Commercial High Technology Innovations Face Uncertain Future Amid Emerging "BRICS" Compulsory Licensing and IT Interoperability Frameworks†

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Diary") (Oct. 26, 2010), *at* http://itssdinternationaliprights.blogspot.com/2010/10/itssd-geneva-diary-ofproceedings-of.html.

I. 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. These issues are particularly prevalent under a regime involving lengthy time horizons for competent research, development, and commercialization, which may require regulatory approvals. These challenges are known to be endemic to capital-intensive technology development which requires significant follow-on funding, particularly in highly regulated industries such as life sciences (e.g., pharmaceuticals/biotechnology[1] and electronic medical devices[2]) and clean technology (which may be subdivided into clean or renewable energy generation[3] and clean or renewable energy efficiency technologies and services, the former having more direct exposure to the regulatory environment[4]). Such conditions also pose considerable obstacles to the development and introduction of new paradigm-setting information and communication technologies (ICTs) categorized by reference to the economic activities generated by their application to and use within other industry sectors,[5] including healthcare, energy and the environment,

1. *See* Scott Gottlieb, *Medical Innovation in Peril*, *in* REFORMING AMERICA'S HEALTH CARE SYSTEM: THE FLAWED VISION OF OBAMACARE 56–57 (Scott W. Atlas ed., Hoover Institution Press 2010) (citing C. Johnston, *Clinical Trials: Rising Costs Limit Innovation*, 62(6) ANNALS OF NEUROLOGY A6, A6–A7 (2007) and J. A. DiMasi, R. W. Hansen, & H. G. Gradbowski, *The Price of Innovation: New Estimates of Drug Development Costs*, 22 J. OF HEALTH ECON. 151, 151–85 (2003), *available at* http://www.aei.org/docLib/Reforming-Americas-Health-Care-System-Gottlieb-101810.pdf).

2. *Impact of the Medical Device Safety Act on Venture Capital Investment in Medical Technology and Innovation: Before the Health Subcomm. of the H. Energy and Commerce Comm.* 2–3 (May 12, 2009) (statement of Nat'l Venture Capital Ass'n.), *available at* http://www.nvca.org/index.php?option=com_docman&task=doc_download&gid=453&Itemid=93.

3. *See Cleantech Investment and Private Equity: An Industry Survey*, NORTON ROSE LLP, 5 (July 14, 2010), *available at* http://www.nortonrose.com/files/clean tech-investment-and-private-equity-an-industry-survey-pdf-5mb-30016.pdf.

4. *See Cleantech and Renewables Update*, SJ BEWIN, 1 (July 14, 2010), http://www.sjberwin.com/Contents/Publications/pdf/210/e421e383_70c2_4d12_8caf_b54b582b4fc6.pdf.

5. *See* U.N. DEP'T. OF ECON. & SOC. AFFAIRS, STATISTICS DIV., INT'L STANDARD INDUSTRIAL CLASSIFICATION OF ALL ECON. ACTIVITIES REV. 4, at 278, ¶¶ 218–20, tbl.4.3,

transportation, information and education, emergency and disaster management, and defense and national security.[6] 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."[7]

The establishment of a technology's economic value is one of the most formidable obstacles faced by inventors and innovators of technologies with long gestation periods (e.g., development, testing, and scaling) and sustained high capital flows. Such economic value is determined by management's ability to reduce associated economic and legal uncertainties that otherwise would impede technology development, commercialization, and market entry. This assessment of value, which is increasingly sought through greater cooperation between financial and corporate investors,[8] is highly contingent on elements of certainty such as, principally robust enforcement of intellectual property rights to ensure market exclusivity.

This is especially the case in the life sciences sector. 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 "creat[es] 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."[9] Yet, patent protection has also become

U.N. DOC. ST/ESA/STAT/SER.M/4/Rev.4, U.N. Sales No. E08.XVII.25 (2008), *available at* http://unstats.un.org/unsd/cr/registry/isic-4.asp.

6. *See* Graham Vickery & Sacha Wunsch-Vincent, *R&D and Innovation in the ICT Sector: Toward Globalization and Collaboration*, *in* THE GLOBAL INFORMATION TECHNOLOGY REPORT 2008–2009 95, 95–97 (World Economic Forum 2009), *available at* http://www.tubisad.org.tr/Tr/Library/Analizler/Toward%20Globalization%20and%20Collaboration.pdf.

7. *Id.* at 97.

8. James Harris, *A Design for Life Sciences: Q&A Stephen Bunting*, REAL DEALS EUROPE 22, 24 (May 20, 2010), *available at* http://www.abingworth.com/images/Real Deals2010.pdf; *see also UPDATE 3-GE, Partners to Invest $55 Mln in Power-Grid Tech*, REUTERS (Nov. 16, 2010), http://www.reuters.com/article/2010/11/16/ge-grid-idUSN1611244920101116 ("General Electric Co and a group of venture capital firms said . . . they would invest $55 million in a dozen start-up ventures and partnerships working on new power-grid technologies.").

9. *See* Harris, *supra* note 8, at 25. *See also Strategy Consultants, Fight or Flight?: Diversification vs. Rx-focus in Big Pharma's Quest for Sustained Growth*, ROLAND BERGER (Oct. 2010), *available at http://www.rolandberger. com/media/pdf/Roland_ Berger_Fight_or_flight_Shortversion_20101025.pdf*; *see also* Ben Adams, *Two Thirds of Pharma Companies Face "Strategic Crisis"*, INPHARM (Oct. 25, 2010), http://www.inpharm.com/news/101025/two-thirds-pharma-companies-face-Strategic-crisis; *see also* Andrew Jack, *Drugs Groups Diversify Away from Patents*, FINANCIAL TIMES, Oct. 21, 2010, at 1, *available at* http://www.ft.com/cms/s/0/d6fb3f60-dc9d-11df-84f5-00144feabdc0.html; *see also* Kenneth Getz & Rachael Zuckerman, *Anticipating Structural Change in the CRO Market—Sponsor Crises Lead to an Unstable Landscape*, 12

an important element in the valuation of computer software companies. For example, a recently released patent study 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 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.[10]

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 intellectual property depends on endogenous outcomes in technology and product markets" (i.e., commercialization efforts).[11] However, this study also shows how certain exogenous (i.e., formal institutional or systemic) factors can be quite determinative of the commercial success of patented technologies. Indeed, there are many economic and legal uncertainties surrounding the patenting of technologies: (1) patent allowance, (2) patent scope, (3) patent grant delay, (4) patent enforceability, and (5) patent value. In particular, the study's findings show that delays surrounding the issuance of a Notice of Patent Allowance by the United States Patent and Trademark Office (USPTO) will effectively delay cooperative commercialization efforts vis-à-vis technology contracting and licensing. This is especially the case in technologies requiring long development periods[12] where alternative forms of intellectual property (IP) protection are not available, leading to longer patent allowance lags.[13] In other words, reduced patent allowance uncertainty can result in reduced patent scope uncertainty, which in turn,

CONTRACTPHARMA 70, 70–74 (Oct. 2010), *available at* http://www.contractpharma.com/articles/2010/10/anticipating-structural-change-in-the-cro-market.

10. Robert Merges & Pamela Samuelson, *Patenting by Entrepreneurs: The Berkeley Patent Survey (Part III of III)*, PATENTLYO BLOG (July 21, 2010), http://www.patentlyo.com/patent/2010/07/patenting-by-entrepreneurs-the-berkeley-patent-survey-part-iii-of-iii.html.

11. 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*, 54 MGMT. SCI. 982, 982–97 (May 2008), *available at* http://works.bepress.com/cgi/viewcontent.cgi?article=1008&context=joshuagans.

12. "[A patent allowance lag is] the time between patent application and patent allowance." *Id*. at 989. "While *electronics* and *scientific instruments* are associated with a relatively short *patent allowance lag* (27months), average allowance lags are much longer in *biotechnology* (38 months)." *Id.* at 991.

13. *Id.* at 29.

can significantly increase both the probability and the frequency of securing patent cooperation and licensing agreements within a relatively shorter period of time.[14] These findings have important implications for start-up 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."[15]

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.

II. DOMESTIC AND FOREIGN REGULATORY AND POLICY RISKS ASSOCIATED WITH HIGH TECHNOLOGY DEVELOPMENT, COMMERCIALIZATION, AND MARKET BEHAVIOR

A. Domestic Risks

Technology innovators, financial and corporate investors, and commercialization partners, despite their different return expectations and respective roles in the innovation process, must overcome challenges posed by national and regional-level regulators, particularly where greater innovation is perceived 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 intellectual property rights for emerging technologies—either create or are themselves a symptom of[16] legal and economic uncertainties, it may be expected that actual and intended capital availability may be placed at risk or withdrawn prematurely as measured by the recipient's economic model.

Financial and corporate investors understand how U.S. domestic regulatory policy can increase economic and legal risks as well as impair the success of new pharmaceutical, medical device, and clean technologies. For example, in June 2009, the National Venture Capital Association and the Medical Device Manufacturers Association, together and individually, urged Congress to consider the likely adverse economic impacts[17] that

14. *Id.* at 990 tbl.1B, 991.
15. *Id.* at 984.
16. Ben Depoorter, *Technology and Uncertainty: The Shaping Effect on Copyright Law*, 157 U. PA. L. REV. 1831, 1853, 1861–62 (2009).
17. *See* NAT'L VENTURE CAPITAL ASS'N, *supra* note 2, at 2–3.

the Medical Device Safety Act of 2009[18] would have 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.[19]

Approximately one year later, during November 2010, the National Venture Capital Association and its partner organization, the Medical Innovation and Competitiveness Coalition, released a white paper[20] that reported the results of a survey of over two hundred medical technology companies to evaluate the impact of U.S. medical device regulation on innovation and patients.[21] Generally speaking, ninety-three percent of those surveyed agreed that the "[U.S.] FDA ha[d] become more risk-averse toward . . . and hesitant to make decisions" concerning new products [during] the last decade," which they believed could seriously delay the introduction of new products and render the regulatory approval process less predictable and more costly.[22] More specifically, the survey revealed that medtech innovators faced significant regulatory uncertainties arising from unclear, unreasonable, nonscientific and unjustified U.S. FDA testing requirements, unpredictable and inefficient U.S. FDA pre-market reviews and inquiry response times, and insufficient transparency in U.S. FDA decision-making

18. *See* Medical Device Safety Act of 2009, H.R. 1346, 111th Cong. (2009), *available at* http://frwebgate.access.gpo.gov/cgibin/getdoc.cgi?dbname=111_cong_bills&docid=f:h1346ih.txt.pdf.

19. *See Medical Technolgy and Venture Capital: A Fruitful Yet Fragile Ecosystem*, MED. DEVICE MFRS. ASS'N & NAT'L VENTURE CAPITAL, 13 (June 2009), *available at* http://www.medicaldevices.org/sites/default/files/MDMA%20NVCA%20Final.June2009.pdf.

20. *See* Press Release, National Venture Capital Ass'n, NVCA Commends Makower Study on the FDA Impact on Med Tech Innovation, (Nov. 18, 2010), *available at* http://www.nvca.org/index.php?option=com_docman&task=doc_download&gid=671&Itemid=93.

21. *See* Josh Makower, Aabed Meer & Lyn Denend, *FDA Impact on U.S. Medical Technology Innovation: A Survey of Over 200 Medical Technology Companies*, NAT'L VENTURE CAPITAL ASS'N & MED. INNOVATION & COMPETITIVENESS COAL. (Nov. 2010), *available at* http://www.nvca.org/index.php?option=com_docman&task=doc_download&gid=668&Itemid=93.

22. *Id.* at 25.

which, in turn, has dampened medtech innovation in the United States among both established and startup companies.[23]

> When it comes to premarket data requests for new products, medtech innovators say they face more uncertainty regarding the FDA's expectations, and that bench, animal, and clinical testing requirements are mounting *without clear justification or benefit*. Even more troubling are an increasing number of examples from industry representatives that FDA reviewers are requesting esoteric scientific testing, or posing questions that are *not reasonably answerable, sometimes at great expense and with little relevance to safety and effectiveness*. Moreover, medtech innovators have reported that the FDA is becoming *less predictable and increasingly inefficient* in its premarket review role. Stakeholders maintain that the CDRH, over the last several years, has become even less transparent in how it makes decisions, as well as slower in responding to inquiries and regulatory submissions. . . . According to device companies, these changes have created nearly insurmountable barriers to medtech innovation in the U.S., with no apparent off-setting public health benefit. The current regulatory environment is particularly challenging for start-up companies, which have historically played a key role in driving innovation, because of their limited financial resources. As a result, regulatory submissions for innovative new medical devices have been declining in the U.S. over the last several years.[24]

These conclusions were subsequently reaffirmed in the context of biologic and pharmaceutical drugs at a subsequent congressional hearing convened on July 7, 2011, by the House of Representatives Committee on Energy and Commerce, Subcommittee on Health, to discuss the Prescription Drug User Fee Act (PDUFA).[25] In his prepared testimony, Mr. Jonathan S. Leff, Managing Director of Warburg Pincus, LLC, highlighted the greater regulatory uncertainty that has resulted from the U.S. FDA's increasingly risk-averse posture. In his opinion, such risk aversion has disturbed the delicate balance struck by regulators and policymakers between innovation and safety and thereby triggered the movement of investment capital away from the U.S. life sciences industries and abroad towards non-U.S. markets where regulators impose lower regulatory thresholds for market approval of such technologies.

> As a long-standing investor in the development of innovative new therapies, I want to emphasize that the way this balance is struck, by regulators and by policymakers, has tremendously important implications for the health of the U.S. medical innovation ecosystem. The FDA's shift in recent years to an increasingly cautious, risk-averse posture toward new drug approvals has had the unintended consequence of reducing investment in life sciences innovation

23. *Id.* at 14.
24. *Id.* (emphases added).
25. *See PDUFA V: Medical Innovation, Jobs, and Patients*: *Hearing Before the Health Subcomm. on Energy and Commerce*, (July 7, 2011), *available at* http://democrats.energycommerce.house.gov/index.php?q=hearing/health-subcommittee-hearing-on-pdufa-v-medical-innovation-jobs-and-patients.

> due to the significant additional time, cost, and[,] uncertainty it has added to the drug development process.[26]
>
> . . . All drugs present risks as well as benefits to patients. Rigorous science helps to identify and measure the benefits and the risks, but the question of how to balance the benefits versus the risks, and the question of how much uncertainty to accept when releasing a new product to the market, is inherently a value judgment. On this score, while the FDA continues to bring great scientific rigor to its decision-making, the last decade has witnessed a major shift in the nature of the value judgments the FDA is making. Compared to a decade ago, the FDA of today is on the whole more risk-averse, and tends to emphasize the risks of new products more than their benefits to patients. This leads the Agency to demand more and more data—larger trials, longer follow-up, and greater statistical certainty about efficacy and safety—before being willing to approve a new product.[27]
>
> . . . As the FDA becomes more cautious, demands more and more data, and emphasizes the risks of new products over their benefits, the cost, time, and risk of investment in medical innovation all go up, *driving investment capital* away from U.S. life sciences and *into* other industries *and other countries*. While this is surely an unintended consequence of a cautious, risk-averse regulatory environment, its impact is very real.[28]

Thereafter, during October 2011, the National Venture Capital Association and the Medical Innovation and Competitiveness Coalition released the results of a more recent survey of more than 150 venture capital firms (accounting for some $10 billion worth of venture investing in life sciences over the past three years).[29] The survey identified "regulatory challenges as *the most significant factor* [along with reimbursement concerns and the adverse financial environment] driving away investment from startup companies that are bringing critical therapies to market" (emphasis added)[30] Notwithstanding apparent FDA

26. *See PDUFA V: Medical Innovation, Jobs, and Patients: Hearing before the Health Subcomm. on Energy and Commerce* (July 7, 2011) (testimony of Jonathan S. Leff, Managing Director, Warburg Pincus, LLC), *available at* http://democrats.energycommerce.house.gov/sites/default/files/image_uploads/Testimony_HE_07.07.11_Leff.pdf.

27. *Id.* at 5.

28. *Id.* at 6 (emphases added).

29. *See Vital Signs: The Threat to Investment in U.S. Medical Innovation and the Imperative of FDA Reform*, NAT'L VENTURE CAPITAL ASS'N & MED. INNOVATION & COMPETITIVENESS COAL. (Oct. 2011), *available at* http://www. nvca.org/index.php?option=com_docman&task=doc_download&gid=796&Itemid=93.

30. *See* Press Release, Nat'l Venture Capital Ass'n & Med. Innovation & Competitiveness Coal., U.S. Medical Innovation at Risk: Fewer Companies and Therapies Receiving Funding, Says Report (Oct. 6, 2011), *available at* http://www.nvca.org/index.php?option=com_docman&task=doc_download&gid=795&Itemid=93.

efforts to address these concerns,[31] the report revealed, furthermore, that VC firms were expecting to significantly reduce their investments in companies operating in the highly regulated U.S. biotechnology and medical device sectors and working within several critically important therapeutic areas. These included companies targeting highly prevalent cardiovascular disease, diabetes, obesity, cancer, and neurological diseases.[32]

The VC firms also indicated that they would likely increase their investments in less regulated life science industry sectors, such as diagnostics life science tools/equipment, healthcare services/consumer health, and healthcare IT.[33] However, one must seriously question the extent to which an investment in healthcare IT could avoid significant regulatory/policy risk if the U.S. FDA were to aggressively implement its proposed "Sentinel Initiative" to electronically monitor the safety of medical products.[34] A key principle of such initiative is to develop *royalty-free open source* tools and capabilities for transforming, characterizing, and analyzing disparate data sources,[35] which will undoubtedly affect companies' ability to generate future revenues both within and beyond the government procurement market. Indeed, this Article reveals in great detail how IT employed by the health, energy, and telecommunications sectors in connection with government procurement initiatives, both within the United States and abroad, may not be as free from regulatory and policy risk as the VC industry believes it to be.

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31. *See* Timothy Hay, *FDA Tries To Mend Fences With Med-Tech Start-Ups, Investors*, WALL ST. J., Oct. 5, 2011, *available at* http://blogs.wsj.com/venture capital/2011/10/05/fda-tries-to-mend-fences-with-med-tech-start-ups-investors/.

32. *See* NAT'L VENTURE CAPITAL ASS'N & MED. INNOVATION & COMPETITIVENESS COAL., *supra* note 29, at 10, 12.

33. *Id.* at 10. *See also* Timothy Hay, *VCs Take Their Case For FDA Reform To Capitol Hill*, WALL ST. J., Oct. 6, 2011, *available at* http://blogs.wsj.com/venture capital/2011/10/06/vcs-take-their-case-for-fda-reform-to-capitol-hill/; Timothy Hay, *VC-Focused Group Says More Voices Better In Pushing FDA Reform*, WALL ST. J., Sept. 15, 2011, *available at* http://blogs.wsj.com/venturecapital/2011/09/15/vc-focused-group-says-more-voices-better-in-pushing-fda-reform/; Timothy Hay, *Is FDA Dysfunction Linked To Failed Start-Ups?* WALL ST. J., June 23, 2011, *available at* http://blogs. wsj.com/ venturecapital/2011/06/23/is-fda-dysfunction-linked-to-failed-start-ups/.

34. *See The Sentinel Initiative: National Strategy for Monitoring Medical Product Safety*, DEP'T OF HEALTH & HUMAN SERVS., U.S. FDA OFFICE OF CRITICAL PATH PROGRAMS (May 2008), *available at* http://www.fda.gov/downloads/Safety/FDAsSentinelInitiative/ UCM124701.pdf.

35. *Id.* at 15; *see* Judy Racoosin, Sentinel Initative Scientific Lead, U.S. FDA, Address at the Engelberg Center for Health Care Reform at Brooking: Overview of FDA's Sentinel Initiative (Sept. 7, 2011), *available at* http://www.brookings.edu/~/media/ Files/events/2011/0907sentinelintiativeoverview/Sentinel%20UpdateBrookings%20 20110907.pdf. "Much of the data involved in the Sentinel Initiative will be covered by the Health Insurance Portability and Accountability Act of 1996 ('HIPAA'), which provides a floor of privacy protections for health information in the United States." *See FDA's Sentinel Initiative*, Electronic Privacy Information Center website, *available at* http://epic.org/privacy/medical/sentinel/ default.html.

Similarly, an analyst at a Washington think-tank expressed deep concerns about how the recently enacted Patient Protection and Affordable Care Act[36] restrictions on drug and medical device insurance expense reimbursement creates legal and economic uncertainties that "will inevitably weigh on entrepreneurship, investment, and innovation" in this medical products sector.[37] In particular, this analyst opined that higher reimbursement uncertainty resulting from greater "government scrutiny of the reimbursement of new medicines . . . could diminish the capital formation that underpins the industry's riskiest endeavors."[38] He also found that such uncertainty was "already chasing investment capital into other endeavors that are more lucrative when adjusted for their risk,"[39] resulting in the shrinkage of "the industry's total R&D effort."[40]

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 presents] . . . a big problem when product development cycles and election cycles don't mesh."[41] Nuclear energy technology is especially prone to public perceptions, policy influences, and related regulatory risk.[42] Some also believe 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.[43] According to one recent Harvard Business School study, a startup company's product

36. *See* Patient Protection and Affordable Care Act, Pub. L. No. 111–48, 124 Stat. 119 (2010), *available at* http://www.gpo.gov/fdsys/pkg/PLAW-111 publ148/pdf/PLAW-111publ148.pdf.

37. *See* Gottlieb, *supra* note 1, at 54.

38. *Id.* at 62.

39. *Id.* at 67.

40. *Id.* at 67–68.

41. Carmen Nobel, *Venture Capital's Disconnect With Clean Tech*, WORKING KNOWLEDGE, HARV. BUS. SCH. (Oct. 18, 2010), http://hbswk.hbs.edu/item/6499.html (paraphrasing Harv. Bus. School professor Joseph Lassiter).

42. *See* Eric Wesoff, *Is There a Role for Venture Capital in Nuclear Power?: A Survey of VC Attitudes Towards Investing in Nuclear Power*, GREENTECH MEDIA (Dec. 14, 2009), http://www.greentechmedia.com/research-blog/post/is-there-a-role-for-venture-capital-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).

43. Arleen Jacobius, *High Costs Taking Wind Out of Clean-Tech Sails: Too Long a Wait for Too Small a Profit, VC Investors Complain*, INV. NEWS 1–4 (Apr. 25, 2010), *available at* http://www.investmentnews.com/article/20100425/REG/304259991.

(e.g., biofuels) is contingent on whether it is provided a subsidy or credit.

> [This susceptibility to policy changes and uncertainties is one of the] 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.[44]

In addition, at least one commentator has opined how the U.S. government's piecemeal approach to energy policy has created regulatory risks which 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."[45]

Information and communication technology (ICT) investors, in the course of undertaking their due diligence, frequently consider the level of regulatory risk of potential investment opportunities. For example, investors "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.[46] Where the *perceived* regulatory risk surrounding a given ICT is high and where the risk is not otherwise susceptible to appropriate mitigation, such technology will less likely attract investment amounts sufficient to assure its financial viability.[47] According to at least one expert, while ICT regulatory risk is quite pervasive throughout the world it is not easily quantified and varies in degree and magnitude from country to country.

> There are only a limited number of ICT investment environments in which there is little or no regulatory risk and thus, great care must be taken in considering the potential risks associated with the ICT framework in any given country. As would be expected, the degree of risk varies from country to country and not all

44. Shikhar Ghosh & Ramana Nanda, *Venture Capital Investment in the Clean Energy Sector* 16 (Harvard Bus. Sch., Working Paper No. 11-020, 2010), *available at* http://www.hbs.edu/research/pdf/11-020.pdf (emphasis added).

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

46. Lynne Dorward & Hal Peters, Impact of Effective Regulation on Investment: an Investor's Perspective 5, 7 (Nov. 20, 2009) (unpublished manuscript presented at the 9th Global Symposia for Regulators (GSR): Hands-on or Hands-off? Stimulating Growth Through Effective ICT Regulation), *available at* http://www.itu.int/ITUD/treg/Events/Seminars/GSR/GSR09/doc/GSR09_Regulation-Investment_Dorward.pdf.

47. *Id.* at 7.

