes%20International%20Development%20-%20Kogan%20-%204-4-09.ppt>.

51 See "Public Health, Innovation and Intellectual Property Rights," Report on the Commission on Intellectual Property Rights, Innovation and Public Health (CIPIH), World Health Organization (2006), at 19–21, accessible online at <www.who.int/intellectualproperty/documents/thereport/ENPublicHealthReport.pdf>.

52 See Bird & Cahoy, *supra* at 16.

53 *Ibid.*, at 16–17.

3. Foreign Government and Civil Society Efforts within the WIPO to Weaken Patent Rights Globally Create Additional Regulatory and Policy Risks for High Technology

The World Intellectual Property Organization (WIPO) is a specialized agency of the United Nations[54] that "administers several treaties aimed at creating a standard global system . . . [by] tak[ing] patent law in the direction of international harmonization."[55] It is one of only two intergovernmental organizations, the other being the World Trade Organization (WTO),[56] which administers the Trade Related Aspects of Intellectual Property (TRIPs) Agreement,[57] that anchor the current international IP system.

Several WIPO secretariat reports released and discussed during the Thirteenth, Fourteenth and Fifteenth Session meetings of the Standing Committee[58] on the Law of Patents (SCP) (i.e., during 2008–2010) reflect an emerging global view about patents and related trade secrets that will surely raise the legal uncertainties and economic risks associated with high technology innovation and investment within OECD member nations.[59] A growing number of emerging market and developing country WIPO Members generally believe that patent-based technology markets are inherently flawed, that patent holders are unreasonable and morally bereft monopolists who exploit the period of temporary exclusivity associated with a patent grant for monetary gain at the expense of the civil society and the public interest, and that an irreconcilable conflict exists between the patent and standards systems that undergird technology development and industrial innovation, which leads to a market result that is antithetical to social, technological, and economic progress and thus inconsistent with the United Nations Millennium Development Goals.[60] The allegations made by these governments are supported by a number of sympathetic academicians and political agenda-based nongovernmental organizations (NGOs)/civil society pressure groups and, to a lesser extent, by industry-based "bias arbitrageurs"[61] seeking to employ and facilitate the expansion of a new services-rather-than-goods oriented high technology business model by persuading certain governments of the potential job growth that such models might entail. If successful, this movement will effectively recharacterize for international law purposes most privately conceived, developed, and/or commercialized health, clean energy, and ICTs as "public goods" that may then be appropriated ("taken") for other than full, complete, and adequate ("just") compensation with few substantive or procedural checks and balances by regional and/or national governments for the purpose of serving the public interest, that is, to facilitate knowledge dissemination, technology transfer, and access to affordable healthcare, clean energy, and broadband communications at prices far less than fair market value.

Two governmental regulatory instruments have particularly galvanized debate among government, civil society, and industry stakeholders participating recently in the WIPO SCP process: they are broadly defined compulsory licenses for healthcare and clean

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54 See "What is WIPO?, About WIPO," WIPO website, at <www.wipo.int/about-wipo/en/what_is_wipo.html>.

55 See "Patent Cooperation Treaty" of Jun. 19, 1970, last modified Oct. 3, 2001, with the supplementing Regulations under the Patent Cooperation Treaty of Jan. 1, 2004 (142 contracting parties), at <www.wipo.int/export/sites/www/treaties/en/documents/pdf/pct.pdf> (accessed Mar. 17, 2010); "Patent Law Treaty," adopted at Geneva on Jun. 1, 2000 (18 contracting parties), at <www.wipo.int/treaties/en/ShowResults.jsp?lang=en&treaty_id=4> (accessed Dec. 18, 2008), with the supplementing Regulations under the Patent Law Treaty, adopted the same date); "Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure," Apr. 28, 1977, amended Sep. 26, 1980; and the Regulations Under the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure, adopted Apr. 28, 1977 and amended Jan. 20, 1981 and Oct. 1, 2002 (72 contracting parties), at <www.wipo.int/export/sites/www/treaties/en/documents/pdf/budapest.pdf> (accessed Mar. 17, 2010).

56 See "The World Trade Organization and Agriculture, U.S. Proposal for Global Agricultural Trade Reform," FASonline (November 2002), at <www.fas.usda.gov/info/factsheets/wto.html>.

57 See Agreement on Trade-Related Aspects of Intellectual Property Rights, Dec. 15, 1993, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, Legal Instruments – Results of the Uruguay Round, vol. 31, 33 ILM 81 (1994) (hereinafter "TRIPs").

58 See "Decision-Making Bodies," About WIPO, World Intellectual Property Organization website (last viewed on Nov. 22, 2010), at <www.wipo.int/members/en/decision_bodies.html>.

59 See OECD Brochure, "The OECD: What is it?, The OECD Organisation for Economic Co-operation and Development" (2008), at 7, accessible online at <www.oecd.org/dataoecd/15/33/34011915.pdf>; Yelena M. Bakulina & Lawrence A. Kogan, "How Market-Based Policies Could Spur Biotechnology Growth in Russia," Washington Legal Foundation Backgrounder (March 2008), at <www.itssd.org/Publications/03-21-08balukina.pdf>.

60 See "United Nations Millennium Declaration," Resolution adopted by the General Assembly 55th Session (A/RES/55/2) (Sep. 18, 2000), accessible online at <www.un.org/millennium/declaration/ares552e.pdf>; "Background," UN Millennium Goals website accessible online at <www.un.org/millenniumgoals/bkgd.shtml>.

61 *Bias arbitrage is the extraction of private benefits through actions that identify and mitigate discrepancies between objective risks and the public's perception of the same risks*. Politicians arbitrage these discrepancies by enacting laws that address the misperceived risk and contain a "placebo effect" – a counter-bias that attempts to offset the pre-existing misperception. *If successful, politicians are able to take credit for the change in perceived risk, while social welfare is enhanced by the elimination of deadweight loss caused by risk misperception*" (emphasis added). See Amitai Aviram, Bias Arbitrage, Wash. & Lee l. Rev. 64, 789 (2007), accessible online at <http://law.wlu.edu/deptimages/Law%20Review/64-3AviramPublished.pdf>.

energy technologies and emerging government procurement rules expressing direct and/or indirect preferences for patent- and/or royalty-free "SMART" technologies embedded in "open" national healthcare, energy, and ICT standards.

The growing popularity of such measures reveals a deep-seeded multi-polar philosophical antipathy toward the institution of exclusive private property rights generally and IP rights specifically[62]. It also engenders a significantly greater degree and magnitude of legal uncertainty and related policy and regulatory risk for patented high technology innovation than has been acknowledged by the investment and corporate communities within OECD member nations. Therefore, unless this emerging world view is peremptorily challenged, such measures are likely to severely jeopardize scientific and technological innovation and investment in these and other promising high technologies conceived and developed within and beyond the United States.

3.1. Government Regulations and Proposals for the Compulsory Licensing of High Technologies

The Government of Brazil is perhaps the staunchest global advocate of establishing a flexible compulsory licensing mechanism within both international treaty and customary international law (i.e., as an absolute global standard) that would afford national emerging and developing country governments (where many of the world's future growth markets are projected to reside[63]) the broad discretion to appropriate and secure third party reverse-engineering (i.e., technology transfer) of foreign privately held patented health-related/medical and ICT technologies whenever a "public interest" is believed to be at stake.[64]

Most troubling, however, is that Brazil's views and efforts in this regard[65] have long been embraced by a large group of developing countries known generally within the United Nations system as the "Group of 77."[66] Such views are currently being shepherded through the WIPO SCP via a report entitled "Exclusions From Patentable Subject Matter and Exceptions and Limitations to the Rights,"[67] by a more focused agenda-based group of developing countries referred to as the WIPO "Development Agenda Group (DAG)."[68] According to the DAG, in order to "preserve[e] national policy space," WIPO should exploit the implementation of IP "flexibilities, exceptions and limitations as well as other special provisions, options or safeguards . . . essential to the needs of developing countries" wherever possible to address "developmental and global challenges such as environment, public health, food security, etc."[69]

A compulsory or non-voluntary license

> refers to the practice by a government to authorize itself or third parties to use the subject matter of a patent without the authorization of the right holder for reasons of public policy . . . In [such] cases, the public interest in broader access to an invention is considered more important than the private interest of the right holder to fully exploit his exclusive rights.[70]

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62 See, e.g., *A Review by Pat Sewell*, Amy Chua, *World on Fire: How Exporting Free Market Democracy Breeds Ethnic Hatred and Global Instability* (New York: Doubleday, 2003), at <http://yaleglobal.yale.edu/about/sewell.jsp> (reflecting the thesis that: "When free market democracy is pursued in the presence of a market-dominant minority, the almost invariable result is backlash. This backlash typically takes one of three forms. The first is a backlash against markets, targeting the market-dominant minority's wealth. The second is a backlash against democracy by forces favorable to the market-dominant minority. The third is violence, sometimes genocidal, directed against the market-dominant minority itself,' and recommending, among other things, the 'controversial strategy' of majority-backed governmental intervention to 'correct' ethnic wealth imbalances' through programs similar to those called 'affirmative action' within the West. This would seem effective and feasible, given a popularly-elected government. But it would violate free-market expectations and, immodestly used, threaten the individual rights (including property ownership rights) or rights of the minority that liberalism associates with majority rule.")

63 See "Top 10 Largest Economies in 2020," Euromonitor Global Market Research Blog (Jul. 7, 2010), accessible online at <http://blog.euromonitor.com/2010/07/special-report-top-10-largest-economies-in-2020.html>.

64 See, e.g., Lawrence A. Kogan, "Brazil's IP Opportunism Threatens U.S. Private Property Rights," *Inter-American Law Review*, 38 (Fall 2006): 1–139, accessible online at <www.itssd.org/Publications/IAL105-II(frompublisher)[2].pdf>; Lawrence A. Kogan, "Forced Licensing of Drug Patents Reflects 'IP Counterfeiting' Efforts on World Stage," *Legal Backgrounder* (Jun. 22, 2007), accessible online at <www.wlf.org/upload/06-22-07kogan.pdf>.

65 See Kogan, 2006, *supra* at 30–98.

66 See "About the Group of 77," The Group of 77 at the United Nations website at <www.g77.org/doc/>.

67 See "Exclusions From Patentable Subject Matter and Exceptions and Limitations to the Rights," Report of the WIPO Secretariat, World Intellectual Property Organization Standing Committee on the Law of Patents Thirteenth Session SCP/13/3 (Feb. 4, 2009) (hereinafter "WIPO Report SCP/13/3"), accessible online at <www.wipo.int/edocs/mdocs/scp/en/scp_13/scp_13_3.pdf>.

68 See "Information on the Development Agenda Group Guiding Principles," Committee on Development and Intellectual Property (CDIP) Fifth Session, World Intellectual Property Organization CDIP/5/9 Rev., at para. 4, and accompanying fn. 1 (April 2010), accessible online at <www.wipo.int/edocs/mdocs/mdocs/en/cdip_5/cdip_5_9_rev.pdf>.

69 *Ibid.*, at paras. 5 and 8.

70 See Jerome H. Reichman & Catherine Hasenzahl, "Non-voluntary Licensing of Patented Inventions: Historical Perspective, Legal Framework under TRIPs, and an Overview of the Practice in Canada and the USA," International Centre for Trade and Sustainable Development (ICTSD) and United Nations Conference on Trade and Development (UNCTAD), Executive Summary at 1 (June 2003), at <http://ictsd.org/downloads/2008/06/cs_reichman_hasenzahl.pdf>.

As one recent WIPO secretariat report reveals, compulsory licenses were historically issued[71] outside the United States,[72] provided certain statutory conditions were first satisfied, "to prevent the abuses which might result from the exercise of the exclusive rights conferred by [a] patent," including the "failure to work or [the] insufficient working" of a patent.[73] Governments eventually broadened the definition of "patent abuses," and hence, the grounds for issuance of compulsory licenses, to encompass also "the refusal [to] grant[] a license on reasonable terms and conditions," (2) "the failure to supply the national market with sufficient quantities of the patent product," (3) "demanding excessive prices for such product," and (4) "anti-competitive behavior."[74] And, gradually, by the early 1990s, approximately 100 national governments other than the United States[75] had opportunistically expanded their use of compulsory licensing to cover *non*-abuse situations, "which can be grouped together under the general heading of compulsory licenses *in the public interest*," which include compulsory licenses (1) "in the fields of military security[;] or [2] . . . public health[;]23 . . . [and 3] to protect the public interest in unhampered technological progress . . . [as in the case of] . . . so-called *dependent patents*."[76] According to at least one international IP law expert, governments' resort to compulsory licensing in cases of *non*-abuse was an "*un*intended consequence" practiced mostly by countries "seeking to regulate patents covering medicinal products and food products,"[77] and later justified by reference to "Article 31 [of the WTO TRIPs Agreement which they alleged] . . . indirectly vindicated the public interest as a ground separate from the category of abuse."[78]

What emerging and developing country governments have failed to acknowledge, however, is that TRIPs Article 31 circumscribes such practices with a robust statutory framework that "imposes strict conditions and procedural requirements for such issuance,"[79] consistent with "one of the two primary objectives of the treaty—*the recognition that intellectual property rights are private rights*" entitled to affirmative due process protections.[80] International IP law commentators have argued that such recognition is enshrined within various provisions of the TRIPs Agreement. These provisions include TRIPs Preamble paragraph 4 and TRIPs Articles 31(h) and 44.2 (ensuring payment of adequate, just, full, and complete remuneration upon issuance of a compulsory license),[81] and TRIPs Articles 31(k) and 62.4 (ensuring against the diminution of patent owner rights, which would otherwise follow from the imposition of remedies/sanctions, including compulsory licenses, for judicially or administratively determined anti-competition violations).[82] They also include proposed new TRIPs Article 31.2*bis* contained within the pending Annex to the Protocol Amending the TRIPs Agreement intended to codify paragraph 3 of 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 (endeavoring to prevent the issuance by both an exporting and importing country of more than one CL).[83] Arguably, these provisions individually AQ5

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71 See *WIPO Report SCP/13/3*, *supra* at paras. 138–184, 36–44.

72 *Ibid.*, at Executive Summary at 4–5.

73 See Art. 5A(2) and 5A(4), Paris Convention for the Protection of Industrial Property of Mar. 20, 1883, as amended, at <www.wipo.int/treaties/en/ip/paris/trtdocs_wo020.html#P123_15283>.