> regulatory risks and their specific financial impact on an investment valuation are easily quantifiable.[48]

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."[49] 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.[50]

In the absence of such a regulatory framework, institutional and corporate investors in high technologies are likely to endeavor to influence regulatory policy[51] to the extent necessary to mitigate risks that would otherwise prevent them from emerging from the "valley of death"[52] and realizing a reasonable economic rate of return or, perhaps, even a return of their original capital.[53] 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 interest groups may seek to embed their own economic, legal, or political positions and preferences at the expense of competing interests through the enactment, repeal, or maintenance of a given regulation—a phenomenon known as "interest group regulatory capture."[54]

48. *Id.*
49. *See* Ghosh & Nanda, *supra* note 44, at 18.
50. *See* Mandla Msimang, Effective Regulation: The "Stimulus Plan" for the ICT Sector 14–15 (Nov. 20, 2009) (unpublished manuscript presented at the 9th Global Symposia for Regulators (GSR): Hands-on or Hands-off? Stimulating Growth Through Effective ICT Regulation), *available at* http://www.itu.int/ITUD/treg/Events/Seminars/GSR/GSR09/doc/GSR09_Regulation-Investment_Msimang.pdf.
51. *See* Frederic Boehm, *Regulatory Capture Revisited—Lessons from Economics of Corruption* 3–6 (Internet Ctr. for Corruption Research, Working Paper No. 22, 2007), *available at* http://www.icgg.org/downloads/Boehm%20-%20Regulatory%20Capture%20Revisited.pdf.
52. "The valley of death refers to the difficult period between proof-of-concept for a technology and large-scale deployment." *See* Stephen Lacey, *Can Cleantech Entrepreneurs Rely on Venture Capital?*, RENEWABLEENERGYWORLD.COM (July 13, 2009), http://www.renewableenergyworld.com/rea/news/article/2009/07/should-entrepreneurs-rely-on-venture-capital. *See, eg.*, Arleen Jacobius, *supra* note 43.
53. *See, e.g.*, Ghosh & Nanda, *supra* note 44, at 18–19.
54. See Boehm, *supra* note 51, at 3–6.

B. Foreign Risks

The phenomenon of regulatory and policy risk has also assumed an international dimension in the current era of globalization, especially with respect to life science, clean energy, and information and communication technologies. Increasingly, foreign governments and international policymakers have deemed these technologies as "public goods" necessary to establishing a twenty-first century domestic knowledge economy capable of competing effectively in the international trading system.

At least one study has noted that "[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."[55] For example, the study 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 i.e., suspicions that other governments would be unable to meet their obligations to that sector, which effectively dampened investor enthusiasm for solar industry portfolios.[56] According to a regulatory director of Iberdola, a Spanish solar and wind technology company, the Spanish and European experience in such technologies[57] revealed how regulation is both the key driver for and the primary risk associated with the development and deployment of renewable energy technologies. In his opinion, the best way to reduce such related regulatory risk is for companies to lobby for stable, predictable, fair, stringent, and efficient regulatory frameworks.[58]

A more recent study—evaluating the effects of policy on large onshore wind farms and utility-scale solar photovoltaic (PV) facilities located in the United States, Spain, and Italy, a concentrated solar power tower in the United States and an offshore wind farm in Denmark—concluded that "policy can affect the investment environment for renewable technologies by influencing the allocation of costs and revenues, the allocation of risks, and the technology choices and business practices of

55. *See* Ghosh & Nanda, *supra* note 44, at 16–17.
56. *Id.*
57. *See* Gerard Wynn, *Regulatory Risk Mounts for European Green Energy*, REUTERS (July 7, 2010), *available at* http://in.reuters.com/article/2010/07/07/us-renewable-eu-support-idINTRE6662FU20100707.
58. *See* Gonzalo Sáenz de Miera, Director of Regulatory Prospective, Iberdola, Presentation at Climate Policy Initiative-Launch Event: Regulation as a Key Driver for Renewable Energy Development: Lessons from the Spanish Case 2, 4, 8 (Apr. 16, 2011), *available at* http:// www.climatepolicyinitiative.org/files/attachments/67.pdf.

electricity market participants and other key stakeholders."[59] In particular, the study found that: (1) the duration of policy support measures often influenced a project's financing term; (2) renewable energy project electricity prices can be reduced to the extent policies directly or indirectly improve revenue certainty; (3) investors' perceptions of project risks are sufficiently intertwined with policy regimes that they often determine the amount and cost of available project financing; (4) policy prescriptions and up-front incentives requiring or encouraging establishment of reserve accounts or performance guarantees can help reduce renewable energy project construction and operational uncertainties or otherwise shift them to other stakeholders willing and able to bear those risks; (5) policy can impact or shift the risk that a renewable energy technology-based generating facility will not meet its target completion and operational dates; (6) policy can broaden the base of interested investors by influencing how risks are allocated among project stakeholders or the impact that such risks have on financing costs; and (7) policies can improve developer capital efficiencies and returns to attract greater investor interest by contributing to the reduction of development timeframes and increasing success rates.[60]

Furthermore, at least one other recent study revealed how the French government has finally come to recognize that *anti-science* regulatory policies, such as those dependent on a broad and extensive application of the precautionary principle, can adversely impact a company's entrepreneurial, innovative, and investment behavior, ultimately contributing to risk aversion and diminished national economic growth and retardation of scientific knowledge.[61] Moreover, institutional investors in Australia have also come to recognize how the "risk of regulatory

59. *See* Uday Varadarajan, David Nelson, Brendan Pierpont & Morgan Hervé-Mignucci, *The Impacts of Policy on The Financing of Renewable Projects: A Case Study Analysis*, CLIMATE POLICY INITIATIVE (Oct. 3, 2011), *available at* http://www.climatepolicyinitiative.org/files/attachments/167.pdf. "CPI is an independent, not-for-profit organization that receives long-term funding from George Soros." *Id.*

60. *Id.* at Executive Summary ii, 2.

61. *See* Jacques Attali, *Commission Pour la Liberation de la Croissance Francaise: Une Ambition Pour 10 Ans [Report of the Comm. for the Liberation of Growth, An Ambition for Ten Years]* 34–35, 149–50 (Oct. 2010), *available at* http://lesrapports.ladocumentationfrancaise.fr/BRP/104000541/0000.pdf, *translated in* Attali Commission, *France Must Strictly Circumscribe Precautionary Principle to Promote Entrepreneurial Risk-Taking, Innovation & Economic Growth*, ITSSD BLOG (Oct. 2010), http://itssdeconomicfreedom.blogspot.com/2010/10/attali-commission-france-must-strictly.html.

change [can have] *negative* implications on renewable energy projects."[62] For example, it was recently reported that the Victorian provincial government enacted new rules requiring "all future wind farm projects to build all turbines at least two kilometres away from residential dwellings" and all wind farm project "developers [to] submit proof of written consent [obtained] from all affected residents [with] homes [located] . . . within the two kilometre setback."[63] According to the report, the wind industry and their counsels are very concerned that "it will be quite hard to find a development site that isn't within two kilometres of a house" and that such rules "have [already] had a chilling effect on future Victorian investment".[64]

Similarly, the World Bank recently evaluated various regulatory strategies that national and regional governments can adopt to facilitate convergence of technologies among different ICT subsectors possessing distinct and divergent business and regulatory histories. It concluded that "[w]hen rules and policy frameworks overlap or conflict, regulatory risk increases which can in turn increase the cost of capital by up to 6 percentage points (depending on the country or region), [thereby] slowing investment in infrastructure and services."[65] It also found that a government's employment of a "wait and see" *ad hoc* rather than a harmonized national response to ICT convergence issues can also diminish the global competitiveness of home country-based ICT companies and produce other suboptimal results.

> The absence of a response can have a significant negative effect by failing to provide certainty for investors, as well as not providing a means to overcome inconsistencies in the legacy frameworks. The United States, for example, is now concerned that it is falling behind its European and Asian peers in broadband penetration and reduction of ICT-related tariffs (Windhausen 2008). This led to calls for government intervention and now the development of a national broadband strategy even in a market that has traditionally adopted a laissez-faire approach to the ICT sector. Thus, while a wait and watch response might not prevent convergence, it may lead to outcomes that result in suboptimal benefits.[66]

62. *See* Rachel Alembakis, *Renewable Energy Poses Opportunities, Risks for Investors*, THE SUSTAINABILITY REPORT (Sept. 16, 2011) (emphasis added), *available at* http://www.thesustainabilityreport.com.au/renewable-energy-poses-opportunities-risks-for-investors/1105/.

63. *Id.* "The new rules . . . may also apply where an amendment is required to a planning approval granted before the 15th of March 2011." *Id.*

64. *Id.*

65. *See* Rajendra Singh & Siddhartha Raja, *Convergence in Information and Communication Technology: Strategic and Regulatory Considerations*, THE INT'L BANK FOR RECONSTRUCTION AND DEV./THE WORLD BANK 24, 27 (May 30, 2010), *available at* http://siteresources.worldbank.org/EXTINFORMATIONANDCOMMUNICATIONANDTECHNOLOGIES/Resources/Convergence_in_ICT.pdf.

66. *Id.* at 24–25.

One such suboptimal result is regulatory arbitrage, and perhaps, even regulatory protectionism, wherein "regulated [ICT] firms [are enabled] to use regulatory processes to secure artificial competitive advantages. Thus, in some cases, regulation may not be picking winners as much as firms skilled in exploiting regulatory processes."[67]

Developed and developing country governments seeking to establish successful industrial, economic growth and technology innovation and transfer policies should therefore avoid enacting laws and regulations that create significant economic and legal uncertainties and opportunities for regulatory arbitrage and protectionism that could increase R&D and licensing costs, and thereby, place the security of existing investments tied to anticipated royalty revenue streams derived from intellectual property right (patents and trade secret) based inventions, at risk.

For example, the recently enacted America Invents Act[68] introduces several new levels of post-patent grant review,[69] including the temporary eight-year review of "covered business method patents"[70] falling within

67. *Id.* at 47, 61.

68. *See Leahy-Smith America Invents Act*, Pub. L. No. 112-29, 125 Stat. 284 (2011) (amending Title 35 of the United States Code and substantially reforming U.S. patent law), *available at* http://www.gpo.gov/fdsys/pkg/PLAW-112publ29/pdf/PLAW-112publ29.pdf.

69. *See* Pub. L. No. 112-29, § 6, 125 Stat. 299-313 (amending ch. 31 of title 35 and adding new ch. 32 to title 35, codified as 35 U.S.C. §§ 311–19 "Inter Partes Review" and 35 U.S.C. §§ 321–29 "Post-Grant Review." In general, the AIA establishes a new post-grant review proceeding (modeled after a European opposition proceeding) that permits any party to file a challenge to the validity of a patent *on any ground for a period up to nine months from the date such patent was granted*. *See* 35 U.S.C. § 321(b)-(c); 35 U.S.C. § 324(a). In addition, the AIA creates a new inter partes review process pursuant to which the validity of a patent can be challenged by any one other than the patent owner on patentability grounds that could be raised under section 102 or 103, and only on the basis of prior art consisting of patents or printed publications, *throughout the life of the patent*, upon showing that there is a reasonable likelihood that the petitioner will prevail with respect to at least one patent claim. *See* 35 U.S.C.§ 311(a)-(b); 35 U.S.C. § 314(a). The inter partes review process can be accessed after the later of the nine month post-grant review period or the completion of a post-patent review. *See* 35 U.S.C. § 311(c). Both procedures will first be available one year after the AIA's enactment—September 16, 2012.

70. Pub. L. No. 112-29, § 18, 125 Stat. 329-331, § 18(a)(3). A "covered business method patent" is defined as "a patent that claims a method or corresponding apparatus for performing data processing or other operations used in the practice, administration, or management of a financial product or service, except that the term does not include patents for technological inventions." *See* Pub. L. No. 112-29, § 18(d)(1).

Patent Class '705'[71] [72] that brings the U.S. patent system much closer to the European patent system which does not recognize business methods *per se* as patentable subject matter and narrowly construes software patents.[73] These new measures, which will for implementation purposes, require the Administrator of the USPTO to promulgate new regulations,[74] could arguably delay and raise the cost of patent litigation, elevate economic uncertainty associated with business method patent (BMP) licensing, and render software patents and related licenses more vulnerable to prolonged reexamination, possible invalidation, revocation, and economic

71. *See* Class 705, "Data Processing: Financial Business Practice, Management, or Cost/Price Determination", USPTO Classification Definitions (Feb. 2011), *available at* http://www.uspto.gov/web/patents/classification/uspc705/defs705.pdf.

72. Some have argued that this provision was intended to serve mainly as a protectionist device for the benefit of the financial services industry which was allegedly besieged by patent litigation initiated by small company holders of business method patents that disrupted the ability of these larger companies to license their own BMPs, which is BIG business. *See* Paul Michel, *Rein in the Big Bank Bail-Out*, PATENTLY-O (July 7, 2011) *available at* http://www.patentlyo.com/patent/2011/07/guest-post-rein-in-the-big-bank-bail-out.html. *See* Scott McKeown, *Proper Business Method Patent Challenges Under the America Invents Act?*, PATENT LAW PRACTICE CTR., PRACTICING LAW INST. (Aug. 16, 2011), *available at* http://patentlawcenter.pli.edu/2011/08/16/proper-business-method-patent-challenges-under-the-america-invents-act/ ("The clear intent of the author of this provision (Sen. Charles Schumer, D-N.Y) was to provide relief to the New York Banking Industry from the likes of *Data Treasury*. Some have gone as far as to label this provision a "bank bailout." (note the provision in the bill excluding ATM machines as a venue tool Sec. 18(c))"); *Patent Litigation Weekly: DataTreasury Wins First Patent Trial, Against U.S. Bank*, THE PRIOR ART BLOG (April 5, 2010), *available at* http://thepriorart.typepad.com/the_prior_art/2010/04/datatreasury-v-usbank-verdict.html; Robert Greene Sterne, Michael Q Lee & Richard M Libman, *Business Method Patents for Financial Products and Services*, STERNE, KESSLER, GOLDSTEIN & FOX PLLC (Jan. 2005), *available at* http://www.buildingipvalue.com/05_NA/147_150.htm. "Large financial institutions have embarked on significant filing programmes to seek protection for their innovati[ve] . . . financial tools given the enormous applicability of business method patents in the financial industry. The giants of the financial industry have made huge investments to build immense systems and methods to more effectively market, sell, administer and deliver financial products and services to their customers, and these giants are protecting their substantial investment with their own patents. But it is a two-way street—these giants are also having to address the business method patents of others that cover their core businesses." *Id.*

73. *See*, e.g., *In Re* Halliburton Energy Services Inc., [2011] EWHC 2508 (Pat), Appeal Nos: CH/2011/0154, IN THE HIGH COURT OF JUSTICE CHANCERY DIVISION PATENTS COURT (Oct. 5, 2011), *available at* http://britishcaselaw.co.uk/re-halliburton-energy-services-inc-2011-ewhc-2508-pat-05-october-2011 (The U.K. IPO Court allowed the appeals of Halliburton Energy Services Inc.'s four patent applications which had been previously rejected on essentially the same grounds, that the inventions were excluded from patentability as schemes, rules or methods for performing a mental act and as computer programs. In the process it explained the case law supporting the treatment of business method and software patents under both the European Patent Convention and the UK Patents Act 2004).

74. *See* 35 U.S.C. § 316; 35 U.S.C. § 326; Pub. L. No. 112-29, § 18(a), (d)(2).

devaluation, with significant economic repercussions for all licensing parties.[75]

Indeed, according to at least one expert, business methods significantly contribute to the commercialization of many scientific and technological discoveries and inventions. Consequently, the USPTO's broad invalidation of such patents would not only adversely impact entrepreneurs' ability to transfer their IP to the startups and new firms they establish, but would also jeopardize the commercialization of many ICTs directed toward electronic commerce applications, thereby placing both mature and new business (startup) investments in the computer hardware, software, communications, and internet sectors at substantial risk.[76]

> [The] undo[ing of] patent protections for business method inventions would create substantial economic costs and *would adversely impact technological change in computer hardware, software, communications, and the Internet.*[77] . . . [P]atents for business method inventions are important for entrepreneurship and for the commercialization of many scientific and technological inventions. A major study conducted by Stuart Graham et al. (2009) finds that entrepreneurs tend to benefit from patents, which confer competitive advantage, protect technology from copying by rivals, assist in obtaining financing, and enhance the startup's reputation. The work of Graham et al. illustrates the complex ways that IP protections for business method inventions affect subsequent innovation by entrepreneurs. I argue further that business method inventions provide a major channel for commercialization of scientific and technological discoveries and are important for entrepreneurship. Business method inventions often contain scientific and technological discoveries and help to commercialize scientific and technological discoveries already developed. Business method inventions that commercialize information and communications technology (ICT) often are targeted toward electronic commerce (e-commerce) applications. Restrictions on patenting business methods would cause inventors to present their discoveries under various other categories and could prejudice the awarding of patents against scientific and technological discoveries that have commercial applications.[78]

75. *See, e.g.*, Letter from Intellectual Ventures to U.S. House of Representatives, Committee on the Judiciary (Democrats) (June 8, 2011), *available at* http://democrats.judiciary.house.gov/sites/democrats.judiciary.house.gov/files/documents/IntelVentures110608.pdf.

76. Interestingly, "the top ten filers of Class 705 Patents are clear technology companies, including: IBM (590 patents) Microsoft (185 patents) Sony (142 patents) Hewlett-Packard (113 Patents) Fujitsu (105 Patents). Companies like AT&T, Oracle, Ebay, Amazon and Pitney Bowes round out the list (with only a sprinkling of companies being clear banking/financial organizations)." *See* Scott McKeown, *supra* note 72.

77. *See* Daniel F. Spulber, *Should Business Method Inventions be Patentable?*, 3 OXFORD J. OF LEGAL ANALYSIS 266 (Spring 2011) (emphasis added), *available at* http://jla.oxfordjournals.org/content/current; http://jla.oxfordjournals.org/content/3/1/265.full.pdf.

78. *Id.* at 268.

In economic terms, it is critical to foster the development of new business methods as much as possible, if need be, through patent grants ensuring temporary monopoly profits, given their indispensable role in extending IP protections to commercial discoveries "which are the foundation of subsequent Schumpeterian[79] innovation."[80]

Similarly, the enactment of national laws and regulations promoting the availability and flexible use by governments of a compulsory licensing mechanism as an exception or limitation to the patent right to secure foreign companies' patented high technologies at less than their fair market value can increase economic risks and result in acts of regulatory arbitrage and protectionist opportunism by home country as well as foreign companies operating pursuant to divergent business models. The security of property rights has been placed into question where compulsory licenses have been issued or threatened against foreign patented high technologies. Studies have shown that a corresponding reduction in the flow of knowledge-based foreign direct investment (FDI) will follow.[81] [82]

79. Austrian economist Joseph "Schumpeter's process of creative destruction states that technological advance is the main source of economic growth and improvements in the quality of life. It further states that a significant part of the incentive to produce leapfrogging innovations is the prospect of achieving monopoly profits. The original 'big-is-better' account adds the view that large incumbent firms are most likely to be the source of leapfrogging innovations. In contrast, the new 'small-is-better' account adds the view that small, new firms are most likely to be the source of leapfrogging innovations." *See* Arthur M. Diamond, Jr., *Schumpeter's Creative Destruction: A Review of the Evidence*, J. OF PRIVATE ENTERPRISE, Vol. XXII No. 1 (Fall 2006), at p. 139, *available at* http://journal.apee.org/index.php/Fall2006_7.

80. *See* Daniel F. Spulber, *supra* note 77, at 329.

81. *See* Robert Bird & Daniel R. Cahoy, *The Impact of Compulsory Licensing on Foreign Direct Investment: A Collective Bargaining Approach*, 45 AM. BUS. L.J. 48 (2008), *available at* http://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, 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." *Id. See also* Christopher Gibson, *A Look at the Compulsory License in Investment Arbitration: the Case of Indirect Expropriation*, 25 AM. U. INT'L L. REV. 357 (2010), *available at* http://digitalcommons.wcl.american.edu/cgi/viewcontent.cgi?article=1072&context=auilr ("Intellectual property rights ('IPRs') have long been recognized as a form of 'investment' entitled to protection under bilateral investment treaties ('BITs') and other international investment agreements ('IIAs'). . . . The inclusion of IPRs in the definition of 'investment' reflects that intellectual property, even as an intangible asset, can be a valuable part of a foreign direct investment ('FDI'). *Id*. at 358–59.

82. See also Lawrence A. Kogan, *Rediscovering the Value of Intellectual Property Rights: How Brazil's Recognition and Protection of Foreign IPRs Can Stimulate Domestic Innovation and Generate Economic Growth*, 8 INT'L J. ECON. DEVELOPMENT, no. 1–2 (Southern Public Administration Education Foundation 2006) at 157–74, 224–48, *available at* http://www.spaef.com/article.php?id=970; http://www.spaef.com/file.php?id=970 (describing how Brazil's increase in IPR protection specifically and the rule of

> [T]he practice of compulsory licensing comes with a price: the temporary or permanent deprivation of some part of a patent owner's right to exclude disrupts the investment-backed expectation of the property right. In the future, pharmaceutical companies and other industries dependent upon intellectual property rights may mistrust licensing nations' promises to protect and enforce patent rights, not to mention copyrights, and trademarks. As a result, *industries that find the security of property rights lacking in a given nation may avoid engaging in foreign direct investment with that nation*. Because foreign direct investment (FDI) is a major potential source of economic growth for recipient nations, the loss of such investment resources arising from compulsory licensing practices could force developing nations to pay a particularly heavy cost for providing needed medicines for its citizens.[83]

While government patent policy by itself is an incomplete measurement of a country's market and investment friendliness, it is generally agreed that such legal protections reflect a country's interest in fostering business and technology development. 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."[84] Consequently, the passage of IP laws that do not include a provision for compulsory licensing, for example, may favorably signal to foreign investors that a government is willing to allow strategic business decisions without undue interference and ensure more transparent and unbiased application of commercial laws with the prospect of reduced government corruption.[85] "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."[86]

If patent ownership rights indicate to prospective investors a firm's proper regard for its intellectual property security, then surely a company's willingness to engage in a foreign market where the government has decided to adopt or enforce *anti*-patent measures will convey *negative* signals to the investment community about the company, the quality of

law generally can improve its ability to attract innovative R&D- related foreign direct investment flows funded mostly by multinational corporations from which other collateral and ancillary skills and knowledge transfer benefits may be realized).

83. *See* Robert Bird & Daniel R. Cahoy, *supra* note 81, at 2–3 (emphasis added).

84. World Intellectual Property Organization [WIPO], *Report on the International Patent System*, 10–11, ¶ 41, SCP/12/3 (Apr. 15, 2008), *available at* http://www.wipo.int/edocs/mdocs/scp/en/scp_12/scp_12_3.pdf.

85. *See* Robert Bird & Daniel R. Cahoy, *supra* note 81, at 284, 297.

86. *Id.* at 330.

its management, and the strength and economic value 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.[87]

Lastly, increased foreign regulatory/policy risks have been triggered as the result of the ongoing international sanctioning of foreign governments' failure to ensure legal recognition and protection of pharmaceutical trade secret and other proprietary know-how and testing data, constituting intellectual property rights distinct from patents, which are sometimes referred to as 'data/market exclusivity' or 'data protection'.[88] Data/market exclusivity consists of a temporary period of time (commencing from when a drug first secures regulatory market authorization) during which a developed country government's food and drug regulator affords the originator of an approved branded drug (i.e., either small chemically synthesized molecules or complex biological products) legal protection against competing generic applications for marketing approval, and restricts generic competitors' ability to reference the data generated by such brand-name manufacturers.[89]

In the United States, the Drug Price Competition and Patent Term Restoration Act of 1984 (i.e., the ''Hatch-Waxman'' Act[90] which is applicable to small chemically synthesized molecules) provides for a market/data exclusivity period of five (5) years, while the recently enacted Biologics Price Competition and Innovation Act of 2009 ('BPCIA'[91] which

87. *Id.* at 298.

88. *See ITSSD Response to WIPO Circular C. 7998, and Comments Regarding SCP/16/7; SCP/16/9; SCP/17/4*, INST. FOR TRADE STANDARDS AND SUSTAINABLE DEV., (Nov. 2011) *at* http://www.wipo.int/export/sites/www/scp/en/meetings/session_17/health/ itssd.pdf.

89. *See* Lawrence A. Kogan, *The U.S. Biologics Price Competition and Innovation Act of 2009 Triggers Public Debates, Regulatory/Policy Risks, and International Trade Concerns*, 6 GLOBAL TRADE AND CUSTOMS J., Nos. 11-12, 2011, pp. 513–15, 521–24, *at* http://itssd.org/GTCJ_6(2)_Lawrence%20A%20Kogan%20(3).pdf, Working Paper version *available at* http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1953316.

90. Public Law 98–417, 98 Stat. 1585 (1984), as enacted, at http://www.kenyon.com/Resources/Hatchman/HTMLHelp/!SSL!/WebHelp/Public_Laws/P_L__98_417__1984_.htm. The provisions of the Hatch-Waxman Act adding Section 505(j) to the Federal Food, Drug, and Cosmetic Act, are codified at 21 U.S.C. 355, *at* http://www.law.cornell.edu/uscode/21/usc sec 21 00000355----000-.html. PL 98-417. PL 98–417 also amended 35 U.S.C. 271(e) and 35 U.S.C. 156 of the Patent Act.

91. *See* Title VII, Subtitle A, Sec. 7001-7003, *The Biologics Price Competition and Innovation Act of 2009*, of The Patient Protection and Affordable Care Act, Public

is applicable to complex biological products) provides for a market/data exclusivity period of twelve (12) years. In each case, generics are approved by permitting appropriate reliance on what is already known about the branded drug, thereby saving time and resources and avoiding unnecessary duplication of human or animal testing.[92] These relative periods of market/data exclusivity, in effect, compensate drug originators for the significant economic risks they assume and costs they incur undertaking the extensive testing, comparative studies and analyses necessary to secure U.S. government regulatory approval of a new pharmaceutical product.[93]

> *The research and development process is characterized by a high degree of scientific, regulatory, and economic risk*. Enormous quantities of time, effort, and money are invested in the research and development process to bring a new medicine to the market. Typically, discovering and developing a new medicine takes an average of 10–15 years, and for every 5,000–10,000 compounds investigated, only one is approved and marketed. The cost of developing a new medicine now totals on average more than USD 1.2 billion [fn]. *These investments in R&D have no guarantee of a return, with statistically far more failures than successes in the laboratory*. The generation of pre-clinical and clinical trial data takes considerable time, effort and expense, and begins when a compound is identified as a potential medicinal product. Scientists and researchers may think that a compound has certain properties and will act in a certain manner, but to ascertain the underlying proof of concept, extensive testing is required. Authorities use these data to assess the product's quality, efficacy and safety before a medicinal product is approved for use in patients. Even after marketing, clinical studies and pharmacovigilance continue. *In this entire process, it is important to note that the innovator assumes the entire risk for the generation of the data.* The innovator will not know in advance whether the data will demonstrate a safe and effective product and/or whether the regulatory authorities will consider the data sufficient to support the marketing of that product. *If, at any stage of the development process, a test or clinical trial is unsuccessful, or if the authorities require further testing, the*

Law 111–148, 124 STAT. 118, 804 (111th Cong.) (2010), *at* http://www.gpo.gov/fdsys/pkg/PLAW-111publ148/pdf/PLAW-111publ148.pdf. The U.S. Senate passed the U.S. House of Representatives' version of comprehensive healthcare reform legislation known as the Patient Protection and Affordable Care Act (H.R. 3590) on December 24, 2009. The House passed this legislation on March 21, 2010. It included Section 7002 amending the Public Health Service Act to permit approval of biosimilar biological products through an abbreviated biological license application (ABLA) submitted to the Food and Drug Administration (FDA).

92. Lawrence A. Kogan, *The U.S. Biologics Price Competition and Innovation Act of 2009 Triggers Public Debates, Regulatory/Policy Risks, and International Trade Concerns*, *supra*, at 513, 515.

93. *Id*. at 513, 521–24.

> *development process may be substantially delayed or stopped altogether*[94] (emphasis added).

Unfortunately, notwithstanding the economic costs and risks endemic to the drug development process, which are typically borne entirely by pharmaceutical innovator companies and their investors, developing and least developed country (LDC) governments have continued to seek additional derogations from their World Trade Organization (WTO) TRIPS obligations—including those contained within TRIPS Article 39.3[95] On November 17, 2011, for example, it was reported that LDCs, had likely secured, with the support and assistance of developing country members such as India (the world's largest exporter of generic drugs[96] and an opponent of market/data exclusivity protections[97]), the approval of the WTO TRIPS Council to extend, beyond July 1, 2013, their ability to *not* "protect trademarks, patents, copyright, geographical indications and other types of intellectual property." Should the TRIPS Council decide in favor of this additional derogation, continued LDC government *non-*

94. *See* International Federation of Pharmaceutical Manufacturers & Associations, *Data Exclusivity: Encouraging Development of New Medicines* (July 2011) at p. 5, *at* http://www.ifpma.org/fileadmin/content/Publication/IFPMA_2011_Data_Exclusivity__En_Web.pdf.

95. *See* Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, The Legal Texts: The Results of the Uruguay Round of Multilateral Trade Negotiations, 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1994) [hereinafter TRIPS] *at* http://www.wto.org/english/docs_e/legal_e/27-trips.pdf. Lawrence A. Kogan, *The U.S. Biologics Price Competition and Innovation Act of 2009 Triggers Public Debates, Regulatory/Policy Risks, and International Trade Concerns*, *supra*, at 528–530, 538. *See also* International Federation of Pharmaceutical Manufacturers & Associations, *Data Exclusivity: Encouraging Development of New Medicines*, supra ("Today, a number of countries maintain that the proprietary data that is provided to the Ministries of Health for obtaining registration of the innovator's products is protected under their unfair competition laws and that it is, consequently, not necessary for them to enact legislation that expressly implements TRIPS, Article 39.3. As a general rule, such protection, which requires non-disclosure of information and puts the burden of enforcement on the owner of the proprietary information, is insufficient to meet the TRIPS, Article 39.3 obligation."). *Id*.

96. "India tops the world in exporting generic medicines worth U.S.$11 billion, and currently, the Indian pharmaceutical industry is one of the world's largest and most developed". *See* Corporate Catalyst India, *A Brief Report—Pharmaceutical Industry in India* (Jan. 2011), Par. 1.2.2 *at* http://www.cci.in/pdf/surveys_reports/indian-pharmaceuticals-industry.pdf; http://www.cci.in/survey_report.html.

97. See *No Data Exclusivity Clauses in Trade Pacts, Assures India*, THIRD WORLD NETWORK (July 8, 2011) *at* http://www.twnside.org.sg/title2/FTAs/info.service/2011/fta.info.185.htm ("The Commerce and Industry Minister of India, Mr Anand Sharma, has given assurances that India will reject any efforts to include 'data exclusivity' clauses in bilateral trade agreements.") *Id. See also India's Commerce Minister Pledges Continued Availability of High Quality Generic Drugs*, UNAIDS PRESS STATEMENT (July 6, 2011) *at* http://www.unaids.org/en/resources/presscentre/pressreleaseandstatementarchive/2011/july/20110706psindia/.

protection of pharmaceutical company trade secrets, proprietary know-how and other confidential information, and clinical and non-clinical testing data would be permitted without the risk that developed country WTO Members would initiate 'non-violation'[98] dispute proceedings.[99] This anticipated derogation from WTO TRIPS Article 39.3 obligations would compliment other WTO (e.g., TRIPS Article 31 compulsory licensing) derogations developing country and LDC Members had previously secured in 2001 and 2005 with respect to pharmaceutical patents, in the name of promoting widespread governmental use of TRIPS 'flexibilities' already sanctioned by the WTO 2001 Doha Declaration on the TRIPS Agreement and Public Health,[100] the World Health Organization and the World Intellectual Property Organization.[101]

98. *See TRIPS: 'NON-VIOLATION' COMPLAINTS (ARTICLE 64.2)—Background and the Current Situation*, World Trade Organization website *at* http://wto.org/english/tratop_e/trips_e/nonviolation_background_e.htm.

99. "Ministers are now expected to ask the council to consider extending the mid-2013 deadline for least developed countries to implement intellectual property protection under the WTO agreement. They are also expected to agree that their countries will continue to refrain from bringing 'non-violation' cases to the WTO dispute settlement system for another two years. The least developed countries are seeking more time in order to identify their needs for assistance, to use the assistance to beef up their ability to protect intellectual property, and ultimately to protect it. They were represented in the discussions by their general coordinator, Bangladesh, and their TRIPS coordinator, Angola, who want ministers to make a political statement, and noted that only six countries have submitted their priority needs (Sierra Leone, Uganda, Bangladesh, Rwanda, Tanzania and Senegal). A number of countries have said they support extending the deadline, some adding that this would be in order to help least developed countries eventually protect intellectual property fully, which in turn will encourage economic activity. (*The [2013] deadline does not apply to pharmaceutical patents. The 2001 Doha Declaration on TRIPS and Public Health extended the period for least developed countries to comply with provisions on pharmaceuticals to 2016*) " (emphasis added). See *Draft Decisions Agreed On Poorest Nations' Intellectual Property and 'Non-violation'*, WTO 2011 NEWS ITEMS (Nov. 17, 2011), *at* http://wto.org/english/news_e/news11_e/trip_17nov 11_e.htm.

100. *Id.*; *Poorest Countries Given More Time to Apply Intellectual Property Rules*, WTO 2005 PRESS RELEASE (PRESS/424) (Nov. 29, 2005) *at* http://wto.org/english/news_e/pres05_e/pr424_e.htm; Declaration On the TRIPS Agreement and Public Health, DOHA WTO MINISTERIAL 2001: TRIPS (WT/MIN(01)/DEC/2) (adopted Nov. 14, 2001) *at* http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm.

101. *See* William New, *IP, Trade And Public Health Leaders Turn A Page In History Together*, INTELLECTUAL PROPERTY WATCH (Nov. 24, 2011) *at* http://www.ip-watch.org/weblog/2011/11/24/ip-trade-and-public-health-leaders-turn-a-page-in-history-together/ ("The focus of the event was the 2001 WTO Doha Declaration on the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement and Public Health . . . The core issue cutting across the areas of trade, IP and health is that market forces do not provide sufficient incentive for private-sector research for some diseases predominately

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

III. THE WORLD INTELLECTUAL PROPERTY ORGANIZATION (WIPO) AS A PLATFORM FOR WEAKENING PATENT RIGHTS: HOW FOREIGN GOVERNMENT AND CIVIL SOCIETY ACTIVITIES WITHIN THE WIPO CREATE ADDITIONAL REGULATORY AND POLICY RISKS FOR HIGH TECHNOLOGY

The World Intellectual Property Organization (WIPO) is a specialized agency of the United Nations that "administers several treaties aimed at creating a standard global system . . . [by] tak[ing] patent law in the direction of international harmonization."[102] It is one of only two intergovernmental organizations that anchor the current international intellectual property system—the other being the World Trade Organization

affecting poor populations, and for the others IP rights provide incentives but drive up prices.") *Id.*; *see also WTO, WIPO and WHO Examine Role of Patent Information in Access to Medicines*, International Centre for Trade and Sustainable Development (ICTSD) (Mar. 2, 2011) ("According to the WHO's Richard Laing, patents do not at present appear to be a major barrier to access to essential medicines on the WHO Model List in low and middle income countries. Access was largely influenced by other factors, such as lack of know-how or financing, and regulatory issues. *However, he pointed to other non-patent barriers such as bilateral trade agreements with 'TRIPS-plus' intellectual property rules related to data exclusivity and patent linkage*") (emphasis added).

102. *What is WIPO?, About WIPO*, WIPO, http://www.wipo.int//about-wipo/en/what_is_wipo.html (last visited July 13, 2011) (These several treaties include the Patent Cooperation Treaty (PCT), the Patent Law Treaty (PLT) and the Budapest Treaty (BT)). *See* Patent Cooperation Treaty, Contracting Parties, June 19, 1970, 28 U.S.T. 7645, 1160 U.N.T.S. 231, *available at* http://www.wipo.int/export/sites/www/treaties/en/ documents/pdf/pct.pdf (showing 142 contracting parties when last modified on Oct. 3, 2001, with the supplementing Regulations under the Patent Cooperation Treaty of Jan. 1, 2004); *see also* Patent Law Treaty, Contracting Parties, June 1, 2000, 39 I.L.M. 1047, *available at* http://www.wipo.int/treaties/en/ShowResults.jsp?lang=en& treaty_id=4 (showing 18 contracting parties when adopted at Geneva on June 1, 2000, with the supplementing Regulations under the Patent Law Treaty, adopted the same date); *see also* Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure, Contracting Parties, Apr. 28, 1977, 32 U.S.T. 1241 1861 U.N.T.S. 361, *available at* http://www.wipo.int/export/sites/ www/treaties/en/documents/pdf/budapest.pdf (showing 72 contracting parties when amended Sept. 26, 1980; the Regulations Under the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure were adopted Apr. 28, 1977 and amended Jan. 20, 1981 and Oct. 1, 2002).

(WTO)[103] which administers the Trade Related Aspects of Intellectual Property (TRIPS) Agreement.[104]

Several WIPO secretariat reports released and discussed during the Thirteenth, Fourteenth, and Fifteenth Session meetings of the Standing Committee[105] on the Law of Patents (SCP) reflect an emerging global view about patents and related trade secrets that will surely exacerbate legal uncertainties and economic risks associated with high technology innovation and investment. A growing number of WIPO members from emerging markets and developing countries generally believe that patent-based technology markets are inherently flawed, that patent holders are monopolists who exploit the period of temporary exclusivity at the expense of the public interest,[106] and that an irreconcilable conflict exists between the patent and standards systems that undergird technology development and industrial innovation, and are thus inconsistent with the United Nations Millennium Development Goals.[107] The allegations are supported by a number of sympathetic academicians and political agenda-based nongovernmental organizations (NGOs) pressure groups, and to a

103. "The World Trade Organization (WTO), established on January 1, 1995 . . . functions as the principal international body concerned with multilateral negotiations on the reduction of trade barriers and other measures that distort competition. . . . The basic aim of the WTO is to liberalize world trade and place it on a secure basis, thereby contributing to economic growth and development." *U.S. Proposal for Global Agricultural Trade Reform*, WTO (July 2002), *available at* http://www.fas.usda.gov/info/factsheets/wto.html.

104. *See* Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, The Legal Texts: The Results of the Uruguay Round of Multilateral Trade Negotiations, 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1994) [hereinafter TRIPS].

105. *Decision-Making Bodies, About WIPO*, WIPO, http://www.wipo.int/members/en/decision_bodies.html (last visited Nov. 22, 2010).

106. *See, e.g.*, *Report on the International Patent System*, *supra* note 84. The term "public interest" is discussed at paragraphs 130, 141, 172, 236, 286–87, 289, 298, 310, 313–14, and Annex II (pp. 72–136), where it is referenced *expressly* within the descriptions of national laws provided by no fewer than twenty-four (24) countries: Belarus, Kyrgyz Republic, Lithuania, Russian Federation, Slovak Republic, Uzbekistan, Barbados, Belize, Dominica, Ghana, Indonesia, Italy, Kenya, Liechtenstein, Luxembourg, Mauritius, Pakistan, Papau New Guinea, Poland, Republic of Korea, Switzerland, Tunisia, Ukraine and Uruguay. Although not catalogued here, it is certain that the laws of other WIPO members also include "public interest" exceptions and limitations to the exercise of privately held intellectual property rights.

107. *See* United Nations Millennium Declaration, U.N. Doc. A/RES/55/2 (Sept. 18, 2000), *available at* http://www.un.org/millennium/declaration/ares552e.pdf (Resolution adopted by the General Assembly 55th Session). *See United Nations Millennium Declaration*, Resolution adopted by the General Assembly 55th Session (A/RES/55/2) (Sept. 18, 2000), *at* http://www.un.org/millennium/declaration/ares552e.pdf.

lesser extent, by some in industry.[108] If successful, this movement will effectively recharacterize, for international law purposes, most privately conceived, developed, and commercialized health, clean energy, and ICT as "public goods" which may then be appropriated for less than adequate compensation and few substantive or procedural checks and balances to serve the public interest.[109]

Two governmental regulatory instruments have galvanized debate among government, civil society, and industry stakeholders participating in the WIPO SCP process: broadly defined compulsory licenses for healthcare and clean energy technologies and emerging government procurement rules expressing direct and indirect preferences for patent- 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.[110] This creates more 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 promising high technologies conceived and developed

108. *See, e.g.*, Laura DiNardis, *E-Governance Policies for Interoperability and Open Standards*, 7, 14, 23–24 (Yale Information Soc'y Project, Working Paper No. 1629833, 2010), *available at* http://ssrn.com/abstract=1629833. Laura DiNardis, *E-Governance Policies for Interoperability and Open Standards*, *Policy & Internet*: *Vol. 2: Iss. 3, art. 6*, POLICY AND INTERNET http://www.psocommons.org/policyandinternet/vol2/iss3/art6/ (last visited July 13, 2011).

109. This emerging view of patents has identified "public interests" as including the facilitation of knowledge dissemination, technology and wealth transfers, and access to affordable healthcare, clean energy and broadband communications at prices far less than fair market value.

110. *See, e.g.*, Pat Sewell, *A Review by Pat Sewell*, YALE GLOBAL ONLINE (2003) (reviewing AMY CHUA, WORLD ON FIRE: HOW EXPORTING FREE MARKET DEMOCRACY BREEDS ETHNIC HATRED AND GLOBAL INSTABILITY, (2003)), 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").

within and beyond the United States, both by entrepreneurs and more established global companies.

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

1. WIPO Reports, UN Agency Initiatives and BRICS Nation Regulations Seek an Expansion of Exceptions and Limitations to the Patent Right on "Public Interest" Grounds

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. Such a globally harmonized licensing mechanism would grant national emerging and developing country governments, which are host to many of the world's future growth markets,[111] the broad discretion to appropriate and secure third-party reverse engineering of foreign, privately-held, patented medical and ICT technologies whenever a "public interest" is claimed.[112]

Most troubling, however, is that Brazil's views and efforts in this regard influence a large group of developing countries generally known within the United Nations as the "Group of 77."[113] Their 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*,[114] by a more focused, agenda-based group of developing countries referred to as the WIPO "Development Agenda Group (DAG)."[115]

111. *See Top 10 Largest Economies in 2020*, EUROMONITOR INT. (July 7, 2010), http://blog.euromonitor.com/2010/07/special-report-top-10-largest-economies-in-2020.html.

112. *See, e.g.*, Lawrence A. Kogan, *Brazil's IP Opportunism Threatens U.S. Private Property Rights*, 38 U. MIAMI INTER-AM. L. REV. 1, 1–139 (2006), *available at* http://www.itssd.org/Publications/IAL105-II(frompublisher)[2].pdf.

113. *See About the Group of 77*, THE GROUP OF 77 AT THE UNITED NATIONS, http://www.g77.org/doc/ (last visited July 24, 2011).

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

115. *See* World Intellectual Property Organization, Committee on Development and Intellectual Property (CDIP) (Apr. 26–30, 2010), *Information on the Development Agenda Group Guiding Principles*, ¶ 4 & n.1, U.N Doc. CDIP/5/9 Rev., 5th Sess. (Apr. 26, 2010), *available at* http://www.wipo.int/edocs/mdocs/mdocs/en/cdip_5/cdip_ 5_9_rev.pdf.

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[,] [and] security."[116] 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.[117]

As one recent WIPO secretariat report reveals, compulsory licenses were historically issued[118] outside the United States,[119] 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.[120] Governments eventually broadened the definition of "patent abuses," and hence, the grounds for issuance of compulsory licenses, to also encompass: (1) "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) "anticompetitive" behavior.[121] Gradually, by the early 1990's, approximately one hundred national governments other than the United States had opportunistically expanded their use of compulsory licensing to cover non-abuse, or public interest situations which included compulsory licenses "in the fields of military security[,] . . . public health[,] . . . [and] public interest in unhampered technological progress . . . [as in the

116. *Id.* ¶¶ 5, 8.

117. 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*, INT'L CENTRE FOR TRADE AND SUSTAINABLE DEV. (ICTSD) & UNITED NATIONS CONFERENCE ON TRADE AND DEV. (UNCTAD), 1 (June 2003), http://ictsd.org/downloads/2008/06/cs_reichman_hasenzahl.pdf [hereinafter Reichman & Hasenzahl].

118. See *WIPO Rep. SCP/13/3*, *supra* note 100, ¶¶ 138–84.

119. Reichman and Hasenzahl, *supra* note 103, at 4–5. ("[T]he US never adopted a general statute to regulate non-voluntary licensing of patented inventions either on grounds of misuse or on public interest grounds," while the federal courts and the Federal Trade Commission from time to time issued non-voluntary licenses to regulate misuses of patent rights and antitrust violations and/or within consent decrees bearing on corporate mergers and acquisition.).

120. *See* Paris Convention for the Protection of Industrial Property, Mar. 20 1883, art. 5A(2), 5A(4), *as amended*, *at* http://www.wipo.int/treaties/en/ip/paris/trtdocs_wo020.html #P123_15283.

121. WIPO Rep. *CP/13/3*, *supra* note 100, ¶¶ 78, 160.

case of] . . . so-called *dependent patents*."[122] 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"[123] 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."[124]

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,"[125] 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.[126] 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, and complete remuneration upon issuance of a compulsory license); 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); and 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.[127] Arguably, these provisions individually and collectively require that a

122. World Intellectual Property Organziation,World Intellectual Property Handbook: Policy, Law and Use, ¶¶ 5.51–5.53, *at* http://www.wipo.int/export/sites/www/about-ip/en/iprm/pdf/ch5.pdf.

123. Reichman and Hasenzahl, *supra* note 103, at 1 (emphasis added).

124. *Id.* at 2.

125. *See ITSSD Comments Concerning Document (SCP/13/3) Patent Exclusions, Exceptions & Limitations*, INST. FOR TRADE STANDARDS AND SUSTAINABLE DEV. 5–6 and accompanying notes (Feb. 2009), http://www.wipo.int/export/sites/www/scp/en/meetings/session_14/studies/itssd_2.pdf [hereinafter *ITSSD Comments Concerning Document SCP/13/3*].

126. *Id.* at 6 (quoting NUNO PIRES DE CARVALHO, THE TRIPS REGIME OF TRADEMARKS AND DESIGNS, 43 (Kluwer Law Int'l, 2d ed., 2006)).

127. *See generally ITSSD Comments Concerning Document (SCP/13/3)*, *supra* note 111, at 5–9.

government's determination of "adequate remuneration" avoid prejudicing a patent holder's "legitimate expectations of commercial opportunity,"[128] 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."[129]

Nevertheless, the BRICS nations (Brazil, Russia, India, China and South Africa)[130] 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 commissioned an external "experts study" on exclusions, exceptions, and limitations to the patent right which focused on the public policy and socio-economic dimensions of public health, education, research and experimentation, and patentability of life form issues, among others to be suggested by members.[131] The completed study, which was released during September 2010 in advance of the SCP's Fifteenth Session, discusses the use of compulsory licenses in two of its six chapters. One chapter relates to life forms and identifies the various provisions of the E.U. directive on biotechnological inventions that establish a compulsory licensing scheme "to deal with the overlap between patent and plant variety protection"[132] and the analogues of several E.U. Member States,[133] as well as the compulsory licensing statutes of IP stalwarts such as Brazil[134] and the Russian Federation.[135] A second chapter 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

128. *Id.* at 20 (quoting Antony Taubman, *Rethinking Trips: 'Adequate Remuneration' for Non-Voluntary Patent Licensing*, 11 J. INT'L ECON. L. 927, 970 (Dec. 2008)).

129. Daniel R. Cahoy, *Confronting Myths and Myopia on the Road from Doha*, 42 GA, L. REV. 131, 158 (2007).

130. *See* Erin Conway-Smith, *South Africa to be a BRIC*, GLOBAL POST, Jan. 8, 2011, http://www.globalpost.com/dispatch/southafrica/110107/south-africa-be-bric.; *South Africa Receives BRIC Invite*, SOUTHAFRICA.info (Jan 3, 2011), *at* http://www.southafrica.info/news/international/brics-030111.htm.

131. *See* World Intellectual Property Organization, Standing Committee on the Law of Patents, Jan. 25–29, 2010, *External Experts' Study Regarding Exclusions, Exceptions and Limitations for the Standing Committee on the Law of Patents*, ¶¶ 1, 4, U.N. Doc. SCP/14/INF/2,14th Sess. (Jan. 26, 2010), *available at* http://www.wipo.int/edocs/mdocs/scp/en/ scp_14/scp_14_inf_2.pdf.

132. World Intellectual Property Organization, *Exclusions from Patentable Subject Matter and Exception sand Limitations to the Rights—Biotechnology*, 34–35, 56, U.N. Doc. SCP15/3 ANNEX III (Jan. 1, 2010) (by Denis Borges Barbosa & Karin Grau-Kruntz), *available at* http://www.wipo.int/edocs/mdocs/scp/en/scp_15/scp_15_3-annex3.pdf.

133. *Id.* at 65–68 (concerning the laws of Belgium, Bulgaria, Latvia, Lithuania, Malta, Romania, Slovakia, Sweden and the United Kingdom).

134. *Id.* at 45–46.

135. *Id.* at 67.

security emergencies, health emergencies, failure to work, government noncommercial use, or one of several other deemed "abuses" of patent rights.[136]

During the SCP's Fifteenth Session which took place in October 2010, there was apparent agreement between Brazil, the DAG, and the experts' study's coordinator and spokesperson concerning the study's 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.[137] The Free Software Foundation Europe (FSFE), an outspoken NGO observer and staunch advocate of royalty-free and 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.[138] 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."[139]

The view that technology and knowledge are "public goods" and that patents are merely temporary incentives provided by governments to correct "market failures" is based on the economic rationale for technology patents articulated within the WIPO SCP's initial *Report on the International Patent System*.[140] According to the report, since

136. *See* World Intellectual Property Organization, Standing Committee on the Law of Patents, Oct. 11–15, 2010, *Draft Rep. prepared by the Secretariat*, ¶ 76, U.N. Doc. SCP/15/6/ PROV, 15th Sess. (Mar. 18, 2011) [hereinafter *Draft Rep. prepared by the Secretariat*: *SCP/15/6/PROV*].