74 See *WIPO Report* SCP/13/3, *supra* at para. 78.

75 See Reichman & Hasenzahl, *supra* at Executive Summary at 4–5; "ITSSD Comments Concerning Document (SCP/13/3) Patent Exclusions, Exceptions & Limitations," Institute for Trade, Standards and Sustainable Development, at 13–16, and accompanying footnotes (February 2009) (hereinafter "ITSSD Comments Concerning Document SCP/13/3"), accessible online at <www.wipo.int/export/sites/www/scp/en/meetings/session_14/studies/itssd_2.pdf>.

76 See "WIPO Intellectual Property Handbook: Policy, Law and Use," 2nd edn, WIPO Publication No. 489E, Ch. 5, at para. 5.51–5.53, 247–248 (WIPO, 2004), accessible online at <www.wipo.int/export/sites/www/about-ip/en/iprm/pdf/ch5.pdf>. See also ITSSD Comments Concerning Document (SCP/13/3), *supra*, at 2–3 and accompanying footnotes.

77 See Reichman & Hasenzahl, *supra* at Executive Summary at 1.

78 *Ibid.*, at 2.

79 See ITSSD Comments Concerning Document (SCP/13/3), *supra* at 5–6, and accompanying footnotes.

80 *Ibid.*, at 6, citing Nuno Pires de Carvalho, *The TRIPS Regime of Trademarks and Designs* (Kluwer Law International, 2006), 43, at <http://books.google.com/books?id=WyNen7A0WUkC&pg=PA46&lpg=PA46&dq=TRIPS+Article+31+%2B+eminent+domain&source=bl&ots=dCuc7H-uk8&sig=F2WIelJDHjx8tNCoK0rFnPnLC2M&hl=en&ei=kLPKSa-JIsyrtgeaqfjuCQ&sa=X&oi=book_result&resnum=2&ct=result#v=onepage&q=TRIPS%20Article%2031%20%2B%20eminent%20domain&f=false>.

81 See de Carvalho, *supra*, discussed in ITSSD Comments Concerning Document (SCP/13/3), *supra* at 6–8, and accompanying footnotes; Daniel R. Cahoy, "Confronting Myths and Myopia on the Road from Doha," *Georgia Law Review* 42, 1 (2007): 156, at <www.personal.psu.edu/faculty/d/r/drc13/Index_files/Myths_and_Myopia.pdf>.

82 See de Carvalho, *supra* at 204, discussed in "ITSSD Comments Concerning Document (SCP/13/3) Patent Exclusions, Exceptions & Limitations," Institute for Trade, Standards and Sustainable Development, *supra* at 9 and accompanying footnote.

83 See de Carvalho, *supra* at 198, discussed in ITSSD Comments Concerning Document (SCP/13/3), *supra* at 8–9, and accompanying footnotes.

and/or collectively require that a government's determination of "adequate remuneration" avoid prejudicing a patent holder's "legitimate expectations of commercial opportunity,"[84] consistent with the "'market compensation theory' followed by the United States in determining the accountability of the federal government for unauthorized use of a patent invention [pursuant to] 28 U.S.C. § 1498."[85]

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Nevertheless, the BRIC nations continue in their efforts to promote debate on the issue of compulsory licensing in domestic as well as international fora such as the WIPO. During the SCP's Fourteenth Session in March 2009, for example, SCP members:

> commission[ed an] external experts . . . 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.[86]

The completed study, which was released during September 2010 in advance of the SCP's Fifteenth Session, discusses the use of compulsory licenses within two of its six chapters. One chapter relates to life forms and identifies the various provisions of the EU directive on biotechnological inventions that establish a compulsory licensing scheme "to deal with the overlap between patent and plant variety protection"[87] and the analogues of several EU Member States,[88] as well as the compulsory licensing statutes of IP stalwarts such as Brazil[89] and the Russian Federation.[90] A second chapter, which details the use of compulsory licensing with respect to pharmaceuticals, focusing on countries other than the United States that have issued compulsory licenses on various grounds including public interest, anti-competition, national security emergencies, health emergencies, failure to work, government noncommercial use, or one of several other deemed "abuses" of patent rights.[91]

During the SCP's Fifteenth Session, which took place in October 2010, Brazil, speaking on behalf of the DAG, publicly expressed its agreement with the experts' articulation of a utilitarian *rather than* a private property rights basis for patents. In particular, the Brazilian delegate interpreted the experts' study as recommending that governments grant technology patents only to the extent necessary to rectify the failure of the market to foster innovation.[92] The Free Software Foundation Europe (FSFE), an outspoken NGO observer and staunch advocate of royalty-free and/or nonproprietary open source software-based ICT standards, agreed with this Brazilian/DAG interpretation and proposed its own three-part test for adjudging the necessity of a patent grant—which it had previously submitted to the European Patent Office. According to the FSFE, a patent should be granted only where there is (1) "a demonstrated market failure to provide innovation; (2) a demonstrated positive disclosure of the invention for patenting and (3) a demonstrated effectiveness of the patent system in the area to disseminate knowledge."[93]

The view that technology and knowledge are "public goods" and that patents are merely temporary incentives (tools) provided by governments to correct "market failures" is based on and consistent with the

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84 See Antony Taubman, "Rethinking Trips: 'Adequate Remuneration' for Non-Voluntary Patent Licensing," *Journal of International Economic Law* (December 2008), at 3 and 20, discussed in "ITSSD Comments Concerning Document (SCP/13/3) Patent Exclusions, Exceptions & Limitations," Institute for Trade, Standards and Sustainable Development, *supra* at 20.

85 See Cahoy, *supra*.

86 See "External Experts' Study Regarding Exclusions, Exceptions and Limitations for the Standing Committee on the Law of Patents (SCP)," Standing Committee on the Law of Patents Fourteenth Session (SCP/14/INF/2) at paras. 1 and 4 (Jan. 26, 2010), accessible online at <www.wipo.int/edocs/mdocs/scp/en/scp_14/scp_14_inf_2.pdf>.

87 See Denis Borges Barbosa & Karin Grau-Kuntz, *Exclusions from Patentable Subject Matter and Exceptions and Limitations to the Rights – Biotechnology*, Ch. 3 (SCP/15/3 Annex III), World Intellectual Property Organization, at 34–35 and 56 (Jan. 1, 2010), accessible online at <www.wipo.int/edocs/mdocs/scp/en/scp_15/scp_15_3-annex3.pdf>.

88 *Ibid.*, at 65–68, concerning the laws of Belgium, Bulgaria, Latvia, Lithuania, Malta, Romania, Slovakia, Sweden, and the United Kingdom.

89 *Ibid.*, at 45–46.

90 *Ibid.*, at 67.

91 See Coenraad Visser, *Patent Exceptions and Limitations in the Health Context*, Ch. 5 (SCP/15/3 – ANNEX V), at 3–24 (January 2010), accessible online at <www.wipo.int/edocs/mdocs/scp/en/scp_15/scp_15_3-annex5.pdf>.

92 See "Paraphrased Statement of the Brazilian delegate," on Behalf of the Development Agenda Group (DAG) (Oct. 12, 2010), in ITSSD "Geneva Diary" of the Proceedings of the 15th Session of the WIPO Standing Committee on the Law of Patents Reflects Developed Country IP Rights Under Third World Assault, ITSSD *Journal on Intellectual Property Rights* (hereinafter "ITSSD Geneva Diary") (Oct. 26, 2010), accessible online at <http://itssdinternationaliprights.blogspot.com/2010/10/itssd-geneva-diary-of-proceedings-of.html>.

93 See "FSFE Submission to European Patent Office" (April 2009), Free Software Foundation Europe website, accessible online at <www.fsfe.org/projects/swpat/epo-response-042009.en.html>. See "Paraphrased NGO Observer Free Software Foundation Intervention, ITSSD Geneva Diary" (Oct. 11, 2010), *supra*; DAG Statement Expert's Study on Exclusion and Exceptions/Limitations (SCP/15/3), accessible online at <www.ip-watch.org/weblog/wp-content/uploads/2010/10/DAG-Statement-On-Exemptions-Limitations.doc>.

economic rationale for technology patents articulated within the WIPO SCP's initial "Report on the International Patent System."[94] According to the report, since technology and knowledge are "nonexcludable" in the sense that they can be used simultaneously by many people and owned exclusively by none, competitive markets, if left to their own devices, would not invest in them. Consequently, governments have intervened by developing patent systems to incentivize markets to undertake the costly and risky investments necessary to generate the production of knowledge.[95]

Professor Lionel Bentley, the designated coordinator of the experts' study,[96] in responding to a comment made by this author during the SCP's October 11, 2010, plenary session,[97] added another dimension to this theory of market failure. He emphasized that a "neoliberal economics" property rights basis for technology patents (i.e., the right of exploitation and commercialization) is not possible in developing countries (LDCs) given the added market failure of asymmetry of information caused by the lack of any willing buyers and sellers to create a market for knowledge goods in such countries.[98] This utilitarian patent "public interest" point of view is also reflected in a related WIPO SCP study on "technology transfer," which extols compulsory licenses as "tools to ensure that the patent system contributes to the promotion of innovation . . . and to the dissemination and transfer of technology . . . [thereby] responding to the public interest at large."[99]

Given the European Union's relatively weaker private property laws vis-à-vis the United States[100] and its continued inability to enact a regional patent law, it is understandable why the Belgian WIPO delegate representing the EU-27, for largely political reasons, agreed with the experts' study assessment. According to the EU, the relative asymmetry of information between patent holders and prospective licensees within developing countries and the relatively different capacities within developing countries to receive technology transfer[101] have resulted in a definition of property rights that is unclear and that justifies the enactment of national legislation that is "most suitable to [each country's] . . . needs." [102] This statement apparently emboldened the Brazilian delegate to thereafter propose the establishment of a government intervention mechanism that would match prospective patent licensors with prospective licensees to correct the perceived market failure deemed to impede technology transfer.[103]

It is quite clear that these views resonate with those of BRIC and developing nations endeavoring to secure an expanded global application of compulsory licensing on public interest grounds to include technologies other than medicines—that is, clean energy technologies (also known as "environmentally sensitive technologies"). And it should be regarded as troubling that this position derives "soft" law[104] support from the "UNEP [United Nations Environment Program] Agenda 21 proposal [on sustainable development] that created the UNFCCC at the 1992 Rio Convention."[105]

During the December 2007 United Nations Framework Convention on Climate Change (UNFCCC) Conference of the Parties (COP), the former Brazilian Foreign Minister "proposed that a statement similar to the Doha Declaration on the TRIPS Agreement and Public Health should be considered in the climate change context."[106] This proposal was taken seriously

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94 See "Report on the International Patent System," Standing Committee on the Law of Patents, World Intellectual Property Organization (SCP/12/3/Rev.2) (Feb. 3, 2009), accessible online at <www.wipo.int/edocs/mdocs/scp/en/scp_12/scp_12_3_rev_2.pdf>.

95 *Ibid.*, at paras. 28–29.

96 See, e.g., "Summary by the Chair," Standing Committee on the Law of Patents, World Intellectual Property Organization, Fifteenth Session (SCP/15/5) (Oct. 15, 2010), at para. 6, accessible online at <www.wipo.int/edocs/mdocs/scp/en/scp_15/scp_15_5.pdf>.

97 See "Paraphrased Intervention by NGO Observer ITSSD," ITSSD Geneva Diary, *supra.*

98 See "Paraphrased Professor Bentley Response to NGO Observer ITSSD Intervention," ITSSD Geneva Diary, *supra*.

99 See "Transfer of Technology," Standing Committee on the Law of Patents, World Intellectual Property Organization (SCP/14/4) (Dec. 11, 2009) at para. 122, accessible online at <www.wipo.int/edocs/mdocs/scp/en/scp_14/scp_14_4.pdf>.

100 See "Comments on the Report on the International Patent System Received from Members and Observers of the SCP," The World Intellectual Property Organization (SCP/12/3 Rev.2 Annex III) at 18–26, accessible online at <www.wipo.int/edocs/mdocs/scp/en/scp_12/scp_12_3_rev_2-annex3.pdf>.

101 The discussion concerned Agenda Item 5E – technology transfer.

102 See "Paraphrased Statement of the Belgian Delegate from Belgium on Behalf of the EU," ITSSD Geneva Diary (Oct. 15, 2010), *supra.*

103 See "Paraphrased Statement of the Brazilian Delegate," ITSSD Geneva Diary (Oct. 15, 2010), *supra.*

104 International lawyers often distinguish between "hard" and "soft" law. See Mark W. Janis & John E. Noyes, *International Law – Cases and Commentary* (West Group, 2001), at 39.

105 See Charles Ebinger & Govinda Avasarala, "Transferring Environmentally Sound Technologies in an Intellectual Property-Friendly Framework," Brookings Policy Brief 09-07, at 23–24, The Brooking Institutions (November 2009), accessible online at <www.brookings.edu/~/media/Files/rc/papers/2009/11_environmental_technology_ebinger/11_environmental_technology_ebinger.pdf>, referencing Agenda 21, s. 4, Ch. 34.10, 34.18, UNCED (Rio de Janeiro, Brazil, Jun. 3–14, 1992) (United Nations, New York).