137. *Id.*; *see also DAG Statement on the Expert's Study on Exclusion and Exceptions/Limitations*(SCP/15/3), *at* http://www.ip-watch.org/weblog/wp-content/uploads/2010/10/DAG-Statement-On-Exemptions-Limitations.doc.

138. *FSFE Submission to European Patent Office*, FREE SOFTWARE FOUNDATION EUROPE (Apr. 2009), *available at* http://www.fsfe.org/projects/swpat/epo-response-42009.en.html. "[T]he economic rationale for patents is based on providing incentives in cases of market failure, disclosure of knowledge into the public domain, as well as technology transfer, commercialisation, and diffusion of knowledge." *Id.*

139. *Id.*; *see also Draft Rep. prepared by the Secretariat*: SCP/15/6/PROV, *supra* note 122, at ¶ 103.

140. *See* World Intellectual Property Organization, Standing Committee on the Law of Patents, June 23–27, 2008, *Report on the Int'l Patent Sys.*, 30, U.N. Doc. SCP/12/3/Rev.2, (Feb. 3, 2009), *available at* http://www.wipo.int/edocs/mdocs/scp/en/scp_12/scp_12_3_rev_2. pdf.

technology and knowledge are "non-excludable" in the sense that they can be used simultaneously by many people and owned exclusively by none in competitive markets, if left to their own devices, people 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.[141]

Cambridge University Law Professor Lionel Bently,[142] the designated coordinator of and spokesperson for the experts' study at the WIPO SCP,[143] in responding to a comment made during the SCP's October 11, 2010 plenary session, added one other dimension to this theory of market failure. He emphasized that a "neoliberal economics" property rights basis for technology patents is *not* possible in developing countries given the added market failure of asymmetry of information caused by the lack of willing buyers and sellers to create a market for knowledge goods in such countries.[144] 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."[145]

Given the E.U.'s relatively weaker private property laws vis-à-vis the United States[146] and its continued inability, despite the considerable efforts of many, to enact a regional patent law,[147] it is understandable why the

141. *Id.* at ¶ 28.

142. *See* Professor Lionel Bently, University of Cambridge Faculty of Law, *available at* http://www.law.cam.ac.uk/people/academic/l-a-f-bently/1109.

143. *See, e.g.*, World Intellectual Property Organization, Standing Committee on the Law of Patents, Oct. 11–15, 2010, *Summary by the Chair*, ¶ 6, U.N. Doc. SCP/15/5 (Oct. 15, 2010), *available at* http://www.wipo.int/edocs/mdocs/scp/en/scp_15/scp_15_5.pdf.

144. During the Q&A portion of Professor Bently's presentation, this author made the following comment: "[Y]our study seems to begin with the flawed premise of market failure such that exclusive private property rights are deemed an impediment to the public interest." *See Draft Rep. prepared by the Secretariat*: SCP/15/6/PROV, *supra* note 122, at ¶ 56.

145. World Intellectual Property Organization, Standing Committee on the Law of Patents, Jan. 25–29, 2010, *Transfer of Technology*, ¶ 122, U.N. Doc. SCP/14/4, 14th Sess. (Dec. 11, 2009), *available at* http://www.wipo.int/edocs/mdocs/scp/en/scp_14/scp_14_4.pdf.

146. World Intellectual Property Organization, *Comments on the Report on the International Patent System Received from Members and Observers of the SCP*, 18–26, U.N. Doc. SCP/12/3 Rev.2 ANNEX III.

147. *See, e.g.*, *Unitary Patent/EU Patent*, EUROPEAN PATENT OFFICE, http://www.epo.org/news-issues/issues/eu-patent.html (last updated June 1, 2011); *Unitary Patent/ EU Patent—Legislative Initiatives*, EUROPEAN PATENT OFFICE, http://www.epo.org/law-practice/legislative-initiatives/eu-patent.html (last updated July 28, 2011); Stephanie Bodoni, *France, Germany Among Nations Urging for Patent Plan*, BLOOMBERG

Belgian WIPO delegate representing the EU-27, for largely political reasons, agreed with the experts' study assessment. According to the E.U., 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 have resulted in a definition of property rights that is unclear and which justifies the enactment of national legislation most suitable to each country's needs.[148] This statement apparently emboldened the Brazilian delegate to propose that a government intervention mechanism be established that would match prospective patent licensors with prospective licensees to correct the perceived market failure deemed to impede technology transfer.[149]

It is quite clear that these views resonate with those of BRICS and developing nations seeking an expanded global application of compulsory licensing on public interest grounds to include technologies other than as troubling that this position derives "soft" legal support from the "UNEP medicines such as clean energy technologies. And, it should be regarded [United Nations Environment Program] Agenda 21 proposal [on sustainable development] that created the UNFCCC at the 1992 Rio Convention."[150]

During the December 2007 United Nations Framework Convention on Climate Change (UNFCCC) Conference of the Parties (COP), the now-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."[151] This proposal was taken seriously enough to attract the attention and analysis of University of

BUSINESSWEEK (Dec. 8, 2010), http://www.businessweek.com/news/2010-12-08/france-germany-among- nations-urging-for-patent-plan.html; Jonathan Stearns, *EU Parliament Rejects Patent Law Backed by Technology Companies*, BLOOMBERG (July 6, 2005), http://www.bloomberg. com/apps/news?pid=newsarchive&sid=a9_JRGCE0h6A.

148. *See Draft Rep. prepared by the Secretariat*: SCP/15/6/PROV, *supra* note 122, ¶ 144.

149. *See id.* ¶ 145.

150. Charles Ebinger & Govinda Avasarala, *Transferring Environmentally Sound Technologies in an Intellectual Property-Friendly Framework* 23–24 (2004), *available at* http://www.brookings.edu/~/media/Files/rc/papers/2009/11_environmental_technologyebinger/11_enfironmental_technology_ebinger.pdf.

151. Background Paper, International Centre for Trade and Sustainable Development (ICTSD) Trade and Climate Change Seminar, Copenhagen, Den., June 18–20, 2008, *Climate Change, Technology Transfer and Intellectual Property Rights* 7 (Aug. 2008), *available at* http://www.um.dk/NR/rdonlyres/F4D753A6-7015-4064-8BC6-FD4FEF1913F9/0/GMF IPRqx.pdf.

Florida law professor Frederick Abbott who was one of the drafters of the Doha Declaration on Public Health.[152]

During the Accra, Ghana Climate Change Talks of August 2008,[153] the Group of 77 and China submitted a proposal that called for "enhanced financial resources and investment to support action on mitigation and adaptation as well as the development and transfer of technology, as required by the Bali Action Plan."[154] According to this proposal, an Executive Body on Technology would be established as a subsidiary body of the Convention (comprised of government representatives) to facilitate climate mitigation and adaptation technology development and transfer.[155] In addition, the Executive Body's Technology Action Plan would

> ensure that privately owned technologies are available on an affordable basis through measures to resolve the barriers posed by intellectual property rights and addressing *compulsory licensing of patented technologies* . . . The [financing] mechanism w[ould] cover technologies in all relevant sectors and endeavor to remove barriers to effective technology development, deployment, diffusion and transfer . . . [Among the] activities and costs eligible for support by the mechanism . . . [are the] . . . [c]reation of manufacturing facilities for EST [environmentally sensitive technologies], including low-GHG emission technologies, inter alia, costs of:-*Compulsory licensing*, cost associated with patents, designs, and royalties.[156]

During the November 2008 Beijing International Conference on carbon abatement technology transfers,

> China and India proposed that the TRIPS flexibility for medicines (i.e. compulsory licensing) should be extended to cover carbon abatement technology. The argument was that climate is a *public good*, just like health, and hence, the international community should follow the principle of "*guidance by government—participation by enterprises*."[157]

152. *See, e.g.*, ICTSD Global Platform on Climate Change, Trade Policies and Sustainable Energy, *Innovation and Technology Transfer to Address Climate Change: Lessons from the Global Debate on Intellectual Property and Public Health*, at vi (June 2009) (by Frederick M. Abbott), *available at* http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1433579.

153. *See Accra Climate Change Talks 2008*, UNITED NATIONS FRAMEWORK ON CLIMATE CHANGE, *available at* http://unfccc.int/meetings/intersessional/accra/items/4437.php.

154. *See* Matthew Stilwell, *G77-China Propose "Enhanced Financial Mechanism" For UNFCCC*, THIRD WORLD NETWORK (Aug. 29, 2008), *available at* http://finance.thirdworldnetwork.net/article.php?aid=186.

155. *See Proposal by the G77 & China for A Technology Mechanism Under the UNFCCC*, 2 (Aug. 2008), *available at* http://unfccc.int/files/meetings/ad_hoc_working_groups/lca/application/pdf/technology_proposal_g77_8.pdf.

156. *Id.* at 3–4 (emphases added).

157. *Are IPRs A Barrier To The Transfer Of Climate Change Technology?*, COPENHAGEN ECON. & THE IPR CO. 7 (Jan. 2009) (emphasis added), *available at* http://

Thereafter, during February 2009, the Chinese government proposed, in comments submitted to the UNFCCC concerning the implementation of the Bali Action Plan, that "[c]ompulsory licensing related patented ESTs [environmentally sound technologies] and specific legal and regulatory arrangement [] curb negative effects of monopoly powers . . . as part of the efforts to implement the UNFCCC."[158] 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, and new green technologies.[159] The U.S. and E.U. governments had agreed previously that they would reject and 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.[160] [161]

trade.ec.europa.eu/doclib/ docs/2009/february/tradoc_142371.pdf a "report . . . commissioned by the European Commission (DG Trade)".

158. *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*, 7 (Feb. 6, 2009), *available at* http://unfccc.int/files/kyoto_protocol/application/pdf/china060209.pdf.

159. *See China, India Push for 'Patent Free' Freen Tech*, EURACTIV.COM (Nov. 23, 2009), *available at* http://www.euractiv.com/en/innovation/china-india-push-patent-free-green-tech/article-187567; *see also* Jim Efstathiou Jr., *Clean-Energy Cause Shouldn't Void Patents, Senators Tell Obama*, BLOOMBERG.COM (Nov.4, 2009, 9:30 AM), http://www.bloomberg.com/apps/news?pid=newsarchive&sid=aug9aycq0lJw.

160. *Id.*; *see also* Andrew C. Revkin & Tom Zeller, Jr., *U.S. Negotiator Dismisses Reparations for Climate*, N.Y. TIMES (Dec. 9, 2009), *available at* http://www.nytimes.com/2009/12/10/science/earth/10climate.html; *Bangkok Blues: Gloom and Pragmatism Ahead of the Copenhagen Climate-Change Summit*, THE ECONOMIST, Oct. 15, 2009, http://www.economist.com/node/14646499 ("Poor countries suggested language that would allow compulsory licensing of low-carbon technologies developed in the rich world. Neither the EU nor America wanted that."). *Id.*

161. In the case of the U.S. it would appear that such rejection had already been agreed upon during prior hearings convened by the U.S. House Select Committee on Energy Independence and Global Warming in September 2009. *See Roadmap to Copenhagen: Driving Toward Success*: *Hearing Before the Comm. on Energy Independence and Global Warming* (2009), *available at* http://republicans.globalwarming.house.gov/Media/file/PDFs/Hearings/091009Road_to_Copenhagen/Questions_ForThe_Record.pdf. At the hearings, ranking Republican Member F. James Sessensbrenner entered into the congressional record the following information and posed the following question to U.S. Special Envoy for Climate Change, Todd Stern: "Developing countries are leading efforts to weaken or even destroy intellectual property rights (IPR) by seeking to gain free access to American and other developed countries IPR for clean-energy technologies. Their proposals include preventing patenting in

Yet, *Draft Decision D-/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 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."[162] The draft decision indicates that one way to achieve this objective is to ensure that "publicly funded technologies and related know-how is placed into the public domain, shared[,] and made universally accessible "in a manner that promotes transfer of and/or access to environmentally sound technology and know-how to developing countries *on royalty-free terms*."[163] Another way is to oblige Parties to "take all necessary steps in all relevant forums *to exclude from Intellectual Property Rights protection, and revoke any such existing intellectual property right protection* in developing countries and least developed countries on environmentally sound technologies to adapt to and mitigate climate change"(emphasis added).[164] Alternatively, Parties can recognize "*the right [of developing countries] . . . to make use of the full flexibilities* contained in the Trade Related Aspects of Intellectual Property Rights agreement, *including compulsory licensing*."[165]

developing countries, requiring compulsory licensing, and ensuring access to new technologies on non-exclusive royalty-free terms. All of which ignore the fact that new technologies will only be developed if there are incentives to create them. Is the Administration committed to protecting our IPR from this assault?" See *Questions for the Record Submitted to Special Envoy Todd Stern by Representative James Sensenbrenner, Jr. (#9)*, H. SELECT COMM. ON ENERGY INDEPENDENCE AND GLOBAL WARMING, 15 (Sept. 10, 2009), *available at* http://republicans.globalwarming.house.gov/Media/file/PDFs/Hearings/091009Road_to_Copenhagen/Response_Stern.pdf. Mr. Stern answered this question, in part, in the following manner: "The Administration will not support any language in the UN Framework Convention on Climate Change (UNFCCC) that seeks to undermine or weaken protection and enforcement of intellectual property rights. We will not support it in a Copenhagen outcome. We have made this very clear in the negotiations, where we have argued intellectual property is an essential building block for technology innovation that we will need if we are to achieve the ultimate objective of the Convention." *Id.* at 16.

162. United Nations Framework Convention on Climate Change, Copenhagen, Den., Dec. 7–15, 2009, *Draft Decision D.—/CP.15—Enhanced Action on Technology Development and Transfer*, in Rep. of the Ad Hoc Working Group on Long-term Cooperative Action under the Convention on its 8th Sess., 22–28 U.N. Doc. FCCC/AWGLCA/2009/17, Annex I (Feb. 5, 2010), *available at* http://unfccc.int/resource/docs/2009/awglca8/eng/17.pdf.

163. *Id.* ¶ 17bis (b) (emphasis added).

164. *Id.* ¶ 17ter (Including environmentally sensitive technologies "developed through funding by governments or international agencies and those involving use of genetic resources that are used foradaptation and mitigation of climate change") (emphasis added).

165. *Id.* ¶ 17quater (emphasis added).

Apparently, by June 2010, these draft decision options had been subsequently incorporated 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"[166] and had triggered objections from the government of Japan.[167] Furthermore, such decision text was referenced by the Expert Group on Technology Transfer of the Subsidiary Body for Scientific and Technological Advice[168] in a stocktaking paper "on the role of IPRs in technology transfer"[169] that has yet to be publicly released.[170] Whether this report and its contents will ever be released and subject to public scrutiny is uncertain. However, the issue of how best to facilitate and implement clean technology transfers via IPR law and policy changes was certainly discussed in less direct terms and extensively referenced within a draft COP decision thereafter

166. Note by the Chair, June 1–11, 2009, *Chapter III—Enhanced Action on Technology Development and Transfer, Text to Facilitate Negotiations Among Parties*, presented at Ad Hoc Working Group on Long-term Cooperative Action under the Convention on its 10th Sess., ¶ 1, 11, U.N. Doc. FCCC/AWGLCA/2010/6 (May 17, 2010), *available at* http://unfccc.int/resource/docs/2010/awglca10/eng/06.pdf.

167. *Divergent Views on Bodies of the UNFCCC Tech. Mechanism*, TWN BONN UPDATE NO. 16 (Ger.), June 8, 2010, at 3, *available at* http://www.twnside.org.sg/title2/climate/news/Bonn06/TWN_bonn6.up16.pdf ("Japan advocated for strict protection of IPRs and called for Option 2 of Paragraph 11 in Chapter III of the Chair's text to be eliminated. (Option 2 relates to measures to address IPRS)"). *See also Rep. of the Ad Hoc Working Group on Long-term Cooperative Action Under the Convention on its Tenth Session*, June 1–11, 2010, ¶ 17, U.N. Doc. FCCC/AWGLCA/2010/7 (June 28, 2010), *available at* http://unfccc.int/resource/docs/2010/awglca10/eng/07.pdf.

168. *Bodies of the Framework Convention, Actors in the Negotiation Process, and the UNFCCC Secretariat*, UNITED NATIONS FRAMEWORK CONVENTION ON CLIMATE CHANGE, UNFCCC.INT, http://unfccc.int/essential_background/feeling_the_heat/2915 (last visited Jul. 20, 2011) (This body "counsels the Conference of the [UNFCCC] Parties on matters of climate, the environment,technology and method.").

169. United Nations Framework Convention on Climate, *Rep. of the Expert Group on Tech. Transfer—Note by the Chair of the Expert Group onTech. Transfer*, Subsidiary Body for Scientific and Technological Advice and Subsidiary Body for Implementation at III.A.2, U.N. Doc. FCCC/SB/2010/INF.4 (Nov. 24, 2010) [hereinafter *FCCC/SB/2010/INF.4* (Nov. 24, 2010)], *available at* http://unfccc.int/resource/docs/2010/sb/eng/inf04.pdf; United Nations Framework Convention on Climate Change, *Rep. of the Expert Group on Tech. Transfer—Note by the Chair of the Expert Group on Tech. Transfer, Subsidiary Body for Scientific and Technological Advice and Subsidiary Body for Implementation, The Updated Rolling Programme of Work of the Expert Group on Tech. Transfer for 2010–2011*, at 11, U.N. Doc. FCCC/SB/2010/INF.1, Annex I (May 30, 2010), *available at* http://unfccc.int/resource/docs/2010/sb/eng/inf01.pdf.

170. *See* FCCC/SB/2010/INF.4 (Nov. 24, 2010), *supra* note 155, at ¶ 12.

issued following the December 2010 UNFCCC Cancun, Mexico climate change conference,[171] despite some media reports that the issue of intellectual property rights had been dropped altogether from the discussion.[172]

Despite 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—the establishment of an SCP working group to "carry out a wide and sustained debate . . . in three phase[s]" 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.[173] However, it remains to be determined whether such a working 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 to release a draft discussion paper in August 2010 to "develop a predictable environment for use of

171. Advance unedited version, United Nations Climate Change Conference Cancun, *Draft decision [-/CP.16]—Outcome of the Work of the Ad Hoc Working Group on Long-term Cooperative Action under the Convention*, U.N. Doc. COP 16/CMP 6, at paras. 1 and (2)(a), 2(c), 14(a), 18, 20(d), 40(a), 40(c), 42(b), 48, 53, 73, 76, 89; 113–116 (Mar. 15, 2011), *available at* http://unfccc.int/files/meetings/cop16/application/pdf/cop16_lca.pdf.

172. *See, e.g.*, Urmi A. Goswami, *Experts raise questions over future of Kyoto Protocol*, THE ECONOMIC TIMES INDIA, Dec. 13, 2010, *available at* http://economictimes.indiatimes.com/news/politics/nation/Experts-raise-questions-over-future-of-Kyoto-Protocol/articleshow/7090659.cms; Catherine Saez, *IP Issues In Shadows At Climate Change Conference*, INTELLECTUAL PROPERTY WATCH, Dec. 10, 2010, *available at* http://www.ip-watch.org/weblog/2010/12/10/ip-issues-in-shadows-at-climate-change-conference/; Martin Khor, *Strange Outcome of Cancun Conference*, THE STAR ONLINE, Dec. 13, 2010, *available at* http://thestar.com.my/columnists/story.asp?col=globaltrends&file=/2010/12/13/columnists/globaltrends/7611715&sec=Global%20Trends; *Final Accord Reached at Cancun Despite Bolivia's Objection*, XINHUANET.COM, http://news.xinhuanet.com/english2010/world/2010-12/12/c_13645374.htm (last visited July 24, 2011).

173. *See* World Intellectual Property Organization, Standing Committee on the Law of Patents, Jan. 25–29, 2010, *Proposal from Brazil*, ¶¶ 23–27, U.N. Doc. SCP/14/7, 14th Sess. Annex 3 (Jan. 20, 2010), *available at* http://www.wipo.int/edocs/mdocs/patent_policy/en/scp_14/scp_14_7.pdf.

such measures."[174] One of the questions raised by the Indian government concerned the wisdom of limiting a government's discretion to issue compulsory licenses, and whether alternative grounds beyond "national emergency," "extreme urgency," and "public non-commercial use" as set forth in Article 31 of the TRIPS Agreement are and should be available to justify the issuance of compulsory licenses.[175] A second question concerned the suitability of compulsory licenses to resolve anti-competition abuses.[176] These two questions sidestepped the issue of employing compulsory licenses on broader public interest grounds beyond "failure to work" abuses. They also left unresolved the types of technologies beyond medicines needed to treat frontline diseases such as HIV, AIDs, Hepatitis C, cancer, and diabetes[177] for which compulsory licenses could theoretically be issued, including climate change and carbon mitigation technologies. A third question concerned the market failure theory, or the impact of compulsory licenses on technological growth in emerging and developing economies. With respect to this latter issue, the discussion cited a 2009 report which had found that "compulsory licensing has a strong and persistent positive effect on domestic invention".[178] The same report 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."[179] It remains uncertain whether India will seriously consider responses received from foreign and domestic 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.[180]

174. INDIA DEP'T OF INDUS. POLICY AND PROMOTION (DIPP), DISCUSSION PAPER ON COMPULSORY LICENSES, 1 (Aug. 24, 2010), *available at* http://dipp.nic.in/.

175. *Id.* ¶¶ 1–2, at 21–23.

176. *Id.* ¶ 5, at 25.

177. *Id.* ¶¶ 15–17, 30, 44 at 4–5, 9–10, 15.

178. *Id.* ¶ 70 (citing Petra Moser & Alessandra Voena, *Compulsory licensing-Evidence from The Trading With The Enemy Act* 21, n.35 (NBER Working Paper No. 15598, Dec. 2009)), *available at* http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1313867.

179. *Id.*

180. CropLife International, Commentary, *Discussion Paper on Compulsory Licenses Published by the Dep't of Indus. Policy and Promotion within India's Ministry of Commerce and Indus.* 2 (Sept. 29, 2010), *available at* http://www.dipp.nic.in/ipr-feedback/Feedback_CropLifeInternational30September2010.pdf.; Pfizer, Response, *DIPP Discussion*

The Indian government would be wise to consider however, that compulsory licensing is not the silver bullet that the 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)."[181] 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, 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,"[182] such as, where a party is unable to "make the technology workable" in the absence of additional "significant tacit [as yet undisclosed trade secret] knowledge."[183] In addition, the Indian government should not interpret the current lack of clear and uniform international legal standards for determining the appropriate level of market-based compensation due private patent holders whose technologies fall subject to government compulsory licensing, as providing a "green light" for IP opportunism. 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 wishing to cut expenditures and, most perversely, even stifle access."[184]

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

Paper on Compulsory Licensing 2–3 (Sept. 27, 2010), *available at* http://www.dipp.nic.in/ipr-feedback/FeedBack_Pfizer_27September2010.pdf.; Biotechnology Indus. Org., Commentary, *Discussion Paper on Compulsory Licenses Published by the Dep't of Indus. Policy and Promotion within India's Ministry of Commerce and Indus.*, 3 (Sept. 29, 2010), *available at* http://www.bio.org/ip/international/20100929.pdf; Organization of Pharmaceutical Producers of India (OPPI), Views and Suggestions, *DIPP 'Discussion Paper' on Compulsory Licensing* 2 (Sept. 30, 2010), *available at* http://www.dipp.nic.in/ipr-feedback/Feedback_OPPI_30September2010.pdf.

181. *See* Daniel K.N. Johnson & Kristina M. Lybecker, *Challenges to Technology Transfer: A Literature Rev. of the Constraints on Environmental Tech. Dissemination* 12 (Colorado College Working Paper, July 2009), *available at* http://www.nationalpeace.org/files/Paper%202%20-%20ccwp09-07_0.pdf, (citing Cameron Hutchison, *Does TRIPSFacilitate or Impede Climate Change Technology Transfer into Developing Countries?*, 3 U. OTTAWA L. TECH. J. 517, 533 (2006), *available at* http://www.uoltj.ca/articles/vol3.2/2006.3.2.uoltj.Hutchison.517-537.pdf).

182. *Id.*

183. *Id.*

184. *See* Cahoy, *supra* note 115, at abstract.

on questionable interpretations of human rights law to the exclusion of WTO law.

Arguably, the European Court of First Instance (CIF) did not adhere to this standard when it affirmed in September 2007 the European Commission's 2004 de facto compulsory licensing decision against Microsoft.[185] In upholding the Commission's determination[186] in *Microsoft Corp. v. Comm'n of the European Cmtys.*, the CIF found that the failure of an already market-dominant Microsoft to license its Windows and Media Player software separately (its refusal to deal on patent and trade secret protection grounds) and its failure to render such software *interoperable* (to authorize the use of interoperability information[187] for the public benefit of both Microsoft competitors and consumers)[188] constituted an impermissible abuse of its intellectual property rights that was per se inconsistent with and in violation of European regional competition (antitrust),[189] statutory and case law,[190] *and innovation policy*.[191]

The CIF's ruling referred to interoperability as a "public interest" ancillary to maintaining effective competition in the marketplace.[192] It implied "that in exceptional circumstances a refusal to license intellectual property rights could be an abuse of a dominant position" and that "the withholding [of intellectual property protected] interoperability information may constitute an abuse of a dominant position,"[193]) without regard to any other alleged form of market abuse. The CIF's decision was apparently based on the following four premises: (1) companies holding an acknowledged market-dominant position have "a special responsibility irrespective of the causes of that position, not to allow its conduct to impair *genuine undistorted competition* on the common market;"[194]

185. *See* Case T-201/04, Microsoft Corp. v. Comm'n of European Cmtys, 2007 E.C.R. II-3601.

186. *See* COMMISSION DECISION of 24.03.2004 relating to a proceeding under Article 82 of the EC Treaty (Case COMP/C-3/37.792 Microsoft), C(2004) 900 final, (Mar. 24, 2004), *at* http://www.microsoft.com/presspass/download/legal/european commission/03-24-06EUDecision.pdf.

187. *Id.* ¶¶ 100.1086, 1116, 1231.

188. *Id.* ¶¶ 816–1167, 1231.

189. *Id.* ¶¶ 229, 236, 240, 1086.

190. *Id.* ¶¶ 331–33, 1086.

191. *See* Alla Pozdnakova, *Court of First Instance Issues a Judgment in Microsoft Case*, INT'L LAW OBSERVER (Sept. 28, 2007), *at* http://internationallawobserver.eu/ 2007/09/28/court-of-first-instance-issues-a-judgement-inmicrosoft-case/.

192. *See* Case T-201/04, *Microsoft Corp.*, at ¶ 691.

193. *Id.* ¶ 1313.

194. *Id.* ¶ 229 (emphasis added).

(2) "interoperability implies a 'two-way' relationship [wherein] the 'function of a computer program is to communicate and work together with other components of a computer system' . . . [and is defined] . . . as the 'ability to exchange information and mutually to use the information which has been exchanged,'"[195] thereby enabling competing software systems to interoperate with the domain architecture of the dominant software "on an equal footing with" the dominant software—referred to as "*client/server interoperability and server/server interoperability*;"[196] (3) market dominant companies that provide less than the degree of interoperability deemed necessary to enable developers of competing software systems "to remain viably on the market for those operating systems . . . retain a competitive advantage in terms of interoperability that hinder[s] . . . the maintenance of effective competition on that market . . . [by] *discourag[ing] . . . competitors from developing and marketing . . . systems with innovative features*"[197]; and (4) the failure of market dominant companies to provide the degree of interoperability deemed necessary to enable developers of competing software systems "to remain viably on the market" for those operating systems "*prejudices consumers*" and creates a situation wherein "an increasing number of consumers are locked into the dominant company's solution," thereby placing "a *limitation . . . on consumer choice*".[198]

During January 2011, the Düsseldorf Court of Appeals effectively repudiated this portion of the CIF's holding in the *Microsoft* case as being in contravention of E.U. law. In a decision involving the defendant's invocation of the compulsory license antitrust defense permitted by E.U.[199] [200] and German law [201] in a patent infringement action alleging

195. *Id.* ¶ 226 (quoting Council Directive 91/250/EEC, On the Legal Protection of Computer Programs, 1991 O.J. (L 122), 42, 43). *See also* Council Directive 91/250/EEC, *supra* note 120.

196. *Id.* ¶¶ 230–31 (emphasis added).

197. *Id.* ¶¶ 229, 653 (emphasis added).

198. *Id.* ¶¶ 650–53 (emphasis added).

199. Article 64(3) of the European Patent Convention (EPC)—"Rights Conferred by a European Patent" provides that "[a]ny infringement of a European patent shall be dealt with by national law." *See The European Patent Convention*, EUROPEAN PATENT OFFICE, *available at* http://www.epo.org/law-practice/legal-texts/html/epc/2010/e/ar64.html. *See also* Article 102 of the Treaty on the Functioning of the European Union (TFEU), Consolidated Version of the Treaty on the Functioning of the European Union, OJ C 115/01 (May 9, 2008), http://eur-lex.europa.eu/JOHtml.do?uri=OJ:C:2008: 115:SOM: en:HTML; http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2008:115:0001: 0012: EN:PDF; http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2008:115: 0047: 0199:en:PDF. "In order to ensure that the rules on competition concerning agreements, decisions of associations of undertakings and restrictive practices (Article 101) and abuses of a dominant position (Article 102), which are liable to be anticompetitive, are applied, the Commission has a number of powers to take decisions, to conduct investigations and to impose penalties. It exercises these powers

an abuse of the patent right by a market dominant holder of patents for the production of ink jet printer cartridges,[202] the Dusseldorf (Germany) Higher Regional Court found that the right of the proprietor of a patent to exclude third parties from manufacturing, offering, and marketing a patented invention without its consent constitutes *the substance of* the exclusive patent right. Therefore, even if a third party's unauthorized use of a patent were undertaken for an appropriate fee, it would still be deemed a "taking" of the patent holder's exclusive right, since a compulsory license attacks the core of an intellectual property right and thereby devalues it. According to the Court, the CIF's findings with respect to interoperability ignored the four-point test articulated in the prior case law of the European Court of Justice (ECJ),[203] which had considered the refusal to license a patent or other intellectual property right an "abuse" of a dominant market position justifying the Court's issuance of a compulsory license *only* in "exceptional circumstances".[204] An "abuse" of the patent right will be found, for example, only where the following evidence has first been presented:

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when, following a complaint or on its own initiative, it considers in a given case that there has been a violation of Article 101 or 102 TFEU." *See Application of Articles 101 and 102 TFEU (formerly Articles 81 and 82 of the EC Treaty)*, Europa Summaries of EU Legislation, *at* http://europa.eu/legislation_summaries/competition/firms/l26092_en.htm.

200. Article 82 of the Treaty establishing the European Community, which prohibited abuses of a dominant position, included within its scope "refusal[s] to license intellectual property" where there is an obligation "to supply the market" for the benefit of consumers. *See Communication from the Commission—Guidance on the Commission's enforcement priorities in applying Article 82 of the EC Treaty to abusive exclusionary conduct by dominant undertakings*, ¶¶ 75-85, OJ C 45/7 (2/24/2009), *at* http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2009:045:0007:0020:EN:PDF (citing in ¶ 78, Joined Cases C-241/91 P and C-242/91 *P Radio Telefis Eireann (RTE)* and *Independent Television Publications Ltd (ITP) v Commission (Magill)* [1995] ECR 743; Case C-418/01 *IMS Health v NDC Health* [2004] ECR I-5039).

201. *See* Patent Law (Ger.) art. 24, 81, 85, 139 (last amended 2009) (Ger.), *available at* http://www.aspenlawschool.com/books/kieff_nack/custom1materials/490GermanPatentLaw.htm.

202. *See* Düsseldorf Court of Appeals, Decision of January 20, 2011, Case I-2 U 92/10 (Ger.), *available at* http://www.justiz.nrw.de/nrwe/olgs/duesseldorf/j2011/I_2_U_92_10urteil20110120.html.

203. *See, e.g.*, Case C-481/01, IMS Health GmbH & Co OHG v. NDC Health GmbH & Co KG, 2004 ECR I-5039.

204. *Id.*; 2 U 92/10–ink cartridge (5), Düsseldorf Decision No: 1566, Düsseldorf Higher Regional Court ruling of 20 January 2011, file number 2 U 92/10, CIP Dusseldorfer Archive, *available at* http://www.duesseldorfer-archiv.de/?q=node/3477.

> (i) the use of the patent must be *indispensable to* exercise a particular activity, (ii) refusing to allow the use prevents the appearance of a *new product or services* for which there is potential consumer demand, (iii) the refusal is not objectively justified, *and* (iv) the refusal is of such a kind as to exclude any effective competition on a neighboring market.[205]

The Dusseldorf Court disagreed with the CIF on two significant points. First, it disagreed with the CIF's conclusion relating to (i) above—"that an input is already *indispensable* if it is necessary for the input-seeker to viably compete in the market".[206] Rather, the Dusseldorf Court determined that "an input is only indispensable if even a sufficient effort of the patent user would not make an actual or potentially realistic substitute of the particular input available."[207] Second, the Dusseldorf Court disagreed with the CIF's conclusion relating to (ii) above—"that it is sufficient for the *new product* criterion that the refusal to supply limits technical development to the detriment of consumers."[208] Rather, the Dusseldorf Court "argued that the new product requirement is only met if the new product is not substitutable with existing products that use the patent, i.e., it has to fall within a different relevant market."[209]

Arguably, the views and motivations of both the CIF and the European Commission had likely been shaped by promoters of the FOSS-driven[210] "software-as-a-service" (SaaS) business model[211] long favored by Microsoft competitors and civil society groups that had intervened in the case to support the European Commission.[212] With the evolution of FOSS-based "cloud computing" service offerings that have since generated the interest of cost-conscious governments,[213] it can be

205. *See Düsseldorf Court of Appeals Disagrees With Compulsory License Conditions in the Microsoft Judgment*, CLEARY GOTTLIEB NATIONAL COMPETITION REPORT, 9 (Jan.–Mar. 2011) (emphasis added), *at* http://www.cgsh.com/files/Publication/826fd136-ce10-4e23-8ba7-5923a4774a5a/Presentation/PublicationAttachment/9f5544e5-7087-40f4-96fe-592db37b3200/NCR%20Q1%202011.pdf; Eingestellt von Michael Thesen, *Compulsory Licenses and Abusive Behavior*, GERMAN IP BLOG (Apr. 11, 2011) (emphasis added), *at* http://germanip.blogspot.com/2011/04/compulsory-licenses-and-abusive.html.

206. *Id.*

207. *Id.*

208. *Id.*

209. *Id.* (emphasis added).

210. *Id.* ¶¶ 650–53 (emphasis added).

211. *Software as a Service: Strategic Backgrounder*, SOFTWARE & INFO. INDUS. ASS'N 4, 6 (Feb. 2001), http://www.siia.net/estore/ssb-01.pdf [hereinafter SOFTWARE & INFO. INDUS. ASS'N].

212. These interveners included Washington DC-based Software & Information Industry Association (SSIA), Hamburg, Germany-based Free Software Foundation Europe (FSFE), Brussels, Belgium-based European Committee for Interoperable Systems (ECIS) and Los Angeles, California-based Audiobanner.com, trading as VideoBanner.

213. *See, e.g.*, Matthew Goodrick, GSA Presentation on Federal Cloud Computing Initiative at the Software & Information Association Conference (June 17, 2010), http://www.siia.net/cloudgov/.

credibly argued in hindsight that the court's ruling reflected a successful lobbying effort to "capture" European governmental institutions for the ultimate purpose of laying the policy and legal groundwork for new regional and national Internet markets favoring a royalty-free or proprietary-free, non-licensing-based business model.[214] However, if the recommendations contained within a recently released European Commission Expert Study on public cloud computing[215] are any indication, it appears that these interest groups continue to be quite persuasive[216] even though there are evident limitations to establishing a proprietary-free "open" cloud forum based on interoperability framework standards.[217]

Therefore, the Indian government must seriously consider whether the CIF's ruling could have been reached without resorting to the very broadly conceived and newly advanced concept of ICT "interoperability" promoted by certain members of industry and civil society. The notion of interoperability articulated by the CIF was apparently derived from, and consistent with, the questionably broad interpretation of the same overstretched socio-economic human rights theory discussed in the WIPO experts' study on compulsory licensing and human health.[218] The CIF's ruling was not premised on an "objective" finding of "exceptional circumstances" consistent with prior European statutory and case law, despite legal commentators' efforts to characterize it as such.[219]

214. *See* SOFTWARE & INFO. INDUS. ASS'N, *supra* note 197, at 12–14.

215. Lutz Schubert, *The Future of Cloud Computing: Opportunities for European Cloud Computing Beyond 2010*, EUR. COMM'N, INFO. SOC'Y AND MEDIA, 3–4 (2010), http://cordis.europa.eu/fp7/ict/ssai/docs/cloud-report-final.pdf.

216. *Id.* at 1–2.

217. *Id.* at 19, 23.

218. *See* World Intellectual Property Organization, *Patent Exceptions and Limitations in the Health Context*, *supra* note 72, at 1–3.

219. *See, e.g.*, Pierre-André Dubois & Shannon Yavorsky, *Cross-border: Europe, The Microsoft Decision: The Evolution of Compulsory Licensing in the European Union*, KIRKLAND & ELLIS INT'L LLP (2008), http://www.buildingipvalue.com/08_ EMEA/119-122Kirkland.pdf.

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

1. WIPO Reports, European Officials and NGOs Have Called For New Public Mechanisms to Regulate Private FRAND/RAND Licensing on "Public Interest" Grounds

According to the WIPO Secretariat's *Report on the International Patent System*[220] and its *Report on Patents and Standards*,[221] 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."[222] Although at least one prominent European standards development organization (SDO)[223] 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 U.K. law, which recognizes patents and patent applications as a form of personal property,[224] 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 intellectual property rights are guaranteed at the domestic and international levels.

The expanding WIPO SCP agenda championed by technology-aspiring developing country governments and United Nations officials, however, generally characterizes this prognosis as overly simplistic and exploitative.[225] In particular, such agenda views the ordinary exercise of

220. World Intellectual Property Organization, *Report on the International Patent System*, *supra* note 84.

221. *See* World Intellectual Property Organization, Standing Committee on the Law of Patents, Mar. 23–27, 2009, *Standards and Patents*, U.N. Doc. SCP/13/2/PROV, 13th Sess. (Feb. 18, 2009).

222. World Intellectual Property Organization, *Report on the International Patent System*, supra note 84, ¶ 116; *see also id*. at ¶¶ 28, 54–64, 66, 117.

223. *See* Karsten Meinhold, Chairman, ETSI IPR Special Committee, The ETSI IPR Policy: A Key Element for the Success of ETSI's Globally Applicable Standards, at 1–2 at the EC Workshop on Intellectual Property Rights in ICT Standardisation (Nov. 19, 2008) (presenting at EC Workshop on Intellectual Property Rights in ICT Standardisation), http://ec.europa.eu/enterprise/newsroom/cf/_getdocument.cfm?doc_id=3635.

224. The Patents Act, 1977, c. 37 §§ 30(1), 31(2), (as amended) (Eng.) (Intellectual Property Office 2010), *available at* http://www.ipo.gov.uk/patentsact1977.pdf.

225. *See* United Nations Conference on Trade and Development, *Addressing the Interface Between Patents and Technical Standards in International Trade Discussions*,

private IP rights as creating an impediment to the critical public role served by technical standardization in promoting ICT system *interoperability*, innovation, jobs creation and investment, and recommends that patent rights be legislatively or administratively curtailed for the benefit of the public interest. Apparently, a growing number of European Commissioners and E.U. Member State government officials also share this negative outlook, especially concerning software. It is arguable, for example, that the E.U. Commission's prior recommendation to E.U. 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)[226] was no less an indictment of exclusive private contractual and patent rights.

European civil society pressure groups have also promoted the notion that patents impede software interoperability and should be severely restricted by governments. For example, the German-based Free Software Foundation Europe (FSFE),[227] an outspoken NGO endeavoring to influence regional and international ICT policy within both the E.U. and the WIPO, has insisted that because "both patents and standards derive their justification from the public benefit" and "[the] [u]pholding [of] one deprives the other of its function,"[228] "patents which limit or prevent *interoperability* should be [rendered legally] *unenforceable*."[229]

Policy Brief No. 3, at 3–4 (Feb. 2009), http://www.unctad.org/en/docs/iprs_pb20093_en.pdf; United Nations Development Programme, e-Government Interoperability: Guide, at 6 (2007), http://www.apdip.net/projects/gif/GIF-Guide.pdf.

226. "When implementing a national interoperability framework the emphasis is obviously on 'interoperability'. Standardisation in technology and harmonisation in legislation are just two ways to achieve this. Other recommendations are . . . *keep administrative systems independent of proprietary technology*." *European Interoperability Framework for Pan-European eGovernment Services Version 1.0*, European Communities Brochure, at 26 (2004), http://www.apdip.net/projects/gif/country/EU-GIF.pdf, [hereinafter *EIFv.1.0 Brochure*]; *European Interoperability Framework for Pan-European eGovernment Services Version 1.0*, European Communities, at 26 (Nov. 2004), http://xml.coverpages. org/IDA-EIF-Final10.pdf, [hereinafter *EIFv.1.0*].

227. *See* FREE SOFTWARE FEDERATION EUROPE, http://www.fsfe.org/.

228. George Greve, *Innovation Policy: The Balance Between Standards and Patent Regulation*, INTELLECTUAL PROPERTY WATCH INSIDE VIEWS, Feb. 26, 2009, http://www.ipwatch.org/weblog/2009/02/26/inside-views-innovation-policy-the-balance-between-standards-andpatent-regulation/.

229. "During the software patent debate in the European Union *there was consensus among SME, Free Software and big businesses representatives from companies such as IBM or Sun Microsystems that patents which limit or prevent interoperability should be unenforceable*. In the European Union, this could be introduced into the ongoing

A similar but more nuanced position has been advanced by the European Committee for Interoperable Systems (ECIS),[230] an influential Brussels-based NGO. ECIS represents ICT companies seeking to secure legislation at the E.U. 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 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) "promot[es] innovation in the public interest;" (3) "take[s] into account the importance of interoperability of information and communications technology;" and (4) ensures against "[o]verbroad patent protection that frustrates interoperability in the ICT sector"—in other words, it "ensure[s] . . . [that] patents cannot be used as a means of confining users to a particular technology by closing off full interoperability."[231]

In its earlier comments submitted in response to an April 2006 European Community patent questionnaire, the ECIS had plainly stated 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.[232] 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' position is strikingly similar in principle to the legislative proposal set forth in the Japanese Ministry of Economy, Trade and Industry's (METI) 2005 Interim Report on the legal protection of software,[233] though the connection between them may never be known. In

Community Patent debate. On a global level, WIPO should consider this as part of its ongoing Development Agenda discussions." (emphasis added). George Greve, *Analysis on Balance: Standardisation and Patents*, FREE SOFTWARE FOUND. EUR. (Dec. 2, 2008), http://www.fsfe.org/projects/os/ps.en.pdf.

230. *About ECIS*, EUROPEAN COMMITTEE FOR INTEROPERABLE SYSTEMS, http://www.ecis.eu/about/index.html.

231. *See ECIS Patent Consultation Contribution* (July 2006), *available at* http://ec.europa.eu/internal_market/indprop/docs/patent/hearing/vinje_ecis_en.pdf.

232. *See ECIS Reply to the EC Patent Consultation*, at 3 (Apr. 2006), *available 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.

233. *See* METI Commerce and Information Policy Bureau, *Interim Report of "Study Group on the Legal Protection of Software and Promotion of Innovation*," (Oct.

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.[234] Fortunately, these interim recommendations were never incorporated within the final proposed (non-binding) "General Rules on Software-related Intellectual Property" (General Rule) legislation METI subsequently released during 2007[235] which boasted other deficiencies. If implemented, the proposed rule changes would have established a software interoperability exception to the broad exercise of software patent rights on "public interest" (promoting software innovation) grounds.[236] For example, such exception would have entitled a party to a full release from liability for infringing another's software patent without a license upon a showing that there was "a *need* to achieve interoperability."[237]

11, 2005), *available at* http://www.meti.go.jp/english/information/downloadfiles/051017LegalProtectionSoftware.pdf.

234. *Id*. at 3–4; *see also* Michael Chapin, *Sharing the Interoperability Ball on the Software Patent Playground*, 14 B.U. J. SCI. & TECH. L. 220, 237 (2008), *available at* http://www.bu.edu/law/central/jd/organizations/journals/scitech/documents/Chapin.pdf ("To promote innovation and to address the needs of interoperability, the study proposes three possible changes to the patent law specifically related to software. These changes include a restriction on the exercise of patent rights on a case-by-case basis by using some type of abuse of rights principle, a compulsory license granted on a case-by-case basis, or a general restriction on the exercise of patent rights through an amendment to the Patent Act specifically aimed at limiting the effects of software patents."). *Id*. at 236.

235. For an English translation and summary of the proposed rule, see Kenji Shimada, Yi-Hsuan Chen, Chi-Yuan Kuo, Alfredo DeLaRosa, and Jeremiah Miller, *Patents as Property: International Injunctive Relief*, 14 CASRIP ONLINE NEWSLETTER (Summer 2007), http://www.law.washington.edu/Casrip/Newsletter/default.aspx?year=2007&article=newsv14i3Shimada; *see also Comments on the Draft of Rule Concerning Software Related Intellectual Property*, BUSINESS SOFTWARE ALLIANCE ASIA, 2 (July 12, 2006), http://www.bsa.or.jp/file/BSA_Comments_English_060712.pdf.

236. *See, e.g.*, Kazuaki Okimoto, Patent Attorney, Yuasa & Hara Compulsory License on Patented Drug for H1N1 Influenza Virus, 2, at APAA 56th Council Meeting (Nov. 10, 2009), http://www.apaaonline.org/pdf/APAA_56th_&_57th_council_meeting/emergingIP/2-Japan%Emerging%20IP%20Rights%20Cttee%20Country%20Report%202009.pdf (presenting at Emerging Intellectual Property Rights Committee Meeting of the APAA 56th Council); Michael Chapin, *supra* note 220, at 224.

237. Michael Chapin, *supra* note 220, at 237 (referencing Press Release, METI, Request for Public Comments on Rules on Software Intellectual Property Rights (June 13, 2006) (emphasis added), *available at* http://www.meti.go.jp/english/newtopics/data/n060613e.html).

The ECIS' position regarding "patent abuses" also borrows from the "license of right," a governmental mechanism [238] provided for under the British[239] and German[240] patent laws and discussed within the WIPO *Report on Patents and Standards*.[241] A license of right is essentially a nonexclusive license entered into voluntarily and under reasonable terms by the patent owner with all interested prospective licensees in exchange for reduced Patent & Trademark Office registration and renewal fees.[242] Once a patent has been registered, any prospective licensee 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, U.K. and German law provide that a designated national patent office official will make such determination.[243] "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."[244] Also, if during the course of an infringement action an E.U. 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 . . . if such a license on those terms had been granted."[245] Since a patent owner's taking of a license of right necessarily entails the surrender of its entitlement to injunctive relief, a license of right, by definition, is incomparable to a private "FRAND" (fair, reasonable, and non-discriminatory) contractual

238. Open Letter to the European Commission, European Committee for Interoperable Systems (Mar. 2010), *available at* http://www.ecis.eu/documents/OpenLettertotheEuropeanCommissionMarch2010.pdf.

239. *See* The Patents Act 1977, *supra* note 210, § 46.

240. *See* Patent Law § 23 (Dec. 16, 1980) (last amended 1994) (Ger.), *available at* http://www.wipo.int/wipolex/en/text.jsp?file_id=126195; *see* Tanuja V. Garde, *Supporting Innovation in Targeted Treatments: Licenses of Right to NIH-Funded Research Tools*, 11 MICH. TELECOMM. & TECH. L. REV. 249, 280 (2005), *available at* http://www.mttlr.org/voleleven/garde.pdf (stating "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.").

241. *See* WIPO, *Standards and Patents*, *supra* note 207, ¶ 143.

242. *See id.* at 279; Patent Law (Ger.), *supra* note 187, § 23(1).

243. Tanuja V. Garde, *supra* note 226, at 279 (citing The Patent Act (Eng.), *supra* note 210, §§ 46(3)(a), 46(3)(b)); Patent Law (Ger.), *supra* note 187, §§ 23(3), 23(4).

244. ITSSD, *ITSSD Comments Concerning SCP/13/2: Standards and Patents*, *supra* note 135, at 39 (citing The Patents Act 1977, *supra* note 210, §§ 46(2), 46(4)).

245. *Id.* (citing The Patent Act (Eng.), *supra* note 210, § 46(3)(c)).

undertaking pursuant to which the injunctive relief remedy remains available to the patent owner.[246]

A historical review of U.K. patent law (the U.K. Patents and Designs Act of 1919) reveals that the license of right once functioned as a compulsory licensing statute. Therefore, the fact that "the UK courts [continue to] look to [UK] case law deciding issues arising under the compulsory licensing provisions as persuasive for cases decided under Section 46, licenses of right" strongly suggests that licenses of right remain closely related to and largely constitute nothing more than *de facto* compulsory licenses in disguise.[247]

Clearly, while BRICS governments and the free and open source software (FOSS) movement[248] generally consider voluntary licenses of right and compulsory licenses (which are each legal measures *internal to* the patent system) as attractive, they nevertheless recognize that such measures alone are incapable of remedying "refusals to license" on reasonable terms and conditions. These same parties similarly view judicially imposed settlements (*de facto* compulsory licenses) in antitrust actions involving patents (which are legal measures *external* to the patent system) as insufficient to curtail noncompetitive behaviors, such as refusals to license, that do not otherwise rise to the level of patent "abuses." In acknowledgement of the legal and political conditions that national laws implementing applicable WTO TRIPS Agreement provisions place upon the accessibility and utility of de jure and de facto compulsory licenses, the FOSS movement has promoted an alternative approach. Such approach invokes the "public interest" *a priori* to restrict the exercise

246. The ECIS had previously tried to portray these two concepts as comparable at a panel organized by the European Commission during November 2010. *See* Agenda of Information and Communication Technologies Conference, *Certainty of Availability and Continuity of Essential IP Rights for Licensing*, at Panel 4: Tensions Between Intellectual Property Rights and Standardisation: Reasons and Remedies (Nov. 22, 2010), http://ec.europa.eu/enterprise/sectors/ict/files/ictpolicies/agenda_ict_workshop_new_en.pdf (summarizing panel moderated by ECIS Legal Counsel Thomas Vinje, and organized by the European Commission and the European Patent Office (EPO)); *see also* Press Release, European Community, Tensions Between Intellectual Property Rights and the ICT Standardisation Process: Reasons and Remedies (Nov. 22, 2010), http://ec.europa.eu/enterprise/sectors/ict/files/10-08-24_announcement_of_the_event.pdf.