106 See "Climate Change, Technology Transfer and Intellectual Property Rights," International Centre for Trade and Sustainable Development (ICTSD) Background Paper (August 2008), at 7, accessible online at <www.um.dk/NR/rdonlyres/F4D753A6-7015-4064-8BC6-FD4FEF1913F9/0/GMFIPRqx.pdf>. See also Thomas J. Bollyky, "Intellectual Property Rights and Climate Change: Principles for Innovation and Access to Low-Carbon Technology," Center for Global Development (December 2009), at 7, accessible online at <www.cgdev.org/content/publications/detail/1423378/>.

enough to attract the attention of Frederick Abbott, the University of Florida law professor who helped to draft the Doha Declaration on Public Health.[107] During the November 2008 Beijing International Conference on carbon abatement technology transfers, "China and India proposed that the TRIPs flexibility for medicines (compulsory licensing) should be extended to cover carbon abatement technology. The argument was that climate is a public good, just like health, and that hence the international community should follow the principle of 'guidance by government—participation by enterprises.' "[108] Thereafter, during February 2009, the Chinese government proposed in comments submitted to the UNFCCC concerning the implementation of the Bali Action Plan that "Compulsory licensing related patented ESTs [environmentally sound technologies] and specific legal and regulatory arrangement to curb negative effects of monopoly powers shall be put in place as part of the efforts to implement the UNFCCC."[109] And, in November 2009, European and American media reported how China and India had intended to condition any agreement reached at the December 2009 Copenhagen Climate Change Conference on developed countries' acceptance of a broad compulsory licensing-based technology transfer regime relating to clean energy/carbon mitigation/new green technologies.[110] Needless to say, the U.S. and EU eventually rejected such proposal out of deep concern that it would stifle investment, research and development, technological innovation, and "green" jobs creation within their economic regions.[111] Yet, Draft decision—/CP.15—Enhanced action on technology development and transfer, contained within the February 2010 Report of the "Ad Hoc Working Group on Long-term Cooperative Action (AWG-LCA) under the Convention," continues to provide UNFCCC Parties with the option of interpreting and/or implementing any international agreement on intellectual property "in a manner that [does not] limit [] or prevent [] any Party from taking any measures to address . . . transfer of, and access to, environmentally sound technologies and know-how."[112] The Draft decision "option" was thereafter incorporated during June 2010 within Chapter III—Enhanced Action on Technology Development and Transfer of a text prepared by the Chair of the UNFCCC Secretariat under a mandate "to facilitate negotiations among Parties, drawing on the report of the AWG-LCA presented to the Conference of the Parties (COP) at its fifteenth session."[113]

Notwithstanding the failure to adopt such a compulsory licensing regime at Copenhagen, the members of the DAG have continued to debate compulsory licensing at the WIPO SCP. For example, in January 2010, during the WIPO SCP's Fourteenth Session meetings, the Government of Brazil proposed a new tool for implementing the WIPO Development Agenda—namely, the establishment of an SCP working group to "carry out a wide and sustained . . . three phase . . . debate" on the issue of "limitations and exceptions to patent rights," including compulsory licensing. According to the Brazilian proposal, the working group would (1) exchange and compile information detailing all national or regional legislation on limitations and exceptions and the reasons for and methods of their use, (2) investigate all effective legislation on limitations and exceptions and the conditions for their implementation, and (3) develop "an exceptions and limitations manual" for WIPO Member reference.[114] However, it remains to be determined whether such a work group will be capable of bringing any further enlightenment to such a highly complex fact-specific subject matter.

Arguably, it was the ongoing legal uncertainty surrounding compulsory licensing that prompted the Indian government, during August 2010, to release a draft discussion paper on the subject of compulsory

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107 See, e.g., Frederick M. Abbott, "Innovation and Technology Transfer to Address Climate Change: Lessons from the Global Debate on Intellectual Property and Public Health," ICTSD Global Platform on Climate Change, Trade Policies and Sustainable Energy, Issue Paper No. 24 (Jun. 2009), Abstract available at <http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1433579>.

108 See Copenhagen Economics and the IPR Company, "Are IPRs A Barrier To The Transfer Of Climate Change Technology?" (January 2009), at 7, a "report . . . commissioned by the European Commission (DG Trade)", accessible online at <http://trade.ec.europa.eu/doclib/docs/2009/february/tradoc_142371.pdf>.

109 See "China's Views on the Fulfillment of the Bali Action Plan and the Components of the Agreed Outcome to be Adopted by the Conference of the Parties at its 15th Session" (Feb. 6, 2009) at 7, accessible online at <http://unfccc.int/files/kyoto_protocol/application/pdf/china060209.pdf>.

110 See "China, India Push for 'Patent Free' Green Tech," EurActiv.com (Nov. 23, 2009), accessible online at <www.euractiv.com/en/innovation/china-india-push-patent-free-green-tech/article-187567>; Jim Efstathiou Jr., "Clean-Energy Cause Shouldn't Void Patents, Senators Tell Obama," Bloomberg News (Nov. 4, 2009), at <www.bloomberg.com/apps/news?pid=newsarchive&sid=aug9aycq0lJw>.

111 *Ibid.*; Ebinger & Avasarala, *supra* at 6.

112 D. Draft decision—/CP.15—Enhanced Action on Technology Development and Transfer, in "Report of the Ad Hoc Working Group on Long-Term Cooperative Action under the Convention on its eighth session, held in Copenhagen from 7 to 15 December 2009," Ad Hoc Working Group on Long-Term Cooperative Action Under the Convention, United Nations Framework Convention on Climate Change (FCCC/AWGLCA/2009/17) (Feb. 5, 2010), at <http://unfccc.int/resource/docs/2009/awglca8/eng/17.pdf>.

113 Chapter III—Enhanced Action on Technology Development and Transfer, Text to Facilitate Negotiations Among Parties—Note by the Chair, presented at Ad Hoc Working Group on Long-Term Cooperative Action under the Convention Tenth session Bonn 1–11, June 2010 (FCCC/AWGLCA/2010/6) (May 17, 2010) at para. 11, Option 2, at 25–26, at <http://unfccc.int/resource/docs/2010/awglca10/eng/06.pdf>.

114 See "Proposal from Brazil and Accompanying Annex 3," Standing Committee on the Law of Patents, 14th Session (SCP/14/7) (Jan. 20, 2010) at paras. 24–28, accessible online at <www.wipo.int/edocs/mdocs/patent_policy/en/scp_14/scp_14_7.pdf>.

licensing, the stated purpose of which was to "develop a predictable environment for use of such measures."[115] One of the questions raised by the Indian government for which public comment was sought concerned the wisdom of limiting a government's discretion to issue compulsory licenses, and whether alternative grounds beyond "national emergency," "extreme urgency," and "public noncommercial use" as set forth in Article 31 of the TRIPs Agreement are and should be available to justify the issuance of compulsory licenses.[116] A second question concerned the suitability of compulsory licenses to resolve anti-competition abuses.[117] These two questions sidestepped the issue of employing compulsory licenses on broader public interest grounds beyond "failure to work" abuses and also left unresolved the types of technologies beyond medicines needed to treat front-line diseases such as HIV/AIDs, Hepatitis C, cancer, and diabetes[118] for which compulsory licenses could theoretically be issued, which arguably would include climate change/carbon mitigation technologies. A third question concerned the impact of compulsory licenses on technological growth in emerging and developing economies—that is, the market failure theory. With respect to this latter issue, the discussion draft cited a 2009 report, which found that "compulsory licensing has a strong and persistent positive effect on domestic invention," and then concluded, without any further analysis, that "[e]ven without any effects on innovation, compulsory licensing may create significant positive welfare effects on consumers in developing countries as a mechanism to maintain product variety."[119] It remains open to question whether India will seriously consider responses received from foreign[120] and domestic[121] industry stakeholders emphasizing how the discussion paper conveys the impression that patent rights susceptible to broad compulsory licensing in India will be weakened along with the incentive to innovate without resolving India's healthcare problems.

The Indian government would be wise to consider, however, that compulsory licensing is not the silver bullet that Brazilian government and the DAG believe it to be. First, "compulsory licensing does not [generally] oblige the patent holder to transfer [as yet undisclosed associated trade secret] know-how (nor does patent law in general)."[122] The triggering of such an obligation will often depend on whether a simple refusal to license rather than anti-competitive behavior or some other *abuse* of the patent right is involved. Second, even where compulsory licensing is called for with respect to a given technology, it may prove ineffective in practice if the prospective developing country government or firm licensee "lacks the expertise to develop the technology without more than just the [patent] blueprint,"[123] that is, where such party is unable to "make the technology workable" in the absence of additional "significant tacit [as yet undisclosed trade secret] knowledge."[124] In addition, the Indian government must not fail to recognize that, although there is a current lack of clear international legal standards for determining the appropriate level of market-based compensation due to private patent holders whose technologies fall subject to government compulsory licensing, it and other governments are being closely watched. According to one legal expert, the lack of such standards "can make patent property rights less predictable, encourage[s] gamesmanship by developing or developed countries

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115 See "Discussion Paper on Compulsory Licenses," India Department of Industrial Policy and Promotion's (DIPP) (Aug. 24, 2010), accessible online at <http://dipp.nic.in/>.

116 *Ibid.*, at paras. 1 and 2, s. XVII – Issues for Resolution, 22.

117 *Ibid.*, at para. 5, 22.

118 *Ibid.*, at para. 30, 9–10; paras. 15-7, 4–5; para. 44, 15.

119 *Ibid.*, at para. 70, 21, citing Petra Moser & Alessandra Voena, "Compulsory Licensing – Evidence from The Trading With The Enemy Act," NBER Working Paper (15598) (December 2009), at fn. 35, 21, accessible online at <http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1313867>.

120 See, e.g., "CropLife International's Comments on the Discussion Paper on Compulsory Licenses Published by the Department of Industrial Policy and Promotion within India's Ministry of Commerce and Industry" (Sep. 29, 2010), accessible online at <www.dipp.nic.in/ipr-feedback/Feedback_CropLifeInternational30September2010.pdf>; "Pfizer's Response to DIPP Discussion Paper on Compulsory Licensing" (Sep. 27, 2010), at 2 and 3, accessible online at <www.dipp.nic.in/ipr-feedback/FeedBack_Pfizer_27September2010.pdf>; "The Comments of the Biotechnology Industry Organization on the Discussion Paper on Compulsory Licenses Published by the Department of Industrial Policy and Promotion within India's Ministry of Commerce and Industry" (Sep. 29, 2010), at 3, accessible online at <www.bio.org/ip/international/20100929.pdf>.

121 See "OPPI Views and Suggestions on the DIPP 'Discussion Paper' on Compulsory Licensing," Organization of Pharmaceutical Producers of India (Sep. 30, 2010), at 2, accessible online at <www.dipp.nic.in/ipr-feedback/Feedback_OPPI_30September2010.pdf>.

122 See Daniel K.N. Johnson & Kristina M. Lybecker, "Challenges to Technology Transfer: A Literature Review of the Constraints on Environmental Technology Dissemination," Colorado College Working Paper 2009–2007 (July 2009), at 12. Abstract accessible online at <http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1456098>, citing Cameron Hutchison, "Does TRIPS Facilitate or Impede Climate Change Technology Transfer into Developing Countries?," *University of Ottawa Law and Technology Journal* 3 (2006): 517, 533, accessible online at <www.uoltj.ca/articles/vol3.2/2006.3.2.uoltj.Hutchison.517-537.pdf>.

123 *Ibid.*

124 *Ibid.*

wishing to cut expenditures and, most perversely, even stifle access."[125]

While the Government of India may recognize that the analysis it must undertake to determine an "abuse" of the patent right justifying the issuance of a compulsory license is a facts-and-circumstances-specific exercise not readily reducible to a fixed formula, it must understand that it cannot base any such determination exclusively on subjective criteria defined by simple reference to culturally motivated policy preferences or on questionable interpretations of human rights law to the exclusion of WTO law. Arguably, the European Court of First Instance did not adhere to this standard when it affirmed in September 2007 the European Commission's 2004 compulsory licensing decision against Microsoft.[126] In upholding the Commission's determination in the *Microsoft vs. European Communities* case,[127] the Court found that the failure of an already market-dominant Microsoft to license its Windows and Media Player software separately (i.e., its "refusal to deal" on patent and trade secret protection grounds), and its failure to render such software interoperable, that is, "to authorize the use of interoperability information,"[128] for the public benefit of Microsoft competitors and consumers[129] constituted an impermissible *abuse* of its intellectual property rights that was per se inconsistent with and in violation of European regional competition[130] statutory and case law[131] *and innovation policy*.[132] In other words, the Court of First Instance referred to interoperability as a "public interest" ancillary to maintaining effective competition in the marketplace.[133] The Indian Government must seriously consider, however, whether the Court's ruling could have been reached without resort to the newly advanced concept of ICT "interoperability," seemingly derived from a questionably broad interpretation of the same overstretched socio-economic human rights theory discussed in the WIPO experts' study on compulsory licensing and human health,[134] despite the efforts of legal commentators to characterize the ruling as having been premised on an "objective" finding of "exceptional circumstances" consistent with prior European case law.[135]

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125 See Cahoy, *supra*.

126 See *Microsoft Corp. v. Commission of the European Communities*, Judgment of the Court of First Instance (Grand Chamber), Case T-201/04 (Sept. 17, 2007), at <http://curia.europa.eu/jurisp/cgi-bin/form.pl?lang=EN&Submit=rechercher&numaff=T-201/04>.

127 *Ibid.*

128 Microsoft alleged that "the refusal to supply the information was objectively justified by the intellectual property rights which it holds over the "technology" concerned. It has made significant investment in designing its communication protocols and the commercial success which its products have achieved represents the just reward. It is generally accepted, moreover, that an undertaking's refusal to communicate a specific technology to its competitors may be justified by the fact that it does not wish them to use that technology to compete with it ... Microsoft relies on the fact that the technology which it is required to disclose to its competitors is secret, that it is of great value for licensees and that it contains significant innovation." *Ibid.*, at paras. 666–667.

129 *Ibid.*, at paras. 816–1167.

130 Article 82 EC deals with the conduct of one or more economic operators involving the abuse of a position of economic strength which enables the operator concerned to hinder the maintenance of effective competition on the relevant market by allowing it to behave to an appreciable extent independently of its competitors, its customers and, ultimately, consumers." *Ibid.*, at para. 229. "The Court observes ... the objective of the [European Commission] decision is to 'ensure that Microsoft's competitors can develop products that interoperate with the Windows domain architecture natively supported in the dominant Windows client PC operating system and hence viably compete with Microsoft's work group server operating system' ... the aim pursued by the Commission is to remove the obstacle for Microsoft's competitors represented by the insufficient degree of interoperability with the Windows domain architecture ..." *Ibid.*, at paras. 236, 240.

131 "[T]he refusal by an undertaking holding a dominant position to license a third party to use a product covered by an intellectual property right cannot in itself constitute an abuse of a dominant position within the meaning of Article 82 EC. *It is only in exceptional circumstances that the exercise of the exclusive right by the owner of the intellectual property right may give rise to such an abuse.* It also follows from that case-law that the following circumstances, in particular, must be considered to be exceptional: in the first place, the refusal relates to a product or service indispensable to the exercise of a particular activity on a neighbouring market; in the second place, the refusal is of such a kind as to exclude any effective competition on that neighbouring market; in the third place, the refusal prevents the appearance of a new product for which there is potential consumer demand. *Once it is established that such circumstances are present, the refusal by the holder of a dominant position to grant a license may infringe Article 82 EC unless the refusal is objectively justified*" (emphasis added). *Ibid.*, at paras 331–333.

132 "The CFI confirmed that refusal to allow interoperability and bundling reduce competition in the relevant markets, thereby preventing innovation and choice to the substantial detriment of consumers. In this respect, legal tests applied by the Commission were upheld by the CFI. *The decision concerning interoperability focused on the promotion of interoperability, which contributes to innovation and competition in the software industry whilst also fully recognizing the importance of intellectual property rights as incentives for innovation.*" See Alla Pozdnakova, "Court of First Instance Issues a Judgment in Microsoft Case," *International Law Observer* (Sep. 28, 2007), accessible online at <http://internationallawobserver.eu/2007/09/28/court-of-first-instance-issues-a-judgement-in-microsoft-case/>. See also "Compulsory Licensing and The European Commission's Case Against Microsoft," *Microsoft News Center Backgrounder* (September 2007), accessible online at <www.microsoft.com/presspass/legal/european/CompulsoryLicensing.mspx>.

133 *See Microsoft Corp. vs. Commission of the European Communities*, Judgment of the Court of First Instance, supra at para. 691.

134 See Visser, *supra* at 1–3.

135 See, e.g., Pierre-André Dubois and Shannon Yavorsky, "Cross-border: Europe The Microsoft Decision: The Evolution of Compulsory Licensing in the European Union," *Kirkland and Ellis Building and Enforcing Intellectual Property Value Newsletter* (2008), accessible online at <www.buildingipvalue.com/08_EMEA/119-122Kirkland.pdf>.

3.2. Proposed Government Procurement Interoperability Regulations Expressing Preferences for Patent-Free and/or Royalty-Free "Open" Standards Applicable to High Technologies

According to the WIPO Secretariat's "Report on the International Patent System[136] and its Report on Patents and Standards,"[137] new government mechanisms are urgently needed to ease the "inherent tensions [that] exist between patents and standards [in the telecommunications, electronic communications and software sectors] which become apparent when the implementation of a standard calls for the use of technology covered by one or more patents."[138] Although at least one prominent European standards development organization (SDO)[139] and some within the European Commission have tacitly acknowledged this cleverly cast disease and diagnosis, they do not share the fundamental principles underlying it. Rather, consistent with market-based principles reflected in UK law, which recognizes patents and patent applications as a form of personal property,[140] they have generally argued that technological innovation and technology transfer is possible, but only if stronger legal recognition and protection of exclusive private contractual and IP rights are guaranteed at the domestic and international levels.

As the expanding WIPO SCP agenda has made abundantly clear, this allegedly simplistic positive prognosis differs markedly from the more widely held assessment of technology-aspiring developing country governments and United Nations officials[141]—that the exercise of such private rights can and often does impede the critical public role of technical standardization in promoting ICT system *interoperability*, innovation, jobs creation, and investment and, therefore, should be legislatively and/or administratively curtailed.[142] Apparently, a growing number of European Commissioners and EU Member State government officials also share this negative outlook, especially concerning software. It is arguable, for example, that the EU Commission's prior recommendation to EU Member States "to keep administrative systems independent of proprietary technology" when "implementing a national interoperability framework" modeled after the initial version of the European Interoperability Framework (EIFv.1.0) (2004)[143] was no less an indictment of exclusive private contractual and patent rights.

The notion that patents impede software interoperability and should be severely restricted by governments has also been promoted by European civil society pressure groups. For example, the German-based FSFE,[144] an outspoken NGO endeavoring to influence regional and international ICT policy within both the EU and the WIPO, has insisted that since "both patents and standards derive their justification from the public benefit" and "the upholding of one deprives the function of the other,"[145] "patents which limit or prevent

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136 See "Report on the International Patent System," Standing Committee on the Law of Patents, World Intellectual Property Organization (SCP/12/3/Rev.2) (Feb. 3, 2009), *supra*.

137 See "Report on Patents and Standards," Standing Committee on the Law of Patents, World Intellectual Property Organization (SCP/13/2) (hereinafter "WIPO Report on Patents and Standards (SCP/13/2)") (Feb. 18, 2009), accessible online at <www.wipo.int/edocs/mdocs/scp/en/scp_13/scp_13_2.pdf>.

138 See "Report on the International Patent System," Standing Committee on the Law of Patents, World Intellectual Property Organization (SCP/12/3/Rev.2) (Feb. 3, 2009) *supra* at para. 116; WIPO Report on Patents and Standards (SCP/13/2), Standing Committee on the Law of Patents, World Intellectual Property Organization (SCP/13/2), *supra* at paras. 28, and 54–64, 66, 117.

139 See Karsten Meinhold, "The ETSI IPR Policy: A Key Element for the Success of ETSI's Globally Applicable Standards," presented at EC Workshop on "Intellectual Property Rights in ICT Standardisation" (Nov. 19, 2008), at 1–2, accessible online at <http://ec.europa.eu/enterprise/newsroom/cf/_getdocument.cfm?doc_id=3635>; "ETSI Guide on Intellectual Property Rights (IPRs)" at p. 48 'Foreword' (November 2008), accessible online at <www.etsi.org/WebSite/document/Legal/ETSI_Guide_on_IPRs.pdf>.

140 See s. 30(1) "Property in Patents and Applications, and Registration" and s. 31(2) "Nature of, and Transactions in, Patents and Applications for Patents in Scotland", The Patents Act 1977 (as amended), an unofficial consolidation produced by Patents Legal Section (Jan. 1, 2010), accessible online at <www.ipo.gov.uk/patentsact1977.pdf>.

141 See "Addressing the Interface between Patents and Technical Standards in International Trade Discussions," UNCTAD-ICTSD Project on IPRs and Sustainable Development, Policy Brief No. 3 (February 2009), at 3–4, accessible online at <www.unctad.org/en/docs/iprs_pb20093_en.pdf>.

142 See "Communication from the Commission to the European Parliament and the Council on the Role of European Standardisation in the Framework of European Policies and Legislation," COM(2004) 674 final (Oct. 18, 2004), at 5–6, accessible online at <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2004:0674:FIN:en:PDF>; *e-Government Interoperability: Guide*, United Nations Development Program (2007), at 4 and 6, at <www.apdip.net/projects/gif/GIF-Guide.pdf>.

143 See "European Interoperability Framework for Pan-European eGovernment Services Version 1.0," European Communities Brochure (hereinafter "EIFv.1.0 Brochure") (2004) at 26, accessible online at <www.apdip.net/projects/gif/country/EU-GIF.pdf>; "European Interoperability Framework for Pan-European eGovernment Services Version 1.0," European Communities (2004) (hereinafter "EIFv.1.0"), at 26, accessible online at <http://xml.coverpages.org/IDA-EIF-Final10.pdf>.

144 "Free Software Foundation Europe (FSFE) is a non-profit and in some countries charitable organisation dedicated to Free Software." See Free Software Federation Europe website at <www.fsfe.org/>.

145 See George Greve, "Innovation Policy: The Balance Between Standards and Patent Regulation," Intellectual Property Watch Inside Views (Feb. 26, 2009), accessible online at <www.ip-watch.org/weblog/2009/02/26/inside-views-innovation-policy-the-balance-between-standards-and-patent-regulation/>.

interoperability should be [rendered legally] *unenforceable*"[146] (emphasis added).

A similar but more nuanced position has been advanced by the European Committee for Interoperable Systems (ECIS),[147] an influential Brussels-based NGO that represents ICT companies seeking to secure legislation at the EU and international levels that promotes their new services-rather-than-goods business model as the cure for the "growing impediments" to software interoperability and innovation. As can be gleaned from the comments it contributed during a July 2006 hearing on the desirability of establishing a European Community patent, the ECIS has decidedly embraced a utilitarian view of patents. In other words, the ECIS advocates in favor of a patent system that (1) "ultimately exists to benefit society as a whole and not merely to service individual interests"; (2) "promote[s] innovation in the public interest"; (3) "take[s] into account the importance of interoperability of information and communications technology"; and (4) ensures against "overbroad patent protection that frustrates interoperability in the ICT sector"—that is, it "ensures that patents cannot be used as a means to confining users to a particular technology by closing off full interoperability."[148]

Indeed, the ECIS plainly stated in more detailed comments submitted as part of a prior April 2006 response to a European Commission community patent questionnaire that if a European Community Patent law were enacted, it should be circumscribed by a provision that treats *any* interference with ICT interoperability resulting from the exercise of a patent right as an *abuse* of that right.[149] The implications of what the ECIS left unstated, however, are quite obvious: such a legal characterization would logically entail the imposition of some type of statutory or judicial restriction on the exercise of such rights, including the sacrifice or limitation of patent royalties.

Interestingly, the ECIS's position is strikingly similar in principle (philosophically) to the legislative proposal set forth within the Japanese Ministry of Economy, Trade and Industry's (METI's) 2005 Interim Report on the legal protection of software,[150] although the connection between them may never be known. In addition to treating the mere interference with software interoperability as an *abuse* of the patent right equivalent in magnitude to an anti-competitive practice, the METI study proposal also recommended broad compulsory licensing or a general restriction on or exception to the exercise of patent rights as a possible legislative remedy.[151] Fortunately, these interim recommendations were never incorporated within[152] the final proposed (nonbinding) "General Rules on Software-related Intellectual Property" (or "General Rule") legislation METI subsequently released during 2007,[153] which boasted other deficiencies. If implemented, for example, the:

> proposed rule changes, [which were] intended to 'clarify the scope of abuse of rights applicable where exercising software patent rights hinders promotion of software innovation, *such as ensuring software interoperability*' . . . [would have] . . . allow[ed] for infringing uses without a license agreement . . . [and] . . . provide[d] . . . a complete release of liability . . . *[upon a showing that] . . . such use is needed to achieve interoperability* (emphasis added),[154]

presumably based on "public interest" grounds.[155]

One governmental mechanism to address potential patent abuses that was discussed within the WIPO

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146 See "Analysis on Balance: Standardisation and Patents," The Free Software Foundation Europe (Dec. 2, 2008), at <www.fsfe.org/projects/os/ps.en.pdf>.

147 See "About ECIS," European Committee for Interoperable Systems website at <www.ecis.eu/about/index.html>.

148 See "ECIS Patent Consultation Contribution" (July 2006), accessible online at <http://ec.europa.eu/internal_market/indprop/docs/patent/hearing/vinje_ecis_en.pdf>.

149 See "ECIS Reply to the EC Patent Consultation" (April 2006) at 3, accessible online at <http://circa.europa.eu/Public/irc/markt/markt_consultations/library?l=/industrial_property/patents/consultation_future/e_contributions/ecispdf/_EN_1.0_&a=d>. See also "ECIS Advocates a Balanced European Patent System that Promotes Interoperability," ECIS Press Release (11 April 2006), accessible online at <www.ecis.eu/news/06_apr11.html>.

150 See "METI Commerce and Information Policy Bureau, Interim Report of 'Study Group on the Legal Protection of Software and Promotion of Innovation'" (Oct. 11, 2005), accessible online at <www.meti.go.jp/english/information/downloadfiles/051017LegalProtectionSoftware.pdf>.

151 *Ibid.*, at 3–4; Michael Chapin, "Sharing the Interoperability Ball on the Software Patent Playground," B.U. J. Sci. & Tech. L. 14 (2008): 220, 236–237, accessible online at <www.bu.edu/law/central/jd/organizations/journals/scitech/documents/Chapin.pdf>.

152 For a discussion, see, e.g., "Comments on the Draft of Rule Concerning Software Related Intellectual Property," Business Software Alliance Asia (Jul. 12, 2006), at 2, accessible online at <www.bsa.or.jp/file/BSA_Comments_English_060712.pdf>.

153 For an English translation and summary of the proposed rule, see Kenji Shimada et al., "Patents as Property: International Injunctive Relief," CASRIP Online Newsletter, vol. 14, Issue 3 (University of Washington School of Law, Summer 2007), accessible online at <www.law.washington.edu/Casrip/Newsletter/default.aspx?year=2007&article=newsv14i3Shimada>.

154 See Chapin, *supra* at 237.

155 See Kazuaki Okimoto, "Compulsory License on Patented Drug for H1N1 Influenza Virus," presented at Emerging Intellectual Property Rights Committee Meeting of the APAA56th Council (Nov. 10, 2009), accessible online at <www.apaaonline.org/pdf/APAA_56th_&_57th_council_meeting/emergingIP/2-Japan%20Emerging%20IP%20Rights%20Cttee%20Country%20Report%202009.pdf> (discussing the public interest grounds of Section 83 of the Japanese Patent Law).

Report on Patents and Standards and is also supported by the ECIS[156] and portrayed by it as being similar to private FRAND contractual undertakings despite the lack of an injunction relief entitlement,[157] is the "license of right"[158] provided under the British[159] and German[160] patent laws. A license of right is described as an ostensibly *voluntary* decision on the part of the patent owner to register a patent following its grant[161] with a national Patent & Trademark Office as a nonexclusive license available to all interested prospective licensees on "reasonable terms,"[162] in exchange for receiving significantly reduced registration and renewal fees.[163] Once a patent has been so registered, any prospective licensee who is interested in taking a license is effectively deemed, for purposes of the law, as possessing a "license of right," even though the terms of such a license may not have been conclusively settled. In cases where the patent owner and licensee cannot agree on reasonable terms (i.e., a reasonable arm's length royalty), UK and German laws provide that a designated national patent office official will make such determination.[164] Licensees of right are entitled to request that the patent owner legally defend the patent, or may defend the patent itself by instituting an infringement action against an unauthorized third party user or even the patent owner itself.[165] Also, if during the course of an infringement action an EU defendant elects to take a license of right under the terms demanded by the patentee, or by the licensee on behalf of the patent owner, "no injunction . . . shall be granted against him and the amount (if any) recoverable against him by way of damages shall not exceed double the amount which would have been payable by him as licensee if such a licence on those terms had been granted before the earliest infringement."[166]

While a historical review of UK patent law (the UK Patents and Designs Act of 1919) reveals that it once functioned as a compulsory licensing statute,[167] the fact that "UK courts [continue today to] look to [UK] case law deciding issues arising under the compulsory licensing provisions as persuasive for cases decided under . . . licenses of right" strongly suggests that licenses of right remain closely related to and essentially nothing more than de facto compulsory licenses in disguise.[168] And the same conclusion may be drawn with respect to the EU-wide European "Soft" Patent (ESP), otherwise known as the *European Interoperability Patent* (EIP) proposed by ECIS member IBM during 2007[169] in an effort to resurrect the license of right provision (Article 43) of the failed draft Model Community Patent Convention.[170]

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156 See "Open Letter to the European Commission," European Committee for Interoperable Systems (March 2010), accessible online at <www.ecis.eu/documents/OpenLettertotheEuropeanCommissionMarch2010.pdf>.