247. *See* Tajuna V. Garde, *supra* note 226, at 280–81.

248. The FOSS movement is represented by the Boston, Massachusetts-based Free Software Foundation, its European sister organization FSFE (Free Software Federation Europe) and the Brussels, Belgium-based OpenForumEurope (OFE). See *What We Do*, FREE SOFTWARE FEDERATION, http://www.fsf.org; *Who We Are and What We Do*, OPEN FORUM EUROPE, http://www.openforumeurope.org/about/who-we-are-and-what-we-do.

of private patent and contract rights that could possibly impede the development of "open ICT standards" designed to ensure interoperability. If employed as intended, this approach would fundamentally enable governments to oversee and determine the self-regulating patent licensing policies and procedures established and enforced by private standards-setting organizations (SSOs) and standards development organizations (SDOs), including informal consortia, vis-à-vis their members, and also potentially, between SSO or SDO members and foreseeable affected nonmembers. It may ultimately even extend to specific FRAND contractual licensing terms.[249]

Implicit in the "public good" of open standards-based interoperability are the legal principles of detrimental reliance and promissory estoppel. According to at least one FOSS commentator, the

> crucial element distinguishing patent licensing in a standard setting from a normal patent licensing situation is that: 1) the IPR owners have promised to license on FRAND terms; 2) the SDO has entered into an agreement to limit inter-technology competition that would otherwise have existed in reliance upon said promise; and 3) industry has relied on said promise by making investments in innovation.[250]

Nevertheless, companies have often successfully argued that an SSO or SDO member promise to license pursuant to FRAND terms is unenforceable in contract or under promissory estoppel principles because it is merely a promise to negotiate.[251] As a result, FOSS-favoring NGOs have called for governments to define, if not to oversee, the implementation of SSO or SDO *ex ante* patent disclosure rules, fair, reasonable and nondiscriminatory licensing terms, and reasonable royalty rates, despite the chilling effect it would have on SSO/SDO activities and member commercial transactions.[252]

If widely adopted, this approach, which champions the broader collective public interests of ICT technology users and consumers over the rights of individual patent holders, would likely serve to minimize the key economic incentives for securing ICT patent grants, whether or not the holders of such patents are members of an SSO/SDO and

249. *See* Lawrence A. Kogan, The Complementarity of Patents and Standards, presented as Part 1–of the Panel on the Intersection of IP, Competition and International Trade, at The Inter-Pacific Bar Association 21st Annual Meeting & Conference (Kyoto, Japan, Apr. 24, 2011), Unabridged Outline, at 11–25, *available at* http://itssd.org/The%20Complementarity%20of%20Patents%20and%20Standards%20-%20Unabridged%20Outline.pdf [hereinafter Kogan, The Complementarity of Patents and Standards].

250. *See, e.g.*, Maurits Dolmans, *A Tale of Two Tragedies—A plea for open standards*, 2 INT'L FREE AND OPEN SOURCE SOFTWARE L.R. 115, 123, at n.38 (Issue 2, 2010), *at* http://www.ifosslr.org/ifosslr/article/view/46/72.

251. *Id.* at 134.

252. *See* Kogan, The Complementarity of Patents and Standards, *supra* note 235.

participating in standards development activities. The evidence seems to reflect that the European Commission had systematically incorporated this approach into the E.U.'s initial interoperability framework for eGovernment services released during 2004, which the European Court of First Instance thereafter relied upon in the *Microsoft* case.

The WIPO *Report on the International Patent System* reflects that the FOSS movement has helped the BRICS nations to characterize ICT "interoperability" as falling within the penumbra of "public interest" concerns anticipated by the WTO TRIPS Agreement.[253] In addition, the WIPO *Report on Patents and Standards* reveals that ICT "interoperability," as a "public interest" concern, must ensure societal "balance" that generally works to the benefit of "the many," namely, commercial information and communication technology users and consumers, at the expense of the relatively few ICT patent holders.[254] This latter report also emphasizes that ICT interoperability, especially in the context of *e*-Government solutions,[255] necessitates the least costly and most universally accessible "open standards" incorporating only those patented technologies deemed "essential" to the functioning of the standard.[256] For example, the report suggests how the FOSS movement was influential in redefining the term "open standard"—from one focused primarily on the "openness" and inclusiveness of the standard development process *and* on the

253. "Article 8 [of the TRIPS Agreement] provides 'principles' which recognize the rights of Members to adopt measures necessary to protect public health and nutrition, and *to promote the public interest in sectors of vital importance to their socio-economic and technological development*, provided that such measures are consistent with the provisions of this Agreement. It also recognizes that appropriate measures, provided that they are consistent with the Agreement, may be needed *to prevent the abuse of intellectual property rights by right holders* or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology." *See* World Intellectual Property Organization, *Report on the International Patent System*, *supra* note 84, at ¶ 141, at 42 (emphasis added). The subjects of ICT interoperability and related standards issues are discussed in ¶¶ 7, 111–22, 252, and 269 of said report.

254. *See* WIPO, *Standards and Patents*, *supra* note 207, at ¶¶ 41, 87, 117, 137, 140, 142, 145 ('balance'); World Intellectual Property Organization, *Report on the International Patent System*, *supra* note 84, at ¶¶ 37, 62–63, 106, 117, 119, 141, 172, 235 ('balance').

255. *See* WIPO, *Standards and Patents*, *supra* note 207, at ¶ 44; ITSSD, *Supplement to ITSSD Comments Concerning the WIPO Report on Standards and Patents (SCP/13/2) Paragraph 44*.

256. *See* WIPO, *Standards and Patents*, *supra* note 207, at ¶¶ 3, 41 ('open standards'); ¶¶ 44, 128 ('open source' software).

prevailing FRAND/RAND private contract-based pricing model[257]—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.[258]

The WIPO *Report on Patents and Standards*, moreover, betrays the assumption that predefined and *ex ante* disclosed royalty-free and unlimited use patent licensing terms employed by such consortia are more compatible with FOSS licenses and less conflict-ridden[259] and legally risky,[260] and hence, more economically efficient than non-binding, flexible, unfixed patent royalty pricing terms that traditional SSOs and SDOs remain unwilling to and incapable of enforcing against member or nonmember technology patent owners.[261] This "public interest" approach also assumes that the allegedly less precise, less transparent, and economically inefficient market-driven private contractual FRAND/RAND pricing and licensing policies adopted by traditional SSOs/SDOs, when implemented by their members, can and often do contribute to a violation of the public trust.[262] In other words, such policies rarely result in the least costly 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 E.U. Member State governments had fallen victim to "vendor lock-in" at taxpayer expense.[263]

However, this last point begs the proverbial question, "which came first, the chicken or the egg?" considering that the national and provincial

257. For a discussion of the definition traditionally adopted by recognized national and international standards organizations such as ANSI and the ITU, see WIPO, *Standards and Patents*, *supra* note 207, ¶¶ 41–42 and accompanying footnotes.

258. *Id.* at ¶¶ 9, 43, 111–16 and accompanying footnotes; *see generally* Lawrence A. Kogan, *How SMART are Standards that Sacrifice Intellectual Property Rights?* (Apr. 15, 2010), http://itssdinternationaliprights.blogspot.com/2010/04/how-smart-are-standards-that-sacrifice_18.html (presented at American National Standards Institute (ANSI) Intellectual Property Rights Policy Committee (IPRPC) Meeting), *at* http://itssd.org/How%20SMART%20are%20Standards%20that%20Sacrifice%20Intellectual%20Property%20Rights%20-%20Full%20Outline.doc.

259. *See* WIPO, *Standards and Patents*, supra note 207, at ¶¶ 111, 128.

260. *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, http://www.osor.eu/idabc-studies/expert-docs/patents-and-opensource-software; http://ec.europa.eu/idabc/servlets/Doce6a8.pdf?id=28129.

261. *See* WIPO, *Standards and Patents*, *supra* note 207, at ¶¶ 117–24, 126–27.

262. *See* Rishab A. Ghosh, *Free/Libre/Open Source Software: An Economic Basis for Open Standards*, MERIT UNIVERSITY OF MAASTRICHT, 13 (Dec. 2005), http://www.flosspols.org/deliverables/FLOSSPOLS-D04-openstandards-v6.pdf.

263. *See* Rishab Aiyer Ghosh, Ruediger Glott, Patrice-Emmanuel Schmitz & Abdelkrim Boujraf, *OSOR Guidelines: Public Procurement and Open Source Software* public draft version 1.0: 10 (Oct. 2008), at 48–51 and 104–10, http://www.osor.eu/idabc-studies/OSS-procurement-guidelinepublic-draft-v1%201.pdf.

governments of several E.U. Member States had already been promoting and expressing preferences for open source software in government procurement bids[264] 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).[265]

Arguably, the E.U. Commission was *driven* initially to establish a FOSS-centric ICT interoperability framework at the E.U. regional level for the following reasons. First, it was believed that such a framework would serve to reconcile and harmonize the differing national government open source software procurement practices consistent with the E.U. regional public interest, namely, to "ensure public policy objectives and societal needs are respected."[266] Second, it was believed that such a framework would likely facilitate the exercise of the E.U. Commission's public procurement function, which as of 2007–2008 had already exceeded 16.3% of E.U. Community GDP.[267] Since government procurement had been predicted to reach 19% of E.U. Community GDP by end of 2010,[268] ambitious E.U. government officials, furthermore, viewed the framework as potentially helping them to also shape and sustain the growth of *private* open source technology markets throughout the E.U. region.[269] Third, it was believed that such a framework would fall within the clear parallels drawn by the FOSS movement between their preferred approach concerning ICT patents and standardization and that ultimately adopted in the EU Software Copyright Directive.[270]

264. *See* ITSSD, *Supplement to ITSSD Comments Concerning the WIPO Report on Standards and Patents (SCP/13/2) Paragraph 44*, *supra note* 241, at 4–7 and accompanying endnotes (Jan. 2010).

265. *Id.* at 7–10.

266. *See Commission White Paper: Modernising ICT Standardisation in the EU–The Way Forward*, at 3, 4, COM (2009) 324 final (July 3, 2009); http://ec.europa.eu/enterprise/ict/policy/standards/whitepaper.pdf.

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

268. *See* Kevin J. O'Brien, *Technology Rivals Lobby to Break Microsoft's Hold*, N.Y. TIMES, Jul. 18, 2010, *available at* http://www.nytimes.com/2010/07/19/technology/19iht-eusoftwar19.html?_r=1.

269. *See Commission White Paper: Modernising ICT Standardisation in the EU–The Way Forward*, *supra* note 252, at 2.

270. *DLA Piper Study*, *supra* note 253, at 109.

Indeed, at least one E.U. Commission-sponsored report specifically recommended that

> open standards for software markets should be defined in order to be compatible with F[]OSS 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.[271]

It would appear in hindsight that the initial version of the European Interoperability Framework (EIF v1.0) contained many of these underlying assumptions and recommendations.[272]

Thereafter, however, the open source community became increasingly dissatisfied with the ICT stakeholder engagement process that had evolved because none of the subsequent versions of the draft EIFv2.0 ((EIF v2.0'A' (2008),[273] (EIFv2.0'B' (2009)),[274] or (EIFv2.0'C' (2010)[275]) 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 had been steadily pared back by industry[276] so that it would become possible for E.U. regional and Member State government officials to continue selecting proprietary ICT standards alongside open source ICT standards in satisfying their procurement needs, a result which the FOSS movement finds completely unacceptable.[277] For example, after comparing the changes contained within each of the versions of the draft EIFv2.0, the OFE accused the E.U. Commission of having been unduly influenced by industry "outside of the democratic and transparent processes that bind

271. Ghosh, *Free/Libre/Open Source Software: An Economic Basis for Open Standards*, *supra* note 248, at 3, 21 (emphasis added).

272. *See EIFv.1.0 Brochure*, *supra* note 212, at 8, 9.

273. European Interoperabiliity Framework for Pan-European eGovernment Services, Draft for Public Comments–As Basis for EIF 2.0, European Communities (© Jan. 15, 2008).

274. *European Interoperability Framework for European Public Services*, Version 2.0, European Commission Unofficial Leaked Draft (Nov. 2009), http://blog.webwereld.nl/wp-content/uploads/2009/11/European-Interoperability-Framework-for-European-Public-Services-draft.pdf.

275. European Interoperability Framework for Pan-European eGovernment Services, Version 2.0 (Apr. 2010) (unpublished manuscript).

276. Karsten Gerloff & Hugo Roy, *EIFv2: Tracking the Loss of Interoperability*, FREE SOFTWARE FOUND. EUR. (Dec. 16, 2010), http://fsfe.org/projects/os/eifv2.en.html#.

277. Stephan Krempl, *Protests Against Proposed Redefinition of Open Standards Within the EU*, THE H (Nov. 10, 2009, 11:12 AM), http://www.h-online.com/open/news/item/Protests-against-proposed-redefinition-of-open-standards-within-the-EU-854651.html.

the European institutions . . . to maintain past practice," and insisted that the E.U. Commission reinstate the first draft of EIFv2.0.[278]

Irrespective of whether these allegations were true, they were largely premised on the E.U. Commission recommendation contained within EIFv1.0 that "EU Member States . . . *keep administrative systems independent of proprietary technology*" when "implementing a national interoperability framework."[279] 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. In such an instance, E.U. government procurement officials could have conceivably precluded 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 or compatible with FLOSS licensing terms.[280]

Judging from the final EIF the European Commission released on December 16, 2010,[281] however, it would be difficult for these groups to claim that their efforts were successful. First, the new E.U. EIF eliminates all references to the term "open standards" and instead 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.[282] Second, the new E.U. 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

278. Letter from Graham Taylor, CEO, OpenSource Europe (Mar. 22, 2010), *available at* http://www.openforumeurope.org/press-room/press-releases/ofe-eif-v2-0-response.pdf/view.

279. EIF v.1.0 Brochure, *supra* note 212 (emphasis added).

280. *Id.*

281. *See Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of Regions 'Toward interoperability for European public services'*, Annex 2, COM (2010) 744 final § 5.2.1. (Dec. 16, 2010).

282. *See* Press Release, European Comm'n, Commission Adopts Interoperability Strategy and Framework for Public Services—Frequently Asked Questions, MEMO/10/689 (Dec. 16, 2010), *available at* http://europa.eu/rapid/pressReleasesAction.do?reference=MEMO/10/689&form.

new E.U. 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).[283] It also requires that any intellectual property rights associated with such specification are licensable on FRAND *or* royalty-free terms that permit the specification's implementation in both proprietary and open source software. As the European Commission explained, "full openness" would enable "companies working under various business models [to] 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 license if they so decide."[284] 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.[285] Although the new E.U. 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, notwithstanding the potential for Member State and interest group arbitrage and gamesmanship to enter into the political equation.[286]

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 had long been engaged. To this

283. *Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of Regions 'Toward interoperability for European public services'*, *supra* note 267, § 5.2.1.

284. *See* European Comm'n, Commission Adopts Interoperability Strategy and Framework for Public Services—Frequently Asked Questions, *supra* note 268.

285. *See Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of Regions 'Toward interoperability for European public services'*, *supra* note 267, § 5.2.1 (stating recommendation 22: "When establishing European public services, public administrations should prefer open specification, taking due account of the coverage of functional needs, maturity and market support").

286. *See id.* §§ 1.5.2, 2.2, 3.2.2.1, 4.2–.3, 4.5; *see also* Press Release, European Comm'n, Towards Interoperability for European Public Services, IP/10/1734 (Dec. 16 2010), *available at* http://europa.eu/rapid/pressReleasesAction.do?reference=IP/10/1734 &, David Meyer, *Europe Backs Open Standards in Interoperability Drive*, ZDNET (Dec. 16, 2010, 5:14 PM).

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 broadband,[287] health,[288] energy,[289] and transport.[290] Consequently, the E.U. Commission's recent ability to ostensibly reconcile these various EIF drafts to the apparent satisfaction of all concerned parties substantially diminishes 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 ICT government procurement preference for universally accessible and disclosed nonproprietary or royalty-free ICT technologies, *especially* in BRICS and developing nations, will implicate related trade secret protected knowledge and information.[291] Trade

287. *See Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions: A Digital Agenda for Europe*, § 2.4, COM (2010) 245 final/2 (Aug. 26, 2010).

288. *See* Flora Giorgio-Gerlach, European Comm'n, Info. Soc'y & Media Directorate-Gen., ICT for Health, European Commission Strategy for eHealth Interoperability, Presentation at CALLIOPE Open Session (Oct. 9, 2008), *available at* http://www.calliope-network.eu/Portals/11/assets/documents/Crete_Presentations/CAL%202008-10-09%20s11%20Giorgio%20%20EC%20Strategy%20Interoperability.pdf; *Communication from the Commission to the Council, the European Parliament, the European Economic and Social Committee and the Committee of the Regions: E-Health—Making Healthcare Better for European Citizens*, at 16–17, COM (2004) 356 final (Apr. 30, 2004).

289. *See ICT for a Low Carbon Economy: Smart Electricity Distribution Networks*, EUROPEAN COMM'N, INFO. SOC'Y & MEDIA DIRECTORATE-GEN., ICT FOR SUSTAINABLE GROWTH UNIT (July 2009), *available 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); *ICT and e-Business Impact in the Energy Supply Industry: Sectoral e-Business Watch Study Report No. 03/2009*, INT'L DATA CORP. (IDC) EMEA on behalf of the European Comm'n, Enter. & Indus. Directorate-Gen. (Dec. 2009), *available at* http://ec.europa.eu/enterprise/archives/e-business-watch/studies/sectors/energy_supply/documents/FR03-2009_Energy-supply.pdf.

290. *See* European Commission, Enterprise & Industry Directorate-General, Standardisation Mandate Addressed to CEN, CENELEC and ETSI in the Field of Information and Communication Technologies to Support the Interoperability of Cooperative Systems for Intelligent Transport in the European Community, M/453 EN (Oct. 6, 2009).

291. *See* Lawrence Kogan, Précis of ITSSD Side-Bar Event: Can Government Intervention Sustain Economic Incentive, Technological Innovation, and Capital Flows?, Remarks at ITSSD Side-Bar Event (Oct. 12, 2010), *available at* http://www.itssd.org/ITSSD%20WIPO%20SCP%20Side-bar%20Geneva%2010-12-10%20Precis%20Final.pdf, at 12.

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.[292]

Perhaps the E.U. 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.[293] Given the increasing "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 "[i]nformation and know-how may be a company's most valuable asset . . . [and] . . . for many Internet companies, it may be their *only* asset."[294] Indeed, as the vaunted Berkeley Patent Study which focuses heavily on software firms[295] 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." Simply stated, 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."[296] 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.]"[297] And, perhaps the E.U. Commission finally recognized that it could not simply ignore that public

> [c]orporations, 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 company's 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

292. "[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." Peter J. Toren, *Protecting Inventions as Trade Secrets: A Better Way When Patents are Inappropriate, Unavailable* (2000), FINDLAW, http://library.findlaw.com/2000/May/1/130451.html. *See also* Karl R. Jorda, *Patent and Trade Secret Complementariness: An Unsuspected Synergy*, 48 WASHBURN L.J. 1, 1 (2008) ("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.").

293. *See* Jorda, *supra* note 278, at 1.

294. *See* Toren, *supra* note 278 (emphasis added).

295. *See* Stuart J.H. Graham, Robert P. Merges, Pam Samuelson & Ted Sichelman, *Hich Technology Entrepreneurs and the Patent System: Results of the 2008 Berkeley Patent Survey*, 24 BERKELEY TECH. L.J. 1255, 1312 (2009).

296. *Id.* at 1309–10.

297. *Id.* at 1312.

> through theft or dissipation [through] . . . control of information leaving the organization . . . This involves . . . keeping close track of the company's secrets.[298]

Ultimately, it is possible that the E.U. Commission came to understand that had it incorporated the "open standards" definition established by EIFv1.0 which expressed a preference for *non*proprietary 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 may also have learned, albeit lately, of the deleterious downstream impacts that its serious consideration of such an administrative preference for *nonproprietary or royalty-free* ICT technologies had already had on third-country government ICT procurement law and policy formulation.[299] Indeed, it could no longer ignore how the prolonged EIF debate had managed to encourage similar adventurism within the U.S. government to reshape the American healthcare and energy sectors.

For example, at the insistence of the same or similar interest groups and industry stakeholders,[300] the Obama administration, like certain E.U. Member States, such as the United Kingdom and Portugal,[301] had enacted legislative and administrative royalty and license-free government procurement open standards criteria to ensure software interoperability of electronic health records[302] ("the standard to govern the transmission and interoperability of medical data between healthcare facilities and insurers, doctors, pharmacies and the wider healthcare establishment")[303]

298. *See* James Pooley & Katherine Nolan-Stevaux, *Trade Secrets and Corporate Governance: Best Practices*, INTELL. PROP. OWNERS ASS'N, 1–2, http://www.ipo.org/AM/Template.cfm?Section=Trade_Secrets&Template=/CM/ContentDisplay.cfm&ContentID=22924 (footnote omitted).

299. *See* discussion *infra*.

300. *See Supplement to ITSSD Comments Concerning the WIPO Reports on Standards and Patents (SCP/13/2) Paragraph 44*, *supra* note 241, at 20–26, 39–43 nn.184–243; Kogan, *supra* note 165, at 4–8.

301. *See* discussion *infra*.

302. *See Supplement to ITSSD Comments Concerning the WIPO Reports on Standards and Patents (SCP/13/2) Paragraph 44*, *supra* note 241, at 21–22, 40 n.198; Kogan, *supra* note 165, at 9–21.

303. Ken Zita, *China Healthcare ICT: Reinventing China's National Healthcare System Through Electronic Medical Records, Telecom Networks and Advanced IT Services*, 1 JOURNAL ON EMERGING KNOWLEDGE ON EMERGING MARKETS 47, 52 (2009), http://digitalcommons.kennesaw.edu/cgi/viewcontent.cgi?article=1005&context=jekem.

and similar but less than transparent final regulations[304] implementing a recently enacted law to ensure the interoperability of electronic medical records[305] ("the data standard for formatting 'cradle-to-grave' patient medical history information.")[306] Furthermore, the Obama administration remains in the process of developing royalty or proprietary-free government procurement open standards criteria to ensure software interoperability of evolving smart energy grid technologies and to avoid vendor lock-in which, in each case, as in Europe, favors the user and consumer rather than the innovator and investor viewpoint.[307] Moreover, the Obama administration arguably has misguidedly ignored industry stakeholder claims that the adoption of such policies will negatively influence standards development and law and policy formulation in third countries such as China.[308]

304. In response to comments seeking confirmation that "that enhanced FFP [Federal financial participation (FFP)] should be available for COTS [commercial off-the-shelf software products] initial licensing and implementation service costs as well as ongoing software licensing and maintenance costs," and questioning "why there [was] no language [in the final regulations] confirming established protections for COTS pre-existing intellectual property (IP) and newly developed IP used in eligibility modernization initiatives," the Centers for Medicare & Medicaid Services (CMS), HHS responded as follows: "We are not dictating specific solutions to States as they undertake their technology projects, as long as the standards and conditions of this final rule are met and we expect to work with States in an effort to share, reuse, and leverage other State solutions. For COTS products, we have a longstanding rule that the State must own any software that is designed, developed, installed or improved with 90 percent FFP (see § 433.112(b)(5)). In other words, software that is developed with public funds must be owned by the public and as a ''public product'' is available to be shared with other States. COTS-based solutions may still receive a 75 percent enhanced funding (that is, for licensing and implementation services costs), if they are related to the MMIS . . . a Medicaid management information system . . . (including the eligibility determination system) and meet all the requirements of this final rule. In addition, current rules protecting intellectual property (such as copyright and/or patent laws) would simply apply in the way that they already do apply to intellectual property. Nothing in this final rule is attempting to alter those rules." *See* Final Rule: Medicaid Program; Federal Funding for Medicaid Eligibility Determination and Enrollment Activities, 76 Fed. Reg. 21950, 21955 (Apr. 19, 2011).

305. The final regulations superceded rules previously proposed during November 2010. *See, e.g.*, Medicaid; Federal Funding for Medicaid Eligibility Determination and Enrollment Activities, 75 Fed. Reg. 68583 (Nov. 8, 2010) (to be codified at 42 C.F.R. pt. 433).

306. Zita, *supra* at note 289.

307. *See Supplement to ITSSD Comments Concerning the WIPO Reports on Standards and Patents (SCP/13/2) Paragraph 44*, supra note 241, at 24–26; Kogan, *supra* note 165, at 4, 8–14, 19–21.

308. *See* Karsten Gerloff, Carlo Piana & Sam Tuke, *Defending Open Standards: FSFE Refutes BSA's False Claims to European Commission*, FREE SOFTWARE FOUND. EUR. (Nov. 15, 2010), http://fsfe.org/projects/os/bsa-eif-letter-fsfe-response.pdf.

2. The Lessons Not Learned by the U.K. Government

The U.K. government, unfortunately, has not since gained from the knowledge or experience acquired by the E.U. Commission as the result of this painful political process. During January 2011, U.K. Cabinet Office of Government Commerce (OGC) issued a Procurement Policy Action Note that defined "open standards" as including only those which "have intellectual property made irrevocably available on a *royalty-free* basis."[309] And, two months later, during March 2011, the U.K. Cabinet Office released its Government ICT Strategy[310] which detailed how the U.K. government would, among other things: (1) "publish a toolkit for procurers on best practice for evaluating the use of open source solutions"; (2) "establish an Open Source Implementation Group, a System Integrator Forum and an Open Source Advisory Panel . . . to educate, promote[,] and facilitate the technical and cultural change needed to increase the use of open source across government"; and (3) "procure open source solutions . . . where appropriate."[311]

Although both documents clearly reflected the influence of the FOSS community, the Action Note was more publicly hailed by FOSS commentators (OpenForumEurope (OFE) and American Attorney Andy Updegrove)[312] given its

> (1) inclu[sion of] informal regional as well as national standards consortia among the internationally recognized specification or standards organizations

309. *See Procurement Policy Note—Use of Open Standards when specifying ICT requirements*, Action Note 3/11 UK CABINET OFFICE, ¶ 6 (Jan. 31, 2011) (emphasis added), *available at* http://www.cabinetoffice.gov.uk/sites/default/files/resources/PPN% 203_11%20Open% 20Standards.pdf.

310. *See Government ICT Strategy* UK CABINET OFFICE 9, 13 (Mar. 2011), *at* http:// www.cabinetoffice.gov.uk/sites/default/files/resources/uk-government-government-ict-strategy_0.pdf.

311. *Id.* at 9, 13.

312. *See* Andy Updegrove, *United Kingdom: U.K. Comes out for Royalty-Free Standards for Government Procurement*, MONDAQ (Apr. 6, 2011), *available at* http://www. mondaq.com/article.asp?articleid=126448; Andy Updegrove, *U.K. Comes out for Royalty-Free Standards for Government Procurement*, THE STANDARDS BLOG (Feb. 25, 2011), *available at* http://www.consortiuminfo.org/standardsblog/article.php?story=2011 0225075112254. *See also* Jochen Friedrich, *UK government issues modern procurement policy statement focussing on openness and interoperability*, JOCHEN FRIEDRICH'S OPEN BLOG (Mar. 4, 2011), *available at* http://jfopen.blogspot.com/2011/03/uk-government-issues-modern-procurement.html; Graham Taylor, *Government takes action on open technology*, GUARDIAN PROF'L (Mar. 10, 2011), *available at* http://www.guardian. co.uk/government-computing-network/2011/mar/10/open-forum-europe-comment-government-it-policy.

> whose "open" standards can and should be considered by the UK for government procurement purposes; (2) its definition of "open" standards [which] constitute[d] a legally acceptable "repudiation" (allegedly consistent with the policy space afforded EU Member State governments vis-à-vis the European regional lawmaking institutions) of and permissible derogation from the final, binding European Interoperability Framework adopted by the European Commission during December 2010, following many years of thoughtful deliberation and contentious debate; (3) it[s]emulat[ion] and embrace [of] a robust definition of "open" standards that is very similar to that contained within the national interoperability framework adopted during November 2010 by the Indian Government; and (4) its [showing] that corporate lobbying and forum shopping undertaken at the EU Member State governmental level on behalf of the . . . open source and "software-as-a-service" (SaaS) industry communities can be successful, at least temporarily.[313]

Perhaps the most controversial aspect of the FOSS community's support for the Action Note was its obvious encouragement of E.U. Member States seeking to retain national government procurement interoperability framework preferences for royalty-free and proprietary-free "open" ICT standards modeled after EIFv1.0, and the corresponding implication that such Member State behavior would likely go unpunished in light of the complex European concept of subsidiarity.[314] Remarkably these activities were permitted to occur in blatant disregard of the E.U. Commission's determination in final EIFv2.0, which although legally nonbinding, implemented legally binding DECISION No 922/2009/EC issued by the European Parliament and Council which called for government procurement ICT standards that are technology and business model-neutral.[315]

A second troubling aspect of such support was the parallel it drew between the

> UK definition of open standards and that contained within the ICT interoperability framework adopted by the Government of India during November 2010. Such a comparison implied that although Britain "ha[d] [long] been part of the high tech intellectual property business regime since its inception," its recent actions reflect that it has [since] changed course and

313. *See* Lawrence A. Kogan, *UK's Promotion of Royalty-Free Government Procurement Standards—NOT AS REPORTED*, MONDAQ (Apr. 14, 2011), *available at* http://www. mondaq.com/article.asp?articleid=129510.

314. *Id.* (citing *Foreword: Achieving European Interoperability*, Report based on an Openforum Academy Roundtable discussion, OPENFORUM EUROPE (Feb. 4, 2011), *available at* http://www.openforumacademy.org/insights/1102ofa%20insights_report %20interoperability_final.pdf); Éva Bóka, *The Idea of Subsidiarity in the European Federalist Thought (A historical survey)*, GROTIUS (2007), *available at* http://www. grotius.hu/publ/displ.asp?id=ECICWF; http://www.grotius.hu/publ/displ.asp?id=ECICWF.

315. *See* Lawrence A. Kogan, *UK's Promotion of Royalty-Free Government Procurement Standards—NOT AS REPORTED*, *supra* (citing COM(2010) 744-2 final, (12/16/2010), *supra* note 299, § 2.12, at 12).

> apparently learned from India, "a comparative newcomer to the practice of automatically patenting everything in ICT that can be patented."[316]

It is doubtful, however, that such support could be considered to presage a *positive* trend in the U.K.'s IP evolution, as was suggested by one FOSS community commentator, in light of a recent U.K. study's findings indicating a distinct pattern of *under*-appreciation of the use and value of IP by U.K. businesses.[317]

A third disquieting aspect of the FOSS community support that such activities engendered concerns the actual level of lobbying influence the FOSS community wielded in securing the U.K. Cabinet Office's production of these documents.[318] Indeed, it is now clear, "given the New York Times' revelation reported last year[,] that the Brussels-based OFE has long served as a 'lobbying front'/mask for U.S.-based industry members IBM, Google, Oracle and Red Hat—a/k/a/ 'IGOR'—which quietly but unsuccessfully endeavored to shape the European Commission's EIF project"[319] to suit their own view of patents as being predominantly "defensive" rather than innovative (offensive) in nature.[320] Considering the size of the U.K. government procurement market (£16.9bn spend)

316. *See* Lawrence A. Kogan, *UK's Promotion of Royalty-Free Government Procurement Standards—NOT AS REPORTED*, *supra* note 299 (citing Andy Updegrove, *United Kingdom: U.K. Comes out for Royalty-Free Standards for Government Procurement*, *supra* note 298).

317. *Id.* (citing Robert Pitketh, *UK Intellectual Property Awareness Survey—2010*, UK INTELLECTUAL PROP. OFFICE (Mar. 2011), *available at* http://www.ipo.gov.uk/ip survey2010.pdf).

318. *See* Lawrence A. Kogan, *supra* note 299.

319. *See* Lawrence A. Kogan, *UK Government Must Heed Dutch Audit Court Warning Prior To Implementing 'Open' IT Procurement Action* (May 9, 2011), *available at* http://www.mondaq.com/x/131628/Government+Contracts+Procurement+PPP/UK+ Government+Must+Heed+Dutch+Audit+Court+Warning. *See also* Kevin O'Brien, *Technology Rivals Lobby to Break Microsoft's Hold*, N.Y. TIMES, July 18, 2010, http://www.nytimes.com/2010/07/19/technology/19iht-eusoftwar19.html; Florian Meuller, *OpenForum Europe: hypocrites lobby the EU but don't get their own houses in order*, FOSS PATENT BLOG (July 21, 2010), http://fosspatents.blogspot.com/2010/07/open forum-europe-hypocrites-lobby-eu.html; *About OFE—Our Members*, OPENFORUM EUROPE, http://www.openforumeurope.org/about/our-members.

320. In an April 2011 interview with Tech Crunch following Google's unsuccessful bid at the Nortel bankruptcy auction to secure the latter company's patent portfolio, Google's Senior Vice President and General Counsel remarked that, in today's spaghetti bowl of Silicon Valley, patents play a greater defensive rather than offensive role for his company. "A patent isn't innovation. It's the right to block someone else from innovating." *See, e.g.*, MG Siegler, *Google On The Nortel Loss, Patents As Government-Granted Monopolies, And Plates Of Spaghetti*, TECH CRUNCH (July 25, 2011), http://techcrunch. com/2011/07/25/google-patent-fight/.

and its growing influence over private market behavior, the promptness with which the U.K. Cabinet Office warmed to IGOR's FOSS-centric ideas,[321] and the U.K. Cabinet Office's more recent appointment of Liam Maxwell[322] as an adviser to the Efficiency and Reform Group and the government's Chief Information Officer[323] "to increase the drive towards open standards and open source software,"[324] is there any lingering doubt that IGOR has influenced and continues to influence the thinking in Whitehall?

A fourth alarming aspect of the FOSS community's support of U.K. ICT activities concerns the lack of deference that the Dutch government's Open Standards and Open Source Software (OSOSS) Programme[325] has received in the U.K. Cabinet Office. Without logic or explanation, the U.K. government has failed to carefully review and heed the warnings of the Netherlands Court of Audit regarding the utility of and economic costs associated with government procured open source software.[326] During 2010, at the request of the Dutch House of Representatives, the Audit Court investigated "whether the phasing out of closed standards and the introduction of open source software would improve the operation of market forces and save costs for the government."[327] On March 15, 2011,

321. *See* Lawrence A. Kogan, *UK Government Must Heed Dutch Audit Court Warning Prior To Implementing 'Open' IT Procurement Action*, *supra* note 305 (citing *Cabinet Office Draft Structural Reform Plan*, UK CABINET OFFICE, Departmental Priorities #s 3 and 4 (June 2010), http://www.number10.gov.uk/wp-content/uploads/cabinet-office-srp.pdf).

322. Liam Maxwell co-authored the 2009 report for then shadow chancellor George Osborne on promoting the use of open source in government." *See* Mark Say, *Liam Maxwell Appointed to Advise on Government ICT: Conservative Adviser Takes Cabinet Office Position for 11 Months*, GUARDIAN PROF'L (June 27, 2011), http://www.guardian.co.uk/government-computing-network/2011/jun/27/liam-maxwell-appointed-director-of-ict-futures; Bryan Glick, *Tory Technology Advisor Liam Maxwell Appointed to Government IT Advisory Post*, COMPUTERWEEKLY.COM (June 28, 2011), http://www.computerweekly.com/Articles/2011/06/28/247123/Tory-technology-advisor-Liam-Maxwell-appointed-to-government-IT-advisory.htm.

323. *Id.*

324. *See Liam Maxwell Engaged by Efficiency and Reform Group*, UK CABINET OFFICE NEWS (June 24, 2011), http://www.cabinetoffice.gov.uk/news/liam-maxwell-engaged-efficiency-and-reform-group.

325. "By 2007, [the OSOSS Programme] had evolved into an affirmative procurement preference action plan that strongly urged all Dutch federal ministries and subsidiary government bodies to use open source software based on open standards wherever possible." *See* Lawrence A. Kogan, *UK Government Must Heed Dutch Audit Court Warning Prior To Implementing 'Open' IT Procurement Action*, *supra* note 305.

326. *Id.*; Lawrence Kogan, *Comment: A Call for Caution on Open Source*, GUARDIAN PROF'L (May 23, 2011), http://www.guardian.co.uk/government-computing-network/2011/may/23/lawrence-kogan-itssd-caution-open-source-government-ict.

327. *See* Open Standards and Open Source Software in Central Government, Report No. 2, from the Netherlands Court of Audit to the Netherlands House of Representatives (Mar. 15, 2011) (English Translation), http://www.rekenkamer.nl/Actueel/Onderzoeksrapporten/Bronnen/2011/03/Open_standaarden_en_opensourcesoftware_bij_de_rijksove

the Audit Court issued a report releasing the results of its investigation.[328] The report "concluded amongst other things that the potential savings the government could [realize] by making more use of open source software were limited," and that the "switch to open source software . . . does not necessarily . . . lead to cost savings" at all.[329] The Audit Court reasoned that although there are no licensing or acquisition fees generally associated with open source software, there are, nevertheless, other significant and accumulative fees, such as those relating to software implementation, management updates and maintenance, that governments must incur to ensure the smooth and uninterrupted operation of open source *e*Government IT systems. Moreover, in some other instances, the switch to open source software may even lead to "destruction of capital because the kingdom has many current license agreements."[330]

In addition, the U.K. Cabinet Office has failed to vigorously assess the relative worth of other official and unofficial reports released by or to other Netherlands government agencies that had secured the support of the FOSS community. One example is the March 2009 report prepared by the Netherlands Bureau of Economic Policy,[331] which was largely an aspirational and academic document. Its purpose was

> to analy[z]e the economic effects of promoting open source software on competition and innovation . . . [b]ased on existing insights from the economics literature . . . [and] . . . policy options in the light of software market characteristics, such as the incentives to innovate under different software licensing regimes and market failures that may occur in these markets.[332]

rheid/Rapport_Open_standaarden_en_opensourcesoftware_bij_de_rijksoverheid; http://www.rekenkamer.nl/Actueel/Onderzoeksrapporten/Introducties/2011/03/Open_standaarden_en_opensourcesoftware_bij_de_rijksoverheid.

328. *See* Open Standards and Open Source Software in Central Government—Background, Netherlands Court of Audit News (Mar. 15, 2011) (English Translation), http://www.courtofaudit.com/english/News/Audits/Introductions/2011/03/Open_standards_and_open_source_software_in_central_government.

329. *See National Savings with Open Source Software May be Limited*, Netherlands Court of Audit Press Release (Mar. 15, 2011) (English Translation), http://www.rekenkamer.nl/Actueel/Onderzoeksrapporten/Introducties/2011/03/Open_standaarden_en_opensourcesoftware_bij_de_rijksoverheid?informatietype=persbericht.

330. *Id.*

331. *See* Michiel Bijlsma, Paul de Bijl & Viktória Kocsis, *Competition, Innovation and Intellectual Property Rights in Software Markets*, CPB, no. 181 (Mar. 2009), http://www.cpb.nl/sites/default/files/publicaties/download/competition-innovation-and-intellectual-property-rights-software-markets.pdf.

332. *Id.* at 7.

The NBEP report also set forth propose[d] "guidelines to determine the circumstances under which various types of policy intervention may be desirable to improve dynamic efficiency."[333] However, the report's scope was rather limited—it "exclusively focused on open source versus proprietary licensing in software markets [and it did] not consider problems and issues related to open versus closed standards."[334] The authors found that the relative benefits that proprietary and open source licenses could bring depended largely on the specific situation, and that "open source licensing across the board would not necessarily bring any benefits compared to proprietary license."[335] In other respects, the report's analysis was less than precise and its findings were quite general and conclusory in nature. For example, it focused on "the potential role of [] government" intervention to address "market failures [which] lead to inefficient market outcomes," when desirable,[336] but declined to make policy recommendations that stressed specific interventions because of the risk of government failure.[337]

> It is important to acknowledge that "good intentions" are not sufficient to motivate government interventions, since they can have benefits as well as costs. Accordingly, to be able to conclude that a policy indeed corrects a market failure, one must ask whether it actually reduces the inefficiency or welfare loss that was caused by the market failure at hand. In other words, one must take into account the possibility of government failures, which are failures that arise when the government introduces a new inefficiency "because it should not have intervened in the first place or when it could have solved a given problem . . . more efficiently, that is, by generating greater net benefits."[338]

Furthermore, the U.K. government inexplicably failed to publicly evaluate why the 2010 informal memorandum prepared for the Dutch Ministry of the Interior[339] had been rejected by the Dutch government. Although the informal memorandum had been prepared under contract jointly by civil administrators from the ministries of the Interior, Finance, and Defense and two IT consultants, it was never used in decision making or officially embraced by the Interior Ministry.[340] An English

333. *Id.*
334. *Id.* at 18.
335. *Id.* at 35.
336. *Id.* at 37.
337. *Id.* at 49.
338. *Id.* at 46. "Because of the risk of government failure, policy instruments have to be used carefully. The government has an information disadvantage compared to market participants; therefore it is generally advisable to abstain from policies that select a winner in advance." *Id.* at 11.
339. *See Sorry We're Open—How the Government Can Improve the ICT Market* (May 11, 2010) (English translation), *available at* http://www.leugens.nl/wp-content/uploads/2011/03/ICT-rapport-Sorry-we-re-open.pdf.
340. *See* Gijs Hillenius, *NL: Court of Audit 'Failed' in its Independent Review of Open Source*, OSOR.EU (Mar. 28, 2011), http://www.osor.eu/news/nl-court-of-audit-

translation of this Dutch language document reveals that it was intended as "an exploration of how a significant [and] . . . necessary savings in IT can be realized."[341] In addition, the memorandum states that its putative conclusions were based on "rough" prognostications bearing a rather broad range of outcomes—from between 60 million and four billion euros worth of savings.[342] Without substantiation, the memo posits that "[t]he use of open standards and the use of software under open source licenses is seen as the most appropriate means to break through the situation . . . [of] 'vendor lock-in'" reinforced by closed standards, where the government is strongly dependent on a few suppliers of ICT components.[343] In support of this proposition, the memorandum lists several software applications limited to a few large software companies that are alleged to dominate 99% of the market for government IT systems,[344] though it does not reveal the source of this data.

To achieve independence from such suppliers, the memorandum recommends that the government reduce its use of close standards rather than increase its use of open standards, which is based on the assumption that the vendor lock-in problem will remain for as long as the Dutch Government continues to use closed standards.[345] This memorandum, further discusses how vendor licensing restrictions do not currently permit the sharing of solutions between and among different government agencies and limit the reuse of solutions by the same agencies; but, it does not substantiate such claims with data. It also recommends that governments use software under open source licenses not subject to such

failed-in-its-independent-review-of-open-source; Gijs Hillenius, *NL: Moving to Open Source Would Save Government One to Four Billion*, OSOR.EU (Mar. 11, 2011), http://www.osor.eu/news/nl-moving-to-open-source-would-save-government-one-to-four-billion; Jasper Bakker, *ICT Open Secret Report Taken Offline*, Webwereld (Mar. 11, 2011) (English translation), http://webwereld.nl/nieuws/105998/geheim-rapport-open-ict-offline-gehaald.html; *Interior Challenged Report: Open Source Delivers Billion*, Binnenlands Bestuur (Mar. 9, 2011) (English translation), http://www.binnenlands bestuur.nl/nieuws/2011/03/gewraakt-bzk-rapport-open-source-levert-miljard-op.855044. lynkx; Letter from J.P.H. Donner, Minister of the Interior and Kingdom Relations To the Speaker of the House of Representatives (Mar. 7, 2011) (English translation), *available at* http://www.rijksoverheid.nl/bestanden/documenten-en-publicaties/kamerstukken/ 2011/03/08/kamerbrief-onderzoek-opensourcesoftware-en-open-standaarden/kamer brief-opensource software-en-open-standaarden1.pdf.

341. *Id.* at 2.
342. *Id.*
343. *Id.* at 2–4.
344. *Id.* at 4.
345. *Id.*

restrictions, because they can be taken over by independent administrative bodies, provincial governments and national governments.[346] The memorandum also claims that since open source software becomes public property, governments will not become dependent on particular ICT vendors to maintain their ICT systems. Rather, government open source ICT systems may be serviced under contract by any number of vendors and can continue to be used at all times without regard to whether a particular ICT vendor is acquired or declares bankruptcy.[347] The memorandum nowhere substantiates any of these claims with data, however.

Moreover, the memorandum admits that exact expenditure figures needed to substantiate the costs savings that can be secured through wider use of open standards and open source software are not easily obtainable because of the diversity of different government department standards, infrastructures and particular licenses and contracts, and that consequently, its data reflect only extrapolations from existing contracts.[348] The memorandum then provides the following caveat: open source software procurement costs include only the direct license costs; the secondary (indirect) costs of maintaining and upgrading the license are not included.[349] In effect, despite being unable to provide precise costing data, because none apparently exists, the report's authors proceeded to make the bold and incredible claim that the open source version of a proprietary application is approximately 50% cheaper than the closed version![350]

A fifth alarming aspect of the FOSS community's support of U.K. ICT activities concerns its subsequent behind-the-scenes influential role in *also* shaping the thoughts and proposed policies of the Public Administration Select Committee (PASC) of the U.K. House of Commons. On July 25, 2011, said committee announced its forthcoming publication of a report[351] focused on government procurement-related ICT interoperability[352] that the U.K. Cabinet will likely rely upon in justifying its ambitious emerging national open-source-friendly, royalty-free-leaning government procurement

346. *Id.* at 6–7.
347. *Id.* at 7.
348. *Id.* at 12.
349. *Id.* at 14.
350. *Id.* at 14–15.
351. *See PASC to Publish Government IT Report*, PARLIAMENT.UK (July 25, 2011), *available at* http://www.parliament.uk/business/committees/ committees-a-z/commons-select/public-administration-select-committee/news/pasc-to-publish-it-report/.
352. *See Government and IT—A Recipe for Rip-offs": Time for a New Approach*, House of Commons Public Administration Select Committee, Twelfth Report of Session 2010–12, HC 715-I (July 28, 2011), *available at* http://www.publications.parliament.uk/pa/cm201012/cmselect/cmpubadm/715/715i.pdf.

ICT standards strategy.[353] Apparently, the prior March 2011 testimony of at least one witness who had echoed the U.K. government's prior characterization of its relationship with major IT suppliers as an "'oligopoly' [consisting] of systems integrators[354] that dominate so many government IT contracts,"[355] resonated with MPs working within the House of Commons PASC[356] and its Public Accounts Committee.[357] Nevertheless, while "the dominance of Government IT by a small number of large systems integrators (SIs)" constituted a "recurring theme throughout" the Select Committee report,[358] the report was rather light on specific practical recommendations to address this alleged problem.[359]

353. *See Information and Communications Technology in Government*, House of Commons Committee of Public Accounts, Fortieth Report of Session 2010–12, HC 1050 (July 5, 2011), *available at* http://www.publications.parliament.uk/pa/cm201012/cmselect/cmpubacc/1050/1050.pdf. This report criticized the UK government's IT strategy as "lack[ing] detail about how it will be delivered . . . [such as] . . . quantitative targets . . . lack[ing] a baseline of current performance, which will make it difficult to measure success" [,and as lacking a] "proposals . . . to address the longstanding problems of high turnover of Senior Responsible Owners (SROs), their lack of experience and their lack of accountability." *Id.* at 3, 5–6. *See also* Kathleen Hall, *Government IT Strategy 'Lacks Detail on Delivery', Say MPs*, COMPUTERWEEKLY.COM (July 5, 2011), http://www.computerweekly.com/Articles/2011/07/05/247179/Government-IT-strategy-lacks-detail-on-delivery39-say.htm.

354. "A systems integrator is a person or company that specialises in bringing together component subsystems into a whole and ensuring that those subsystems function together." *Government and IT—A Recipe for Rip-offs": Time for a New Approach*, *supra* note 338, at 14, n.46.

355. *See Government ICT Strategy* UK Cabinet Office (Mar. 2011) *supra* note 296, at 8 ¶ 14. For example, "Martin Rice, chief executive of software development company Erudine, slammed the IT sector for taking advantage of the government's lack of in-house IT expertise. Since *Rice gave evidence to the select committee*, Erudine has collapsed after a major private sector customer refused to pay an unpaid bill. But *Rice also cited the difficulty of winning government deals as a factor in the firm's demise*" (emphasis added). *See* Bryan Glick, *MPs to Publish 'Rip-off' Report into Government IT*, COMPUTERWEEKLY.COM (July 27, 2011), http://www.computerweekly.com/Articles/2011/07/27/247428/MPs-to-publish-39rip-off39-report-into-government.htm. Mr. Rice further "described the situation as a 'cartel.'" *Government and IT—A Recipe for Rip-offs": Time for a New Approach*, *supra* note 338, at 14 ¶ 28 and accompanying note 53.