157 ECIS Legal Counsel Thomas Vinje recently moderated a panel entitled "Certainty of Availability and Continuity of Essential IP Rights for Licensing" at a Brussels conference convened recently by the EU Commission and the European Patent Office, wherein he was quoted as proposing the license of right mechanism as a "complement to the FRAND regime" and the inclusion of such mechanism "or something similar to it" within the EU patent regulation (e.g., so that the owner of an EU patent may choose to make a FRAND statement to the EPO). *Tensions between Intellectual Property Rights and Standardisation: Reasons and Remedies*, Agenda of Information and Communication Technologies Conference, organized by The European Commission and The European Patent Office (EPO) (Nov. 22, 2010), at <http://ec.europa.eu/enterprise/sectors/ict/files/ictpolicies/agenda_ict_workshop_new_en.pdf>. See also Press Release at <http://ec.europa.eu/enterprise/sectors/ict/files/10-08-24_announcement_of_the_event.pdf>.

158 See "Report on Patents and Standards," Standing Committee on the Law of Patents, World Intellectual Property Organization (SCP/13/2) (Feb. 18, 2009) *supra* at para. 143.

159 See UK s. 46, "Patentee's Application for Entry in Register that Licences are Available as of Right," The Patents Act 1977 (as amended), an unofficial consolidation produced by Patents Legal Section (Jan. 1, 2010), accessible online at <www.ipo.gov.uk/patentsact1977.pdf>.

160 See German Patent Law, s. 23. "Licenses of right . . . provided for under the German patent laws . . . [are] called Lizenzbereitschaft[s] . . . The provisions and incentives for applying for a Lizenzbereitschaft are very similar to those provided for under the UK law." See Tanuja V. Garde, "Supporting Innovation in Targeted Treatments: Licenses of Right to NIH-Funded Research Tools," *Michigan Telecommunications and Technology Law Review* 11 (2005): 249, 280, at <www.mttlr.org/voleleven/garde.pdf>.

161 Although a license of right under German law extends beyond the "main patent to all its patents of addition," UK law does not seem to address this issue. See German Patent Law s. 23(1). See also *Patent Additions*, IP Australia, Australian Government (2005), accessible online at <www.ipaustralia.gov.au/pdfs/patents/specific/add.pdf>; Arnold B. Silverman, "Understanding the Benefits Obtainable from 'Related' United States Patent Applications," JOM Material Matters, vol. 57, No. 9 (September 2005), accessible online at <www.tms.org/pubs/journals/JOM/matters/matters-0509.html>; David V. Radack, "Understanding 'Related' U.S. Patent Applications," JOM Material Matters vol. 56, No. 56 (June 2004), accessible online at <www.tms.org/pubs/journals/JOM/matters/matters-0406.html>.

162 See "ITSSD Comments Concerning Document SCP/13/2 Patents and Standards" (hereinafter "ITSSD Comments Concerning SCP/13/2") at 38 (March 2009), accessible online at <www.wipo.int/scp/en/meetings/session_14/studies/itssd_1.pdf>.

163 See Garde, *supra* at 279; German Patent Law, s. 23(1).

164 *Ibid.*, citing UK Patents Act 1977 ss. 46(3)(a) and 3(b); German Patent Act ss. 23(3) and (4).

165 See ITSSD Comments Concerning SCP/13/2, at 39, citing UK Patents Act 1977 ss. 46(2) and (4).

166 *Ibid.*, citing UK Patents Act 1977 s. 46(3)(c).

167 See Garde, *supra* at 279.

168 *Ibid.*, at 280–281.

169 See Duncan Bucknell, "Big Blue Proposes New Type of Patent Right," Magazine of Intellectual Property and Technology (Aug. 16, 2007), accessible online at <www.mondaq.com/australia/article.asp?articleid=51252>; "The European Community Patent – A Realisable Dream," IBM Discussion Paper (Jul. 20, 2007), at <www.ipjur.com/data/070720European-Interoperabily-Patent-1-0.pdf>.

170 See ITSSD Comments Concerning SCP/13/2, *supra* at 39–40, and accompanying footnotes.

The attractiveness of compulsory licenses to remedy patent abuses and/or anti-competitive behaviors notwithstanding, the free and open source software (FOSS) movement (represented by the Boston, Massachusetts-based Free Software Foundation,[171] its European sister organization FSFE, and the Brussels-based OpenForum Europe (OFE)[172]) have considered the compulsory licensing remedy by itself insufficient to eliminate the perceived impediments to "full interoperability" between and among the different patented ICT technologies often embedded within a single standard, whatever the term "full interoperability" means. In acknowledgment of the numerous legal and political conditions placed upon member government compulsory license usage by the WTO TRIPs Agreement,[173] the FOSS movement has promoted a different approach that endeavors to impose general public interest restrictions *a priori* on the exercise of patent rights and to minimize the economic basis underlying a patent grant. Arguably, their favored approach was systematically incorporated into the European Union's initial interoperability framework for e-Government services released during 2004 whose principles were likely relied upon by the European Commission and the European Court of First Instance thereafter in the *Microsoft* case previously discussed.

The WIPO *Report on Patents and Standards* reveals somewhat the role of the FOSS movement in defining systems interoperability as a "public interest" that should benefit commercial technology users as well as consumers, the protection of which necessitates the least costly and most universally accessible "open standards" incorporating only those ICT technologies (whether patented or not) deemed "essential" to the functioning of the standard. The report also suggests how the FOSS movement was also influential in redefining the term "open standard"—from one focused primarily on the "openness" and inclusiveness of the standard development process *and* on the prevailing FRAND/RAND ("fair, reasonable and nondiscriminatory") private contract-based pricing model[174] to one now focused on the FOSS contractual and pricing model that calls for patent-free or *unlimited* royalty-*free* patented technology usage as practiced by internet standards-setting consortia such as W3C.[175]

Implicit in the "public good" of open standards-based interoperability is the assumption that predefined and ex ante disclosed royalty-free and unlimited use patent licensing terms employed by such consortia are more compatible with FLOSS[176] licenses and less conflict-ridden[177]and legally risky,[178] and hence, more economically efficient[179] than nonbinding flexible unfixed patent royalty pricing terms that traditional SDOs[180] remain incapable of enforcing against member or non-member technology patent owners.[181] Also implicit within this concept of the public good is the assumption that the allegedly less precise and economically inefficient FRAND/RAND pricing terms adopted by traditional SDOs violate the public trust[182] and rarely result in the least cost alternative for society due to "royalty stacking" and anti-competitive contractual "tie-ins," especially in the case of procurement contracts where it was found that several EU Member State governments had fallen victim to "vendor lock-in" at taxpayer expense.[183] However, this last point begs the proverbial question, "which came first,

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171 See "What We Do," Free Software Federation website, accessible online at <www.fsf.org>.

172 See "Who We Are and What We Do," OpenForum Europe website, accessible at <www.openforumeurope.org/about/who-we-are-and-what-we-do>.

173 See discussion, *supra*.

174 For a discussion of the definition traditionally adopted by recognized national and international standards organizations such as American National Standards Institute (ANSI) and the ITU, see WIPO Report on Patents and Standards (SCP/13/2), at paras. 41–42 and accompanying footnotes.

175 *Ibid.*, at para. 43, 111–116 and accompanying footnotes; see also generally Lawrence A. Kogan, *How SMART are Standards that Sacrifice Intellectual Property Rights?*, presented at ANSI Intellectual Property Rights Policy Committee (IPRPC) Meeting (Apr. 15, 2010), accessible online at <http://itssd.org/How%20SMART%20are%20Standards%20that%20Sacrifice%20Intellectual%20Property%20Rights%20-%20Full%20Outline.doc>.

176 "FLOSS" means 'free, liberal open source software.''

177 See WIPO Report on Patents and Standards (SCP/13/2), at paras. 111 and 128.

178 See Rishab Ghosh, Reinier Bakels & Patrice-Emmanuel Schmitz, "Patents and Open Source Software: What Public Authorities Need to Know," EU IDABC Open Source Observatory (Apr. 5, 2005), Executive Summary at 2–3, accessible online at <www.osor.eu/idabc-studies/expert-docs/patents-and-open-source-software>; <http://ec.europa.eu/idabc/servlets/Doce6a8.pdf?id=28129>.

179 See Kogan, 2010, *supra*.

180 For a discussion of the patent disclosure and licensing and competition policies of well-known SDOs such as ITU, ISO, IEC, ETSI, ANSI, IEEE Standards Association, see WIPO Report on Patents and Standards (SCP/13/2), at paras. 76–110 and accompanying footnotes.

181 *Ibid.*, at paras. 117–124, 126–127.

182 See Rishab A. Ghosh, "Free/Libre/Open Source Software: An Economic Basis for Open Standards," MERIT University of Maastricht (December 2005), at 13, accessible online at <www.flosspols.org/deliverables/FLOSSPOLS-D04-openstandards-v6.pdf>.

183 See Rishab Aiyer Ghosh et al., "OSOR Guidelines: Public Procurement and Open Source Software" public draft version 1.0: 10 (October 2008), at 48–51 and 104–110, at <www.osor.eu/idabc-studies/OSS-procurement-guideline-public-draft-v1%201.pdf>; "EU Commission: Open Bids Favor Proprietary Software," Linux Magazine (Oct. 22, 2008), at <www.linuxmagazine.com/Online/News/EU-Commission-

the chicken or the egg?," considering that the national and/or provincial governments of several EU Member States had already been promoting and/or expressing preferences for open source software in government procurement bids[184] by the time these debates had unfolded (Germany (2001), Spain (2002), France (2004), and the United Kingdom (2004), with the Netherlands (2005), Denmark (2006), Belgium (2009), and Hungary (2009) to follow thereafter).[185]

Argubaly, the EU Commission had been challenged by the prospect of having to reconcile differing national government software procurement practices, by the promise of harnessing and then reshaping a regional government procurement market for the public benefit that as of 2007–2008 had already exceeded 16.3% of EU Community GDP[186] and is predicted to reach 19% of EU Community GDP by the end of 2010,[187] and by the efforts of the FOSS movement, which has drawn distinct parallels between their preferred approach concerning ICT patents and standardization and the approach adopted in the EU Software Copyright Directive.[188] In other words, it may safely be concluded that the EU Commission was *driven* to establish a FLOSS-centric ICT interoperability framework at the EU regional level for government procurement that could also influence and sustain the growing private EU technology markets[189] to the detriment of proprietary ICT developers and vendors.

Indeed, at least one EU Commission-sponsored report specifically recommended that:

> open standards for software markets should be defined in order to be compatible with FLOSS licenses . . . [that] . . . compatibility with proprietary technologies should be explicitly excluded from public procurement criteria . . . [and that] . . . open standards should be mandatory for eGovernment services and preferred for all other public procurement of software and software services (emphasis added).[190]

It would appear in hindsight that the initial version of the EIF v1.0 contained many of these underlying assumptions and recommendations.[191]

The open source community, nevertheless, remains dissatisfied with the evolving process of ICT stakeholder engagement since none of the subsequent versions of the draft EIFv2.0 ((EIF v2.0"A" (2008)),[192] (EIFv2.0"B" (2009),[193] or (EIFv2.0"C" (2010))[194]) have reflected all of these features. According to the FSFE, with each successive version of the draft EIFv2.0, the original concepts of interoperability and open standards originally championed by the FOSS movement have been steadily pared back by industry[195] so that it would be possible for EU regional and Member State government officials to continue selecting proprietary ICT standards alongside open source ICT standards in satisfying their procurement needs, a result that the FOSS

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Open-Bids-Favor-Proprietary-Software>. See also "OFE Monitoring Report: Discrimination in Public Procurement Procedures for Computer Software in the EU Member States," OpenForum Europe (October 2008), at <www.epractice.eu/files/media/media2296.pdf>; Paul Meller, "Study Finds Open Software Excluded From EU Procurement," IDG News (Oct. 22, 2008), at <www.pcworld.com/businesscenter/article/152616/study_finds_open_software_excluded_from_eu_procurement.html>; CIO Magazine (Oct. 22, 2008) at <www.cio.com/article/455912/Study_Finds_Open_Software_Excluded_From_EU_Procurement?source=home_ln>.

184 See "Supplement to ITSSD Comments Concerning the WIPO Report on Standards and Patents (SCP/13/2) Paragraph 44" (January 2010), at 4–7, and accompanying endnotes, accessible online at <www.wipo.int/scp/en/meetings/session_14/studies/itssd_supplement.pdf>.

185 *Ibid.*, at 7–10.

186 See Patrick Van Eecke, Paulo Pinto Fonseca & Tineke Egyedi, "EU Study on the Specific Policy Needs for ICT Standardization," prepared for the European Commission (July 2007) (hereinafter "DLA Piper Study"), at 107, at <http://ec.europa.eu/enterprise/ict/policy/standards/piper/full_report.pdf>.

187 See Kevin J. O'Brien, "Technology Rivals Lobby to Break Microsoft's Hold," *New York Times* (Jul. 18, 2010), accessible online at <www.nytimes.com/2010/07/19/technology/19iht-eusoftwar19.html?_r=1>.

188 See Van Eecke, Fonseca & Egyedi, *supra* at 109.

189 See "EU White Paper: Modernising ICT Standardisation in the EU – The Way Forward (7/3/09)," at 2, accessible online at <http://ec.europa.eu/enterprise/ict/policy/standards/whitepaper.pdf>.

190 See Ghosh, *supra,* at Executive Summary 3 and 21.

191 For example, EIFv.1.0 defined the term "open standard" as one where (i) "the specification document [is] available either freely or at a nominal charge . . . [and] . . . all [are able] to copy, distribute and use it for no fee or at a nominal fee"; (ii) "the patents possibly present [in the standard or part of it are] made irrevocably available on a royalty free basis"; and (iii) the standard may be reused without any constraints.'' See EIFv.1.0 Brochure, *supra* at 9; EIFv.1.0, *supra* at 8.

192 See European Interoperabiliity Framework for Pan-European eGovernment Services, Draft for Public Comments – As Basis for EIF 2.0, European Communities (Jul. 15, 2008).

193 See "European Interoperability Framework for European Public Services (EIF) Version 2.0," European Commission Unofficial Leaked Draft (November 2009), accessible online at <http://blog.webwereld.nl/wp-content/uploads/2009/11/European-Interoperability-Framework-for-European-Public-Services-draft.pdf>; see "Supplement to ITSSD Comments Concerning the WIPO Report on Standards and Patents (SCP/13/2) Paragraph 44," *supra* at 14–15 and accompanying endnotes.

194 This version of draft EIFv2.0 is unpublished at the current time.

195 See "Open Standards – EIFv2: Tracking the Loss of Interoperability," Free Software Foundation Europe website accessible online at <http://fsfe.org/projects/os/eifv2.en.html#>.

movement finds completely unacceptable.[196] For example, after comparing the changes contained within each of the versions of the draft EIFv2.0, the OFE accused the EU Commission of having been unduly influenced by industry "outside of the democratic and transparent processes that bind the European institutions . . . to maintain past practice" and insisted that the EU Commission reinstate the first draft of EIFv2.0.[197]

Irrespective of whether these allegations were true, they were largely premised on the EU Commission recommendation contained within EIFv1.0 that "EU Member States . . . *keep administrative systems independent of proprietary technology*" when "implementing a national interoperability framework."[198] In other words, these stakeholders had continued to endeavor to influence the European Commission so long as it remained possible for the 'open standards' definition in Section 5.2.1 of EIFv.1.0 to be incorporated within a final EIFv.2.0, such that government procurement officials could conceivably preclude the implementation of a technical specification in *proprietary* software, whether or not royalty-based, and whether or not otherwise functionally 'interoperable' with open source software and/or compatible with FLOSS licensing terms.

Judging from the final EIF the European Commission released on December 16, 2010,[199] however, it would be difficult for these groups to claim that their efforts were successful. First, the new EU EIF eliminates all references to the term "open standards" and in its place employs the term "formalized specifications." This change in terminology is significant considering that in Europe only technical specifications approved by a recognized standardization body can qualify as "standards." Consequently, the term 'formalized specification' was selected to cover *both* the proprietary specifications developed mostly by recognized standardization bodies and the non-proprietary specifications developed mostly by informal ICT consortia and fora.[200] Second, the new EU EIF eliminates the requirement in EIFv.1.0 that in order to be "open" a standard specification must be "made irrevocably available on a royalty-free basis." Instead, the new EU EIF adopts a more logical, equitable and economically reasonable approach to interoperability that recognizes how the public interest is best served when government procurement officials prefer 'open specifications'. It achieves this objective by viewing technical standard specifications as falling along a continuum of "openness." "Full openness," where available, requires public administrations to grant all stakeholders the same possibility of contributing to the development of a standard specification relating to a software component(s).[201] "Full openness," where available, also requires that any intellectual property rights associated with such specification are licensable on fair, reasonable and non-discriminatory (FRAND) *or* royalty-free terms that permit the specification's implementation in both proprietary and open source software. "In this way, companies working under various business models can compete on an equal footing when providing solutions to public administrations while administrations that implement the standard in their own software (software that they own) can share such software with others under an open source licence if they so decide."[202] And, where "fully open" specifications are either unavailable (because they are not yet mature or are unsupported by the market) or are incapable of satisfying functional interoperability needs, government agencies could seek less open specifications.[203] Although the new EU EIF "is not subject to the approval of the European Parliament or member states" it is expected that Member States and the Commission will act together to implement it,

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196 See "Protests Against Proposed Redefinition of Open Standards Within the EU," The Open H Blog (Nov. 10, 2009), at <www.h-online.com/open/news/item/Protests-against-proposed-redefinition-of-open-standards-within-the-EU-854651.html>, citing FSFE's letter to EU Member States, "Karsten on Free Software blog" (Nov. 6, 2009), accessible online at <http://blogs.fsfe.org/gerloff/?p=285>.

197 See "OFE Letter of complaint re EIF v. 2.0 2009-02-22" (Mar. 22, 2010), OFE Press Releases, OFE website, accessible online at <www.openforumeurope.org/press-room/press-releases>.

198 See EIFv.1.0 Brochure, *supra* at 26.

199 *See European Interoperability Framework (EIF) for European Public Services*, Annex 2 to the Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of Regions 'Towards interoperability for European public services', COM(2010) 744 final (12/16/10) at <http://ec.europa.eu/isa/strategy/doc/110113__iop_communication_annex_eif.pdf>.

200 See *Commission Adopts Interoperability Strategy and Framework for Public Services—Frequently Asked Questions*, Europa RAPID Press Release, MEMO/10/689 (12/16/10) at <http://europa.eu/rapid/pressReleasesAction.do?reference=MEMO/10/689&form>.

201 Section 5.2.1 of *European Interoperability Framework (EIF) for European Public Services*, Annex 2 to the Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of Regions 'Towards interoperability for European public services', COM(2010), *supra*, at 26.

202 *See Commission Adopts Interoperability Strategy and Framework for Public Services—Frequently Asked Questions*, Europa RAPID Press Release, MEMO/10/689, *supra*.

203 Section 5.2.1 of *European Interoperability Framework (EIF) for European Public Services*, Annex 2 to the Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of Regions "Towards interoperability for European public services," COM(2010), *supra*. "Recommendation 22. When establishing European public services, public administrations should prefer open specifications, taking due account of the coverage of functional needs, maturity and market support." *Ibid*.

notwithstanding the potential for Member State and interest group arbitrage and gamesmanship to enter into the political equation.[204]

In any event, the ongoing debate that led to the several redrafts of the EIFv2.0 clearly reflected the economic and legal significance of the lobbying battle in which these competing domestic and international industry and civil society interest groups[205] had long been engaged to. To this end, it must be remembered that the results of these stakeholders' efforts to shape future European ICT interoperability standards will likely transcend the internet to include also the broadband,[206] health,[207] energy,[208] and transport[209] sectors.[210] Consequently, the EU Commission's continued inability to reconcile these various EIF drafts to the satisfaction of all concerned parties substantially increases the regulatory risks that proprietary technology industry stakeholders and their investors must bear and the legal and economic uncertainties those risks engender.

What appears to have been ignored or forgotten in the heat of this debate, however, is the likely required interface of software with technologies developed by and used within other industry sectors and the probability that any enacted ICT government procurement preference for universally accessible and disclosed nonproprietary and/or royalty-free ICT technologies, *especially* in BRIC and developing nations, will implicate related trade secret-protected knowledge and information as well.[211] Trade secret-protected information and know-how needed to implement patented inventions often accompany patents and are chosen by entrepreneurs as an alternate form of economic assurance despite the inherent inconsistencies between patents and trade secrets.[212]

Perhaps the EU Commission finally recognized that it could not simply ignore that legal practitioners frequently advise their clients to seek patent protection for an invention and trade secret protection for related information.[213] In fact, given the increasing

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204 *Ibid.*, at ss. 1.5.2; 2.2; 3.2.2.1; 4.2-4.3; and 4.5. See also *Towards Interoperability for European Public Services*, European Commission Press (17.12.2010) at <www.balkans.com/open-news.php?uniquenumber=85145>; David Meyer, *Europe Backs Open Standards in Interoperability Drive*, ZDNet (12/16/10) at <www.zdnet.co.uk/blogs/communication-breakdown-10000030/europe-backs-open-standards-in-interoperability-drive-10021324/>.

205 See O'Brien, *supra*.

206 See "A Digital Agenda for Europe," Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions COM(2010) 245 final/2 (Aug. 26, 2010), accessible online at <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2010:0245:FIN:EN:PDF>.

207 See Flora Giorgio-Gerlach, "European Commission Strategy for European eHealth Interoperability," DG Information Society and Media, ICT for Health, European Commission (October 2008), accessible online at <www.calliope-network.eu/Portals/11/assets/documents/Crete_Presentations/CAL%202008-10-09%20s11%20Giorgio%20%20EC%20Strategy%20Interoperability.pdf>; "e-Health-Making Healthcare Better for European Citizens: An Action Plan for a European e-Health Area," Communication from the Commission to the Council, the European Parliament, the European Economic and Social Committee, and the Committee of the Regions, COM(2004) 356 final (4/30/04) at 16–17, accessible online at <http://eurlex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2004:0356:FIN:EN:PDF> (discussing the development of *common interoperability approaches and standards* for patient identifiers, medical data messaging, [and] electronic health records, "based on adoption of Open Source reference implementations for care services . . . [and] . . . open and more free access to future and existing e-Health standards . . . taking inspiration from models such as the World Wide Web Consortium").

208 See "ICT for a Low Carbon Economy. Smart Electricity Distribution Networks," European Communities (July 2009), accessible online at <http://ec.europa.eu/information_society/activities/sustainable_growth/docs/sb_publications/pub_smart_edn_web.pdf> (summarizing "the role of the ICT sector in smart grids"). See also "Functionalities of Smart Grids and Smart Meters," Expert Group 1, EU Commission Task Force for Smart Grids Draft Report (Jun. 22, 2010), accessible online at <http://ec.europa.eu/energy/gas_electricity/smartgrids/doc/expert_group1.pdf> (discussing Mandate M/44 by the Commission to the European Standardization Organisations (ESOs) "To create European standards that will enable interoperability of utility meters (water, gas, electricity, heat) which can then improve the means by which customers' awareness of actual consumption can be raised in order to allow timely adaptation in their demands").

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210 See "Accompanying the Communication on 'A Single Market for 21st Century Europe' – Services of General Interest, Including Social Services of General Interest: A New European Commitment," Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions COM(2007) 725 final (Nov. 20, 2007) at 3–4, 7–10, accessible online at <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2007:0725:FIN:EN:PDF>.

211 See "Can Government Intervention Sustain Economic Incentive, Technological Innovation, and Capital Flows?," Précis Of ITSSD WIPO Side-Bar Event, Institute for Trade, Standards and Sustainable Development (Oct. 12, 2010), Moderator's Comments at 12, accessible online at <www.itssd.org/ITSSD%20WIPO%20SCP%20Side-bar%20Geneva%2010-12-10%20Precis%20Final.pdf>.

212 "[S]ince patent protection depends on publishing the invention to the world and trade secret protection depends on keeping the matter secret, consideration should be given to protecting the same invention by both methods." See Peter J. Toren, "Protecting Inventions as Trade Secrets: A Better Way When Patents Are Inappropriate, Unavailable," Sidley Austin, LLP (May 2000), accessible online at <http://library.findlaw.com/2000/May/1/130451.html>. See also Karl F. Jorda, "Patent and Trade Secret Complementariness: An Unsuspected Synergy," *Washburn Law Journal* 48, 1, accessible online at <www.washburnlaw.edu/wlj/48-1/articles/jorda-karl.pdf ("What I have practiced in my career, and what I endorse as the best policy and practice, is to obtain patents as the centerpiece in an intellectual property portfolio and maintain trade secrets as underpinnings for patents to protect unpatentable collateral know-how and show-how.").

213 *Ibid.*

"difficult[y] for e-commerce companies to come up with inventions that are truly novel and non-obvious as required by the Patent Act," such scrupulously undisclosed "information and know-how may be a company's most valuable asset . . . [and] . . . for many Internet companies it may be their *only* asset" (emphasis added).[214] Indeed, as the vaunted Berkeley Patent Study, which focuses heavily on software firms,[215] reveals, two of the key reasons why startup firms often decide against patent protection, aside from the "high costs associated with prosecuting and enforcing [a] patent," are a "fear of disclosure," that is, startups do not want "to disclose information" in a patent capable of being reverse engineered, and the "belie[f] that trade secret was adequate protection."[216] The study, in fact, shows that "the reluctance to disclose information appears to be more of a deterrent for large firms than for . . . early-stage" firms.[217] And, perhaps the EU Commission finally recognized that it could not simply ignore that public "Corporations, through their boards and management, are duty bound to take informed action to protect the company's assets . . . [and that] . . . individual directors and officers can also be liable [to shareholders] for failing to monitor the companies activities to ensure compliance with the [corporate governance aspects of common and statutory] law. Where trade secrets are concerned . . . management [has a duty] . . . to conserve the corporation's property from loss through theft or dissipation [through] . . . control of information leaving the organization . . . This involves . . . keeping close track of the company's secrets."[218] Ultimately, it is possible that the EU Commission came to understand that had it incorporated the "open standards" definition established by EIFv1.0 which expressed a preference for *non*proprietary and/or royalty-*free* ICT technologies within its recently issued final EIF, it would have unwittingly eliminated the trade secret option for and trade secret assets of many startup and large software firms, thereby contributing to an even greater future economic and legal risk scenario.

Furthermore, the European Commission has seemingly ignored the potential impact that any decision to adopt EIFv1.0's preference for *nonproprietary and/or royalty-free* ICT technologies would have upon third country government law and policy formulation, considering that it has already managed to encourage similar adventurism within the Obama administration to reshape the US healthcare and energy sectors. For example, at the insistence of these same, related and/or other similar-minded interest groups and industry stakeholders,[219] the Obama administration, like the EU Commission, (1) has enacted legislative and administrative royalty and license-free government procurement open standards criteria to ensure software interoperability of electronic health records[220] ("the standard to govern the transmission and interoperability of medical data between healthcare facilities and insurers, doctors, pharmacies and the wider healthcare establishment")[221] and proposed similar new administrative rules implementing recently enacted law to ensure interoperability of electronic medical records[222] ("the data standard for formatting cradle-to-grave patient medical history information"[223]); (2) is in the process of developing royalty and/or proprietary-free government procurement open standards criteria to ensure software interoperability of evolving smart energy grid technologies and avoid vendor lock-in, which, in each case, as in Europe, favors the user and consumer rather than the innovator and investor viewpoint;[224] and (3) has misguidedly ignored industry stakeholder claims that the adoption of such

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214 *Ibid.*

215 See Stuart J.H. Graham et al., "High Technology Entrepreneurs and the Patent System: Results of the 2008 Berkeley Patent Survey," *Berkeley Technology Law Journal* 24 (2010): 1255, 1312, accessible online at <www.btlj.org/data/articles/24_feature.pdf>.

216 *Ibid.*, at 1309–1310.

217 *Ibid.*, at 1312.

218 *See* James Pooley & Katherine Nolan-Stevaux, *Trade Secrets and Corporate Governance: Best Practices*, Intellectual Property Owners Association (IPO) Articles & Reps., Trade Secrets Sec., No. 5 (2005) at 1–2, at <www.ipo.org/AM/Template.cfm?Section=Home&Template=/CM/ContentDisplay.cfm&ContentID=22924>; <www.ipo.org/AM/Template.cfm?Section=Trade_Secrets&Template=/CM/ContentDisplay.cfm&ContentID=1572>.

219 These stakeholders include individuals and organizations, among them, the NGO Open Source America inclusive of its industry members, IBM-sponsored Yale Information Society Project, the Computer and Communications Industry Association, The National Energy Marketers Association, The Standards Consortia OASIS, The Independent System Operator (ISO)/Regional Transmission Organization (RTO) Council, Intelligent Energy, and certain individuals with ex officio or professional credentials. See "Supplement to ITSSD Comments Concerning the WIPO Report on Standards and Patents (SCP/13/2) Paragraph 44," at 20–26 and accompanying endnotes; Kogan, 2010, *supra*.

220 *Ibid.*

221 See Ken Zita, "China Healthcare ICT: Reinventing China's National Healthcare System Through Electronic Medical Records, Telecom Networks and Advanced IT Services," *Journal of Emerging Knowledge on Emerging Markets*, vol. 1, Issue 1 (November 2009), at 52, accessible online at <www.icainstitute.org/ojs/index.php/working_papers/article/viewFile/13/8>.

222 See "Proposed Rule for Medicaid; Federal Funding for Medicaid Eligibility Determination and Enrollment Activities," 75 FR 68583, 42 CFR 433 (Nov. 8, 2010), accessible online at <www.gpo.gov/fdsys/pkg/FR-2010-11-08/pdf/2010-27971.pdf>.

223 See Zita, *supra*.

224 See "Supplement to ITSSD Comments Concerning the WIPO Report on Standards and Patents (SCP/13/2) Paragraph 44," at 20–26 and accompanying endnotes; Kogan, 2010, *supra*.

policies will negatively influence standards development and law and policy formulation in China.[225] Indeed, the EU ICT interoperability debate has also influenced patent and technology law and standardization efforts[226] within several BRIC nations—Brazil, China and India—and not for the better.

3.2.1. Brazil

Since 2005, the Government of Brazil has published an evolving set of interoperability standards for electronic government known as the e-PING program, which "address technical, semantic, and organizational issues, as well promote open standards and public or free software."[227] It covers (federal) government-to-government, federal government-to-state government, federal government-to-citizen, federal government-to-business, and federal government-to-foreign government information exchanges. The most recent version of e-Ping was released during December 2009 ("Version 2010").[228]

E-ping standards and policies are mandatory for all federal government agencies[229] and apply to all new and legacy systems.[230] As a matter of general policy, government agencies are to prioritize the adoption of "open standards" meeting technical specifications wherever possible. In the absence of open standards, *proprietary standards will be accepted, but only on a temporary interim basis* until an open standard replacement can be secured.[231] In addition, consistent with the general policy, *government agencies must prioritize the use of public software and/or free software* in the implementation of interoperability standards.[232] For purposes of implementing such policy, "free software" has been defined as source code available for anyone to use, copy, and distribute in its original or modified form either free or at cost and "is necessarily nonproprietary."[233] And an "open standard" is one that (1) "enables the interoperability between several applications and platforms, internal and external"; (2) "enables application *without any restriction or fee payment*"; and (3) is capable of being "fully and independently implemented by multiple suppliers of computer programs, in multiple platforms, with *no charge relating to intellectual property* for the necessary technology".[234] Accordingly at least one Brazilian commentator has opined that the e-Ping definition of "open standard" is that contained within EIFv1.0.[235]

3.2.2. China

On November 2, 2009, the Standardization Administration of the People's Republic of China (SAC) released proposed standardization interoperability rules[236] governing the disposition of patents involved in the development or revision of both compulsory[237] and voluntary[238] national standards.[239] If adopted, these rules would treat patented technologies even more harshly than would EIFv1.0.

Pursuant to the proposed rules, only patented technology that is "essential" to the implementation of a

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225 See Karsten Gerloff, Carlo Piana & Sam Tuke, "Defending Open Standards: FSFE Refutes BSA's False Claims to European Commission," Free Software Foundation Europe (Oct. 15, 2010), accessible online at <www.fsfe.org/projects/os/bsa-letter-analysis.en.html>.

226 See, e.g., "Intellectual Property Right (IPR) Issues in Standardization," Background paper for Chinese Submission to WTO on Intellectual Property Right Issues in Standardization, Communication from the People's Republic of China Addendum (G/TBT/W/251) (Nov. 9, 2006), accessible online at <http://chinawto.mofcom.gov.cn/accessory/200702/1171346578955.doc>.

227 See "Report on the Global Meeting on Government Interoperability Frameworks 2010" (May 4–6, 2010), at 3 and 8, accessible online at <www.gif4dev.net/wp-content/uploads/2010/05/Report-on-the-Global-Meeting-on-Government-Interoperability-Frameworks-2010-PDF.pdf>.

228 See "e-PING Electronic Government Interoperability Standards, Reference Document Version 2010," Brazilian Government Executive Committee of the Electronic Government (Dec. 11, 2009), at 7, accessible online at <www.governoeletronico.gov.br/anexos/e-ping-versao-2010>.

229 *Ibid.*

230 *Ibid.*, at 8.

231 *Ibid.* at s. 3.1.

232 *Ibid.*, at s. 3.2.

233 *Ibid.*, at Glossary of Acronyms and Technical Terms, at 51.

234 *Ibid.*, at 50 (emphasis added).

235 See Jomar Silva, "Standards and the Control of Communication," in *Citizenship and Digital Networks*, Brazilian Internet Steering Committee CGI.br, ed. Sergio Amadeu da Silveira (2010), at 238 and fn. 4, accessible online at <www.cidadaniaeredesdigitais.com.br/_files/011jomar_ing.pdf>.

236 See "Regulations for the Administration of the Formulation and Revision of Patent-Involving National Standards (Interim) (Exposure Draft)," Standardization Administration of China (Nov. 2, 2009) (hereinafter "SAC Interim Draft"), accessible online at <www.ipprospective.com/wp-content/uploads/2009/11/091118chinastandard_e1.pdf> and <www.giprs.org/node/575>.

237 "National standards . . . for safeguarding human health[] and ensuring the safety of the person and of property and those for compulsory execution as prescribed by the laws and administrative rules and regulations *shall be compulsory standards*, the others shall be voluntary standards" (emphasis added). See Art. 7, "Standardization Law of the People's Republic of China" (4/1/89), accessible online at <www.sac.gov.cn/templet/english/ShowArticle.jsp?id=2325>.

238 *Ibid.*

239 See Art. 2, SAC Interim Draft.

voluntary national standard may be incorporated into its development.[240] Once deemed "essential," a patented technology may be included in a voluntary national standard only if the patentee chooses to "license on a *free-of-charge*, reasonable and nondiscriminatory basis" *or* "on a reasonable and nondiscriminatory basis . . . *at a price significantly lower than the normal royalties.*"[241] A patentee's refusal to enter into a license at all will deny the patent inclusion within such a standard.[242] In addition, the failure by any patentee or affiliate involved in the drafting of a voluntary national standard to "promptly" disclose the existence of a technology patent[243] will result in the deemed free licensure of the patented technology and will trigger legal liability in the event that ''such disclosure failure is [subsequently] found to be a "purposeful concealment"[244] (i.e., an act of concealment that "bring[s] losses to the setting and implementation of national standards.")[245]

In general, a "compulsory national standard" compliance with which is mandatory[246] shall not involve any patents.[247] However, where "a compulsory national standard needs to involve a patent the patentee shall grant a license free of charge [i.e., royalty-free]" or shall enter into licensing negotiations with the appropriate administrative authorities.[248] If the patentee and the authorities fail to enter into a mutually agreeable licensing arrangement, the compulsory national standard's release will be temporarily withheld or the patent will fall subject to a compulsory license by force of law.[249]

The recently released results of the U.S. International Trade Commission investigation of China's intellectual property laws, policies, and practices clearly reflects USTR's view that the practices called for by the SAC Interim Draft discussed above are "in conflict with those followed by standards developing organizations in other countries, where reasonable and nondiscriminatory (RAND) licensing policies are incorporated into the standards."[250] When combined with China's national "indigenous innovation" policy, the purpose of which is to promote "the development of technological innovation in domestic firms, eventually leading to the ownership of their own core IP rights,"[251] it is clear that the proposed Chinese standardization interoperability rules would have had a severe impact on developed country renewable/alternative energy companies, especially considering that most manufacturing of solar panels windmills, hybrid auto batteries, and compact fluorescent light bulbs occurs in China.[252]

Pursuant to and in implementation of Art. 17 of the SAC Interim Draft, the General Administration of Quality Supervision, Inspection and Quarantine, and the Standardization Administration of the People's Republic of China jointly issued during January 2010 draft *Disposal Rules for the Inclusion of Patents in National Standards*.[253] Although these rules apply directly to the formulation/revision of public national standards, they may be referred to within and thereby apply indirectly to private industry standards and local standards under formulation/revision.[254] Unlike the SAC Interim Draft, the Disposal Rules require disclosure of not only published and issued patents, but also of published patents awaiting examination and non-published patents (patents pending) during the national standard formulation and revision phases.[255] The sample disclosure form accompanying

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240 See Art. 3, SAC Interim Draft.
241 See Art. 9(1)–(2), SAC Interim Draft.
242 See Art. 9(3), SAC Interim Draft.
243 See Art. 5, SAC Interim Draft.
244 See Art. 8, SAC Interim Draft.
245 See Zhong Yi, Ni Jia & Liu Jiayin, "The Comparison and Commentaries on Version 2009 and 2004 of Regulations on National Standard Involving Patent (Interim)," Global IPRs Research Center (Nov. 21, 2009), accessible online at <www.giprs.org/node/577>.
246 See Art. 14, Standardization Law of the People's Republic of China, *supra*.
247 See Art. 12, SAC Interim Draft.
248 See Art. 13, SAC Interim Draft.
249 *Ibid.*
250 *China: Intellectual Property Infringement, Indigenous Innovation Policies, and Frameworks for Measuring the Effects on the U.S. Economy*, United States International Trade Commission Investigation No. 332–514 USITC Publ. 4199 (Nov. 2010), at 5–19, at <www.usitc.gov/publications/332/pub4199.pdf>.
251 See Peng Heyue, "China's Indigenous Innovation Policy and its Effect on Foreign Intellectual Property Rights Holders," China Law Insight, King (Sep. 9, 2010), accessible online at <www.chinalawinsight.com/2010/09/articles/intellectual-property/chinas-indigenous-innovation-policy-and-its-effect-on-foreign-intellectual-property-rights-holders/>.
252 See Ebinger & Avasarala, *supra* at 30.
253 *See Disposal Rules for the Inclusion of Patents in National Standards*, General Administration of Quality Supervision, Inspection and Quarantine, and the Standardization Administration of the People's Republic of China, Draft for Comments (1/21/10) (English version) (hereinafter referred to as the "Disposal Rules") referenced in *CNIS is Soliciting the Public Comments about the Draft Disposal Rules for the Inclusion*, Quality Brands Protection Committee, China Association of Enterprises With Foreign Investment website (February 2010) at <www.qbpc.org.cn/Activities/Upcoming_Events/2010-02/24_968.html>.
254 See Art. 1, Disposal Rules.
255 See Arts. 4.1.1 and 4.1.2, Disposal Rules.

the Disposal Rules requires at least a summary description of the technology relating to the known or pending patent(s) and a description of those features within the specific technical standard in question that relate to such patent(s).[256] According to at least one legal commentator the interests of holders of pending patents will be placed at risk since the rules fail to provide any assurance of confidentiality prior to patent publication.[257]

As concerns the licensing of essential patents,[258] the Disposal Rules provide patent holders with the same three options as does the SAC Interim Draft, namely: (1) a royalty-free license on reasonable and nondiscriminatory terms (RF-RAND); (2) a royalty fee-based license on reasonable and nondiscriminatory terms (RAND); or no license at all.[259] However, a royalty-based license issued under option 2 of the Disposal Rules need not be "at a price significantly lower than the normal royalties" as required by the SAC Interim Draft. In addition, where a patent holder refuses to license a patented technology both regimes require its exclusion from the national standard.[260] However, unlike the SAC Interim Draft, the Disposal Rules do not impose a penalty on a patentee for nondisclosure of an essential patent or for failing to negotiate a mutually agreeable licensing arrangement with the authorities, which may be attributable to their process/procedural rather than substantive nature.[261]

At least one legal commentator has emphasized that the ministerial nature of the SAC Interim Draft and the Disposal Rules precludes the imposition against private entities or individuals of obligations and/or penalties not otherwise prescribed by law that is, enacted by the legislature—the People's Congress or its standing committee—or by a State administrative regulation. Consequently, in the absence of a compulsory licensing law or administrative regulation, the implied compulsory license imposed by the SAC Interim Draft would not be binding upon private entities or individuals.[262] Nevertheless, this would not preclude the State Intellectual Property Office (SIPO) from "us[ing] the Interim Regulations Draft as a reference point in deciding whether to issue a compulsory license, because it is authorized to issue compulsory licenses *in the public interest*."

3.2.3. India

On November 12, 2010, the Indian Government finalized its national policy on open standards for e-Governance 2010,[263] ending approximately three years of debate[264] and amid concern that "Europe's equivalent European Interoperability Framework has been hijacked by rights holders."[265] The policy's purpose is to "provide a set of guidelines for identifying . . . Open Standards for the consistent, standardized and reliable implementation of e-Governance solutions . . . [in order] to facilitate interoperability between systems developed by multiple agencies . . . promote[] technology choice, and avoid[] vendor lock-in."[266] The policy applies "at [the] interface and data archival level[s] of all systems used for e-Governance . . . [and] . . . is applicable to all prospective eGovernance systems including businesses (G2G [government-to-government], G2B [government-to-business], G2E [government-to-employee] and G2C [government-to-citizen])."[267] And owners of "legacy systems" will be responsible for ensuring that the interfaces ("bridges") between legacy and existing systems and between new versions of legacy and existing systems adhere to the mandatory characteristics of open standards,[268] that is, that they are interoperable.[269]

In fulfillment of these policy objectives, the Indian Government will adopt a single *royalty-free* "open standard" for each specific purpose within a given domain that meets six mandatory characteristics.[270] Two of these characteristics incorporate the key goals of the FOSS movement whose efforts were assisted by the media, the academic community, civil society pressure

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256 See Art. 4.1.2, Disposal Rules and Form A.1 Patent Information Disclosure Form, Appendix A, accompanying Disposal Rules.
257 See Freshfields Bruckhaus Deringer LLP, *Patents and Standard-Setting in China* (March 2010), at 2, at <www.freshfields.com/publications/pdfs/2010/Mar10/27730.pdf>.
258 See Art. 3.1, Disposal Rules.
259 See Arts. 4.3.2(a)–(c), 3.2–3.3, Disposal Rules and Form A.3 Patent License Statement Form, Appendix A accompanying Disposal Rules.
260 See Art. 5.3.5, Disposal Rules.
261 See *Patents and Standard-Setting in China, supra* at 2.
262 *Ibid.*, at 1.
263 See "Policy on Open Standards for e-Governance," Government of India Ministry of Communications & Information Technology Department of Information Technology (Nov. 12, 2010), accessible online at <http://egovstandards.gov.in/>.
264 See Michael Tiemann, "Indian Open Standards Policy for e-Governance Finalized," Open Source Initiative blog (Nov. 12, 2010), <www.opensource.org/node/551>.
265 See Mark Ballard, "India Mandates Open IT Standards as Fears Grow Over EU Policy," ComputerWeekly.com (Nov. 19, 2010), accessible online at <www.computerweekly.com/Articles/2010/11/19/244014/India-mandates-open-IT-standards-as-fears-grow-over-EU.htm>.
266 See Policy on Open Standards for e-Governance, *supra* at Preamble 2nd para. and s. 1.
267 *Ibid.*, at ss. 3.1–3.2.
268 *Ibid.*, at s. 3.3.
269 See Deep Kurup, "A Radical Shift in e-Governance," *The Hindu* (Nov. 24, 2010), accessible online at <www.thehindu.com/todays-paper/tp-features/tp-opportunities/article908199.ece>.
270 *Ibid.*, at s. 4.

groups, and a number of government agencies[271]: (1) "The Patent claims necessary to implement the Identified Standard shall be made available on a Royalty-Free basis for the life time of the Standard"[272] and (2) "[The] Identified Standard shall be recursively open[273] as far as possible."[274] However, contrary to the FOSS movement's desire to exclude proprietary technologies from the definition of an "open standard," the Indian Government policy provides that a "standard with patents can be considered as [an] Open standard if [it] adheres to [the] mandatory characteristics of the Policy."[275] In the event that an open standard fails to meet all of the mandatory characteristics, the policy allows for the temporary adoption of an interim standard that progressively relaxes the mandatory characteristics in a prescribed order "until the standard becomes eligible."[276] For example, the life time royalty-free characteristic is the first that must be relaxed to allow for the consideration of standards with FRAND and RAND terms bearing NO royalty payment.[277] If royalty-free FRAND or RAND standards are unavailable, then a royalty-based FRAND or RAND standard may be considered.[278] In setting forth a definition of a royalty-free standard, the policy document brings these distinctions in terms to light by emphasizing the nonmonetary consideration aspects of the underlying license.[279] With the adoption of this policy, India has joined Brazil in becoming the second country in the developing world to mandate "open" royalty-free, and effectively proprietary-free standards in e-Governance.[280]

4. Conclusion

Based on this brief Tour D'Horizon, it is clear that growing OECD nation industry concerns are justified that national and regional governments in both emerging and developing countries are actively pursuing, on predominantly "public interest" and "black economy" job creation grounds, regulatory agendas originally conceived but later dismissed by European regulators to advance the "public interest" that are actually undermining economically valuable private patents and trade secrets. As a result, unless such companies endeavor to mitigate these risks through available public and/or private means, these investors may ultimately decide to modify their investment strategies such that capital funds previously committed and/or new capital funds necessary to enable small and medium-sized entrepreneurs (SMEs) and multinational innovators to conduct basic R&D and undertake technology critical commercialization efforts will be diminished or prematurely withdrawn and diverted to less risky and innovative ventures.

4.1. Public Law Opportunities to Mitigate Such Risks

The international trade agreements that fall under the auspices of the WTO acknowledge that proposed or enacted regulatory changes in one country can and often do affect the investment, trade, and regulatory landscapes in another and aim to prevent one member country's laws and regulations from creating *non-tariff*-related trade and investment barriers that impede the flow of goods and/or services offered for sale and/or sold by the citizens of another. Implicit in this recognition is an unspoken appreciation for the economic and legal uncertainties and the associated market risks that such measures may engender. Consequently, consistent with the mutual concessions made by each WTO Member State at the Uruguay Round of trade negotiations, WTO Member State governments are obliged as a matter of due process and transparency to consider other WTO Members' economic interests and to notify them promptly *before enactment* of proposed legislative and/or regulatory measures that could potentially affect the property and due process rights of citizens engaged in the international trade of goods and services.[281] This

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271 See Venkatesh Hariharan, "Open Standards Policy in India: A Long, But Successful Journey," OpenSource.com (Nov. 19, 2010), accessible online at <http://opensource.com/government/10/11/open-standards-policy-india-long-successful-journey>.

272 *Ibid.*, at s. 4.1.2.

273 "The mandatory characteristics are applicable recursively to the normative references of the Identified Standard i.e. standards which are essential for the implementation of the Standard of a particular version of the Standard." *Ibid.*, at A-II-9, Annexure – II Frequently Asked Questions (FAQs).

274 See Policy on Open Standards for e-Governance, *supra* at s. 4.1.4.

275 *Ibid.*, at A-II-3, Annexure – II Frequently Asked Questions (FAQs).

276 *Ibid.*, at s. 4.3.

277 *Ibid.*, at s. 4.3(a).

278 *Ibid.*, at s. 4.3(c).

279 *Ibid.*, at Annexure – I, "Royalty-Free (RF)."

280 See Kurup, *supra*.

281 See Art. 12.4 (relating to *Administration*) of the Sanitary and Phytosanitary (SPS) Agreement and accompanying Annex B (relating to *Transparency Of Sanitary And Phytosanitary Regulations*; Arts. 2.9 (relating to *Preparation, Adoption and Application of Technical Regulations by Central Government Bodies*), 3.2 (relating to *Preparation, Adoption and Application of Technical Regulations by Local Government Bodies and Non-Governmental Bodies*), and 10 (*Information About Technical Regulations, Standards and Conformity Assessment Procedures*) of the Technical Barriers to Trade (TBT) Agreement.

obligation applies as well to WTO Member State laws and regulations that may possibly impair the exploitation by WTO Member citizens of validly held IP (patent and trade secret) rights and trade in high technology goods in which such IP rights are embedded,[282] in addition to WTO Member State laws and regulations that may "condition the approval of [IP-related] foreign investments on compliance with laws, policies or administrative regulations that favor domestic [technology-based] products" for the direct or indirect purpose of achieving industrial and economic development policy goals.[283] Furthermore, the obligations to ensure "national treatment" and transparency and to prevent "like" product discrimination or the creation of disguised restrictions on international trade also extend to the regulatory promulgations of a number of central and sub-central government entities seeking to procure high technology products and related services beyond certain thresholds.[284]

Arguably, the inquiry and analysis that national and/or regional governments and policymakers should undertake in each market (within developed *and* developing countries) to ascertain the presence and degree of regulatory and policy risk and its impact on foreign as well as domestic high technology innovation and investment should be the same, entailing a broad examination of the domestic *purposes* and the domestic and cross-border *effects* of the particular measure(s) in question. Did economic or civil society interests derive a direct or indirect benefit from the enactment, repeal, or maintenance of a given regulation(s) (e.g., compulsory licensing) or the adoption of ostensibly private standards? Did this occur as the result of particular constituencies' "home court" advantage? Did this occur at the expense of competing foreign interests? Did such measure(s) qualify as permissible trade-related political safeguard measure(s)? Were less intrusive and trade restrictive alternatives to those selected available? The answers to these questions may ultimately help determine whether WTO rules have been violated in the process.

It must be emphasized that the use of an expressed preference (as opposed to a direct mandate) is a nuanced way for governments to say that if you seek a government contract, you must satisfy our demands, which can amount to a de facto mandatory imposition. It is possible, therefore, that such a preference can also rise to the level of a potential trade barrier if, contrary to WTO rules, its adoption, implementation, or enforcement by governments (1) deny "national treatment" to foreign high technology imports, (2) directly or indirectly "discriminates" against "like" competing foreign and domestic high technology products, or (3) effectively creates an unnecessary (e.g., overly costly and burdensome) obstacle to international trade that could have otherwise been avoided through the selection of alternative mechanisms—that is, it is not the least trade-restrictive alternative available—to satisfy a legitimate national policy objective.[285]

Indeed, GATT/WTO case law reveals that government preferences or recommendations can potentially rise to the level of indirect governmental mandates even if the government itself does not directly impose the mandate, but rather, private standards bodies or consortia do. In cases where governments indirectly facilitate development, promotion, enactment, adoption, implementation, and/or enforcement of government policy preferences and/or prescriptions by private standards bodies or consortia, GATT/WTO case law holds that there may exist enough of an imprimatur of government involvement in a given case to hold the government culpable under WTO law. Thus, the relevant inquiry in each case should be whether foreign high technology competitors employing a product-based business model dependent on patent protection have been directly or indirectly disadvantaged economically as the result of a preference for a business model based on royalty-free and/or proprietary-free services.[286]

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282 Article 63.2 of the WTO Trade Related Aspects of Intellectual Property Rights (TRIPs) Agreement (relating to *Transparency*) "requires Members to notify the laws and regulations made effective pertaining to the subject-matter of the Agreement (the availability, scope, acquisition, enforcement and prevention of the abuse of intellectual property rights)," which the WTO Secretariat, pursuant to TRIPs Art. 2.4, then "transmits to the International Bureau of WIPO [World Intellectual Property Organization]." See "Notifications Under the TRIPs Agreement," World Trade Organization website at <www.wto.org/english/tratop_e/trips_e/intel7_e.htm>.

283 See Art. 6 (relating to *Transparency*) of the Trade Related Investment Measures (TRIMs) Agreement. See also WTO Trade Related Investment Measures (TRIMs) Agreement, Trade Policy Directorate (August 2001), at <http://webarchive.nationalarchives.gov.uk/tna/+/http://www.berr.gov.uk/files/file22992.pdf>. The function of the Trade Policy Directorate appears to have been incorporated into the Department for Business, Innovation and Skills (BIS). See "About the Department for Business, Innovation and Skills," Civil Service website at <www.civilservice.gov.uk/my-civil-service/networks/professional/ges/what/about-bis.aspx>.

284 See Arts. III.1(a) and (b), XIX, and XXIII.2 of the Agreement on Government Procurement, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 4B, Art. III, Legal Instruments – Results of the Uruguay Round vol. 31, 1915 UNTS 103, accessible online at <www.wto.org/english/docs_e/legal_e/gpr-94_e.pdf>; see also Uruguay Round Trade Agreements, Texts of Agreements, Implementing Bill, Statement of Administrative Action and Required Supporting Statements, H.R. Doc. 103–116, 103d Cong. 2d Sess. (1994).

285 See "Can Government Intervention Sustain Economic Incentive, Technological Innovation, and Capital Flows?," Précis Of ITSSD WIPO Side-Bar Event, *supra* at 13.

286 See Lawrence A. Kogan, "Discerning the Forest from the Trees: How Governments Use Ostensibly Private and Voluntary Standards to Avoid WTO Culpability," *Global Trade and Customs Journal* 2, no. 9 (2007): 319–337 accessible online at <www.itssd.org/GTCJ_03-offprints%20KOGAN%20-%20Discerning%20the%20Forest%20from%20the%20Trees.pdf>.

4.2. Private Law Opportunities to Mitigate Such Risks

Beyond recourse to public international law remedies, the innovator and investor community that is to be affected by the trends in evidence may avail itself of other initiatives and subsequent activity designed to support practical proactive measures. These measures traditionally include structural vigilance, wide external diligence, and carefully crafted communications with individuals and organizations, both public and private, all of which is predicated upon astute monitoring and analysis of relevant events in international and national fora discussing these issues.

Structural vigilance would entail, among other efforts, the undertaking of an organizational review of existing security regarding IP (e.g., patents, technical know-how, information, data, etc.); correcting, revising, or replacing any areas of vulnerability as may be permitted; scrutiny of all R&D, product testing, licensing, and distribution regimes and commercialization relationships in light of legal enforceability venues; and licensee and agent performance and compliance with established standards. Management assessment must be made of the advisability of strategic placement of company R&D and commercialization assets in distinct business locations to prevent any one or more business units from acquiring the capability of reverse engineering of technology with or without the assistance of local third parties, as may be possible.

External diligence would entail managing access to or development of information pathways through credible sources or reportage and/or analysis to facilitate due diligence necessary to follow and measure the extent to which IP-based rule of law is adopted and enforced within each jurisdiction in which company business units operate or are to be deployed, and/or creating a flexible decision matrix to support a regime of identity or nonidentity to be associated with such efforts, and concentrate and limit personnel therein involved to reduce possible leakage or other unwanted or unintended consequences. External considerations would also include vigorous supply-chain-enforced protocols for information exchange, conformity assessment, and compliance with quality, performance, and integrity of shipment standards, loss control, and verified real-time reporting, among others.

Carefully crafted communications with individuals and organizations would preserve credibility and access whether contracted for, gratuitous, or circumstantial. An external communications policy must be established that conveys clear guidelines to all vetted personnel who will be acting as representatives governed by an information regime designed to assess and ensure the identity, accuracy, and protection of relevant information; where required, secure communications may have to be utilized. Responses to external sources of information, including civil society pressures groups and policy initiatives arising in government and intergovernmental venues, must be anticipated and conform to predetermined protocols whether the respondent is corporate or retained.