356. *Government and IT—A Recipe for Rip-offs": Time for a New Approach*, *supra* note 338, at 14 ¶ 27, and accompanying notes 51–52.

357. "The Government ICT strategy described the current situation as an 'oligopoly', a sentiment echoed by the Public Accounts Committee." *See Government and IT—A Recipe for Rip-offs": Time for a New Approach*, *supra* note 338, at 14 ¶ 27.

358. *Id.* ¶ 26, at 14.

359. The Committee did, however, recommend that the following *general* courses of action be taken: "The Government should urgently commission an independent, external investigation to determine whether there is substance to these serious allegations of anti-competitive behaviour and collusion. The Government should also provide a

Perhaps, the Public Administration Select Committee report could have done more to emphasize *how* successive U.K. governments, through excessive software systems integration outsourcing, have left the current U.K. government vulnerable to the vendor lock-in problem.[360] In other words, the real issue is government failure, not market failure.[361] As the result of excessive outsourcing, U.K. government agencies and personnel now lack the IT skills and knowledge to ensure the interoperability of *e*Government systems which the U.K. Cabinet desires to build in furtherance of its public IT policy objectives. The PASC is correct in focusing on organizational and structural issues within government, but it needs to examine the outsourcing problem in much greater depth.

Consequently, it may be credibly argued that the U.K. Cabinet policy actions undertaken during January and March 2011, as influenced by the FOSS community, including IGOR,[362] are misguided. It is not primarily the cost of patent license (royalty) fees and the restrictions imposed by FRAND/RAND licensing terms (i.e., a market failure) that have largely impeded *e*Government systems interoperability at the expense of the "public fisc". Rather, it has been primarily a government lack of IT knowledge and skills brought about and exacerbated by the U.K. government's ongoing outsourcing of the systems integrator function that has resulted in its present IT predicament. Indeed the PASC's recognition of this fact is belied by the report's relatively limited discussion of open standards and open source software.[363] The U.K. public should be able to learn of the multitude of challenges faced by its new government, including those legacy problems generated by prior governments' actions, and the Cabinet should account to the public for such failings.

For all of the above reasons, and more, the U.K. Cabinet must seriously study the lessons learned by the Dutch Government and the E.U. Commission. Furthermore, the U.K. Cabinet must also carefully review the potential regulatory and policy risks and economic impacts engendered by the pursuit of its own emerging ICT policy agenda initiatives,

trusted and independent escalation route to enable SMEs confidentially to raise allegations of malpractice." *Id.* at 49 ¶ 30.

360. The report discusses the issues of "vendor lock-in" and "legacy systems." *Id.* at 15–16 ¶¶ 31–34.

361. "It is these underlying causes of failure which we sought to assess in our inquiry. *There was a recurring theme in our evidence: that the failure of 'IT projects' was rarely due to the technology itself. Failure occurred because of flaws in the underlying policy, or its implementation.*" *Id.* ¶¶ 12, at 9 (emphasis added).

362. *See* discussion *supra*. "IGOR" consists of FOSS allies IBM, Google, Oracle and Red Hat.

363. *See Government and IT—A Recipe for Rip-offs": Time for a New Approach*, *supra* note 338, at 140–42 ¶¶ 138, and conclusion ¶¶ 27–28 ("open standards"); ¶ 167 and conclusion ¶ 32 ("open source software").

focusing particularly on inventors and patent and trade secret holders, to ensure against the impairment of U.K. ICT innovation. As discussed above, it might even consider whether the real problem at hand concerns the use of open standards and open source software at all, considering the organizational, logistical, and structural difficulties created by the steady outsourcing, by successive U.K. governments, of IT knowledge and skills to third party IT systems integrators. BRICS nation governments would be wise to do the same.

3. BRICS Officials and NGOs Have Called For New Public Mechanisms to Regulate Private FRAND/RAND Licensing

The E.U. and U.K. ICT interoperability debates have also likely triggered downstream impacts in the BRICS nations where the governments have been encouraged to reshape their national ICT standardization efforts[364] and to rebalance their national IP rights regimes in favor of the public interest.

a. 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."[365] It covers federal government-to-government, federal government-to-state government, federal government-to-citizen, federal government-to-business, and federal

364. As early as 2005, China proposed to the WTO Technical Barriers to Trade (TBT) Committee that it further study with respect to IPR-based technologies how standardization interoperability needs at the societal level may be appropriately balanced with IPR protection needs at the innovator level, in order for standards to facilitate and eliminate barriers to international trade, especially in the case of WTO Developing Country Members which typically require technical assistance and capacity building. *See 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), http://chinawto.mofcom.gov.cn/accessory/200702/1171346578955.doc.

365. Global Meeting on Government Interoperability Frameworks 2010, Rio de Janiero, Braz., May 4–6 2010, *Report on the Global Meeting on Government Interoperability Frameworks 2010*, at 3, 8, *available at* http://www.gif4dev.net/wp-content/uploads/2010/05/Report-on-the-Global-Meeting-on-Government-Interoperability-Frameworks-2010-PDF.pdf.

government-to-foreign government information exchanges. The most recent version of e-Ping was released during December 2009 (Version 2010).[366]

E-PING standards and policies are mandatory for all federal government agencies[367] and apply to all new and legacy systems.[368] 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.[369] In addition, consistent with the general policy, *government agencies must prioritize the use of public software or free software* in the implementation of interoperability standards.[370] 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 for free or at cost, and "is necessarily non-proprietary."[371] 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."[372] Accordingly at least one Brazilian commentator has opined that the e-Ping definition of "open standard" is that contained within former EU EIFv1.0.[373]

b. China

On November 2, 2009, the Standardization Administration of the People's Republic of China (SAC) released proposed standardization interoperability rules[374] (interim draft regulations) governing the disposition

366. *See* BRAZILIAN GOV'T EXECUTIVE COMM. OF ELEC. GOV'T, E-PING ELECTRONIC GOVERNMENT INTEROPERABILITY STANDARDS, 7 (2009), *available at* http://www.governoeletronico.gov.br/anexos/versao-2010-da-e-ping-ingles.

367. *Id.* at §§ 2–2.1.

368. *Id.* at § 2.1.

369. *Id.* at § 3.1.

370. *Id.* at § 3.2.

371. *Id.* at § 11.

372. *Id.* (emphasis added).

373. *See* Jomar Silva, *Standards and the Control of Communication*, *in* CITIZENSHIP AND DIGITAL NETWORKS 238 n.4 (Sergio Amadeu da Silveira, ed., 2010), http://www.cidadaniaeredesdigitais.com.br/_files/011jomar_ing.pdf.

374. *Regulations for the Administration of the Formulation and Revision of Patent-Involving National Standards (Interim) (Exposure Draft)*, STANDARDIZATION ADMIN. CHINA (Nov. 2, 2009) [hereinafter *SAC Interim Draft*], *available at* http://www.giprs.

of patents involved in the development or revision of both compulsory[375] and voluntary[376] national standards.[377] If adopted, these rules would have treated 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 voluntary national standard may be incorporated into its development.[378] 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*.[379] A patentee's refusal to enter into a license at all will deny the patent inclusion within such a standard.[380] 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 during the formulation or revisions phases[381] will result in the deemed (implied) free licensure of the patented technology, and will trigger legal liability in the event such disclosure failure is subsequently found to be a purposeful concealment.[382]

In general, a "compulsory national standard," compliance with which is mandatory,[383] shall not involve any patents.[384] However, where "a

org/sites/default/files/National%20Standard%20Involving%20Patent_Reg_Draft_20091119_En.pdf.

375. "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." Standardization Law of the People's Republic of China, art. 7 (emphasis added), http://www.sac.gov.cn/sac_en/AffairsOpening/LawsandRegulations/201011/t20101123_4214.html (promulgated by Standing Comm. Nat. People's Cong. Dec. 29, 1988, effective Apr. 1, 1989).

376. *Id.*

377. *See SAC Interim Draft*, *supra* note 360, art. 2.

378. *See id.* at art. 3.

379. *See id.* at art. 9(1)–(2).

380. *See id.* at art. 9(3).

381. *See id.* at 222, art. 5.

382. *See id.* at art. 8. A purposeful concealment is defined as an act of concealment that "bring[s] losses to the setting and implementation of national standards." *See* Zhong Yi, Ni Jia & Liu Jiayin, *The Comparison and Commentaries on Regulation on the Administration of Setting and Revision of The National Standard Involving Patent (Interim) (Exposure Draft)* (2009 Nov.) and *Regulations on National Standard Involving Patent (Interim) (Exposure Draft)* (2004 Sept.), GLOBAL IPRS RESEARCH CTR., 5 (Nov. 21, 2009), *available at* http://www.giprs.org/sites/default/files/Comparison%20and%20Commentaries_National%20Standard%20Involving%20Patent_20091120_En.pdf.

383. *See Standardization Law of the People's Republic of China*, *supra* note 361, art. 14.

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.[385] 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.[386]

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."[387] 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,"[388] it is clear that the proposed Chinese standardization interoperability rules (interim draft regulations) if adopted, would have had a severe impact on developed country renewable or alternative energy companies, especially considering that most manufacturing of solar panels windmills, hybrid auto batteries, and compact fluorescent light bulbs occurs in China.[389]

Pursuant to and in implementation of Article 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 draft *Disposal Rules for the Inclusion of Patents in National Standards* in January 2010.[390] Although these rules

384. *See SAC Interim Draft*, *supra* note 361, at art. 12.
385. *See id.* at art. 13.
386. *Id.*
387. China: Intellectual Prop. Infringement, Indigenous Innovation Policies, and Frameworks for Measuring the Effects on the U.S. Econ., Inv. No. 332–514, USITC Pub. 4199, at 5–19 (Nov. 2010).
388. *See* Peng Heyue, *China's Indigenous Innovation Policy and its Effect on Foreign Intellectual Property Rights Holders*, CHINA L. INSIGHT, (Sept. 9, 2010), http://www.chinalawinsight.com/2010/09/articles/intellectual-property/chinas-indigenous-innovation-policy-and-its-effect-on-foreign-intellectual-property-rights-holders/.
389. "Only one of the top ten solar photovoltaic (PV) producers in the world is American; only one of the top ten wind turbine producers is American; and only two of the top ten advanced battery producers are from the U.S. China and Japan host seven of the ten leading producers of photovoltaics. India's Suzlon Corporation is a leading producer of wind turbines, another renewable energy category dominated by Chinese firms." *See* Ebinger & Avasarala, *supra* note 136, at 30.
390. *See Disposal Rules for the Inclusion of Patents in National Standards (Draft for Comments)*, GEN. ADMIN. QUALITY SUPERVISION, INSPECTION, & QUARANTINE, & STANDARDIZATION ADMIN. PEOPLE'S REPUBLIC OF CHINA (Jan. 21, 2010) [hereinafter

apply directly to the formulation and revision of public national standards, they may be referred to within and thereby apply indirectly to private industry standards and local standards under formulation and revision.[391] Unlike the SAC Interim Draft, the Disposal Rules require disclosure of not only published and issued patents, but also published patents awaiting examination and non-published patents (patents pending) during the national standard formulation and revision phases.[392] The sample disclosure form accompanying 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).[393] 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.[394]

With respect to the licensing of essential patents,[395] 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 (3) no license at all.[396] 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.[397] In addition, where a patent holder refuses to license a patented technology, both regimes require its exclusion from the national standard.[398] 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

Disposal Rules], *available at* http://www.qbpc.org.cn/uploads/Tracy/CNIS%20is%20Soliciting%20the%20Public%20Comments%20about%20the%20Draft%20Disposal%20Rules/Disposal%20Rules%20for%20the%20Inclusion%20of%20Patents%20in%20National%20Standards%20(draft%20for%20comments-EN).doc.

391. *Id.* at art. 1.
392. *See id.* at art. 4.1.1–.2.
393. *See id.* at art. 4.1.2, app. A at 10–11 (form A.1).
394. *See Patents and Standard-Setting in China*, FRESHFILDS BRUCKHAUS DERINGER LLP, 2 (Mar. 2010), http://www.freshfields.com/publications/pdfs/2010/Mar10/27730.pdf.
395. *See Disposal Rules*, *supra* note 376, art. 3.1.
396. *See id.* arts. 4.3.2(a)–(c), 3.2–.3, app. A at 13 (form A.3).
397. *Cf. SAC Interim Draft*, *supra* note 360, at art. 9(1)–(2).
398. *See id.* art. 5.3.5.

licensing arrangement with the authorities, which may be attributable to their procedural rather than substantive nature.[399]

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 penalties not otherwise prescribed by law, namely measures 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.[400] 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 licence [sic], because it is authorized to issue compulsory licenses *in the public interest*."[401]

c. India

On November 12, 2010, the Indian government finalized its national policy on open standards for e-governance 2010,[402] ending approximately three years of debate[403] and amid concern "that Europe's equivalent European Interoperability Framework had been hijacked by rights holders."[404] 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."[405]

399. *See Patents and Standard-Setting in China*, *supra* note 380, at 2.

400. *See id.* at 1.

401. *Id.* (emphasis added); *see also* Mark Cohen et. al., *Amendment Provides New Roadmap for Compulsory Licenses*, CHINA DAILY, Nov. 30, 2009, at 9, *available at* http://www.chinadaily.com.cn/bw/2009-11/30/content_9074436.htm (discussing how "[t]he amendment makes it more feasible and likely for compulsory licenses to be granted in the area of pharmaceuticals under a new Article 50 and semiconductor technology under a new Article 52").

402. *See Policy on Open Standards for e-Governance*, MINISTRY OF COMM'NS & INFO. TECH., (Nov. 2010) (India), *available at* http://egovstandards.gov.in/policy/policy-on-open-standards-for-e-governance/policy_doc_and_manual_used_in_printing__recd_on_Nov_12.pdf/view.

403. *See* Michael Tiemann, *Indian Open Standards Policy Finalized*, OPEN SOURCE INITIATIVE BLOG (Nov. 12, 2010, 3:10 PM), http://www.opensource.org/node/551.

404. *See* Mark Ballard, *India Mandates Open IT Standards as Fears Grow Over EU Policy*, COMPUTERWEEKLY.COM (Nov. 19, 2010, 4:55PM), http://www.computerweekly.com/Articles/2010/11/19/244014/India-mandates-open-IT-standardsas-fears-grow-over-EU.htm.

405. MINISTRY OF COMM'NS & INFO. TECH., *supra* note 388, at Preamble and Section 1.

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]."[406] Owners of "legacy systems" will be responsible for ensuring that the interfaces between legacy and existing systems and between new versions of legacy and existing systems adhere to the mandatory characteristics of open standards,[407] i.e., that they are interoperable.[408]

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.[409] 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 groups and a number of government agencies:[410] (1) "[t]he Patent claims necessary to implement the Identified Standard shall be made available on a Royalty-Free basis for the life time of the Standard";[411] and (2) "[the] Identified Standard shall be recursively open[412] as far as possible."[413] 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."[414] In the event 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

406. *Id.* at §§ 3.1–3.2.
407. *Id.* at § 3.3.
408. *See* Deep Kurup, *A Radical Shift in e-Governance*, THE HINDU, (Nov. 24, 2010), http://www.thehindu.com/sci-tech/technology/article907442.ece.
409. MINISTRY OF COMM'NS & INFO. TECH., *supra* note 388, at § 4.
410. *See* Venkatesh Hariharan, *Open Standards Policy in India: A Long, But Successful Journey*, OPENSOURCE.COM (Nov. 19, 2010), http://opensource.com/government/10/11/open-standardspolicy-india-long-successful-journey.
411. MINISTRY OF COMM'NS & INFO. TECH., *supra* note 388, at § 4.1.2.
412. "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." *Id.* at A-II-9, Annexure–II Frequently asked Questions (FAQs).
413. MINISTRY OF COMM'NS & INFO. TECH., *supra* note 388, at § 4.1.4.
414. *Id.* at A-II-3, Annexure–II Frequently asked Questions (FAQs).

standard becomes eligible."[415] 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.[416] If royalty-free FRAND or RAND standards are unavailable, then a royalty-based FRAND or RAND standard may be considered.[417] In setting forth a definition of a royalty-free standard, the policy document brings these distinctions in terms to light by emphasizing the non-monetary consideration aspects of the underlying license.[418] 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.[419]

d. Russia

On December 17, 2010, one day following the release of the European Commission's final EIF, Russian Federation Prime Minister Vladimir Putin signed an executive order setting forth specific guidelines that mandate the complete transition from proprietary to *free software* by all Russian federal executive bodies and agencies during 2011–2015.[420] Apparently, the concept underlying the executive order was first openly discussed by the Russian Ministry of Communication during 2007 when Mr. Putin still held the Office of the Russian Presidency. The open forum had followed from the results of a cursory study entitled, *Concept of the Development and Use of Free Software in the Russian Federation*, which cited "the importance of open source software for [the development of] Russia, [for the securing of] 'significant budgetary savings', [for] 'reduc[ing] dependence on foreign manufacturers and software providers' and [for] 'increas[ing] the intellectual potential of the country.'"[421] Consistent therewith, in October 2008, the Russian Ministry of

415. *Id.* at § 4.3.
416. *Id.* at § 4.3(a).
417. *Id.* at § 4.3(c).
418. *Id.* at Annexure–I, "Royalty-Free (RF).
419. *See* Kurup, *supra* note 394.
420. *See* Government of the Russian Federation, Executive Order No. 2299-p, Transition of Federal Executive Bodies and Agencies of the Federal Budget [to] the Use of Free Software from 2011–2015 (Dec. 17, 2010), *available at* http://filearchive.cnews.ru/doc/2010/06/17/2299p.doc, English translation at http://translate.google.com/ translate?hl=en&ie=UTF-8&sl=auto&tl=en&u=http://filearchive.cnews.ru/doc/2010/06/17/2299p.doc&prev=_t&rurl=translate.google.com&twu=1.
421. *See* Vladislav Meshcheryakov, *Ministry of Communications Invites Citizens to Talk about Linux*, CNEWS (Mar. 14, 2008, 7:48 PM), http://open.cnews.ru/news/top/index.shtml?2008/03/14/292161, English translation at http://translate.google.com/translate?js=n&prev=_t&hl=en&ie=UTF-8&layout=2&eotf=1&sl=auto&tl=en&u=http%3A%2F%2Fopen.cnews.ru%2Fnews%2Ftop%2Findex.shtml%3F2008%2F03%2F14%2F292161 (quoting *Concepts of the Development and Use of Free Software in the Russian Federation*).

Communication announced a framework for the mandatory installation of free software on all Russian school computers by year end 2009.[422]

These activities were subsequently followed by a late February 2009 meeting convened by "the principal of the Russian Federation's Ministry of Communications and Mass Communications [and] representatives of Russian Free and Open Source Software (RFOSS) development companies, including VDEL . . . *to discuss concrete steps that [could] be taken by the state to support the RFOSS development process*."[423] One possible step that had previously been discussed but not resolved during an earlier February 2009 roundtable meeting concerned whether the Russian government should actively seek to *create and control* a closed national system of open source software for Russian developers. Apparently, some within the Russian FOSS community did not favor such an outcome. According to VDEL CEO Milan Prohaska,

> [t]he governments of China and Brazil made efforts to control the process of open source software development, i.e. to create closed operating systems. This approach just led them to a dead end. . . . The idea of creating an exclusive Russian information system (to be developed in Russia and for Russian users only) is, in essence, an attempt to build an "information ghetto" for Russian programmers, to limit them both at home and foreign markets.[424]

Rather, "in order to create a real operating system in Russia," it was recommended that Russia fully integrate itself "into the global development process."[425]

If recent Russian media announcements and the Putin executive order are any indication, it would seem that the Russian government continues to favor the creation of a closed and indigenous Russian FOSS similar to that established by Brazil and China. On September 13, 2010, the

422. *See* Glyn Moody, **All* Russian Schools to Use Free Software*, COMPUTER WORLDUK BLOG (Oct. 23, 2008, 10:12 AM), http://blogs.computerworlduk.com/open-enterprise/2008/10/all-russian-schools-to-use-free-software/index.htm. *Until the End of 2009 Will Introduce Free Software in all Russian Schools*, CNEWS OPEN (Oct. 22, 2008, 5:10 PM), http://open.cnews.ru/news/line/index.shtml?2008/10/22/324234, English translation at http://translate.google.com/translate?js=n&prev=_t&hl=en&ie=UTF-8&layout=2&eotf=1&sl=auto&tl=en&u=http%3A%2F%2Fopen.cnews.ru%2Fnews%2Fline%2Findex.shtml%3F2008%2F10%2F22%2F324234.

423. *Russian Government IT Development Strategy: Free and Open Source Software*, GOV'T TECH.'S DIGITAL CMYTS. (Mar. 2, 2009) (emphasis added), http://www.digitalcommunities.com/articles/Russian-Government-IT-Development-Strategy-Free.html.

424. *Id.* (quoting Milan Prohaska, CEO of VDEL).

425. *Id.* (quoting Dmitry Efanov, Representative, of The All-Russian Research Institute of Control Automation in the Non-Industrial Sphere (VNIINS)).

Russian press announced "that Russian President Dmitry Medvedev was being briefed on the development of a 'national operating system,' which could be launched in 2012." The government-funded ($350 million annually) and supported Linux-based indigenous system "dubbed *Linuksovskaya*" was lauded as being capable of saving the Russian government "'hundreds of millions' of dollars spent annually on Windows and Windows-based applications" and providing the Russian government with "complete control over how computer security is implemented and enforced in the country's infrastructure."[426] At least one IT commentator has alleged that the recently released executive order reflects Prime Minister Putin's direct and personal involvement in Russia's emerging IT infrastructure to ensure the establishment of a FOSS-based indigenous national operating system that could provide the Russian government with control over not only source code, but also the ability to monitor and censor private transactions.[427] He has thus warned readers that the executive order is not likely to be limited to government procurement markets.[428] The commentator emphasizes, in particular, how the section of the executive order covering education charges several government ministries with "rewir[ing] the entire Russian education system to preferentially use and teach open source software, from secondary school through vo-tech [vocational technical training schools) to university *for the edification of all students, not just those being prepared for civil service*."[429]

The technical and organizational sections of the Putin executive order identify other ministries responsible for implementing distinct mandates that must be completed within certain timeframes.[430] For example, by the third quarter of 2011, the appropriate ministries must approve specifications for free software-supported data formats[431] and financial accounting rule changes that would facilitate the government's fiscal recording of the economic value of free software for which no current provision exists.[432] According to the same IT commentator, the fact that

426. *See* Tim Negris, *Has Microsoft Russia Gone Rogue on Redmond?*, SYS-CON NEDERLANDS (Sept. 15, 2010), http://ne.sys-con.com/node/1533165.

427. *See* Tim Negris, *Putin Says 'Da' to Free Software*, CLOUD COMPUTING J. (Dec. 29, 2010), http://au.sys-con.com/node/1660689.

428. *Id.*

429. *Id.* (emphasis added).

430. *See* Vladislav Meshcheryakov, *Putin Ordered the Transfer of Power on Linux*, CNews Open (Dec. 27, 2010, 7:23 PM), English translation at http://open.cnews.ru/news/top/index.shtml ?2010/12/27/421556; http://translate.google.com/translate?hl=en&sl=ru&tl=en&u=http://open.cnews.ru/news/top/index.shtml%3F2010/12/27/421556.

431. *See* GOVERNMENT OF THE RUSSIAN FEDERATION, *supra* note 406, at point 11.

432. *Id.* at point 21.

the financial accounting changes are to be carried out by the Russian Ministries of Communications, Finance, and Economic Development which

> control most aspects of how business is done and how information technology is acquired and used in the country by both businesses and individuals . . . *could be speaking volumes about the (non-)future of commercial western software in the Russian Federation. If Putin wants to tax Microsoft, Oracle, and others out of existence in Russia, this would be a good way to start making that happen.*[433]

Besides promoting indigenous innovation and saving money, it appears that the adoption of such a policy under cover of the current global recession would also enable the Russian government "*to funnel any remaining software expenditures to Russian firms instead of foreign software companies*."[434]

In addition, a basic package of free software solutions including operating systems, drivers, and application software for servers[435] must be approved for use in pilot sites by the second quarter of 2012.[436] And, free software containing transferred data from previously used information systems must be introduced within specific government and financial institutions by the third quarter of 2014.[437] Further, the executive order provides for the creation of a single repository "for Linux distros [distributions][438] and other free operating systems by the second quarter of 2012"[439] which will be used throughout all of the federal bodies of executive power.

Whether or not the Putin executive order will enable Russia to achieve its stated objective without jeopardizing its access to international intellectual and financial capital and without violating international trade laws as it prepares itself for WTO accession[440] remains uncertain.[441] In

433. *See* Negris, *supra* note 413 (emphasis added).

434. Eric Brown, *Russia's Latest Five-Year Plan Calls for Switch to Linux*, DESKTOPLINUX.COM (Dec. 29, 2010) (emphasis added), http://www.desktoplinux.com/news/NS8433092393.html.

435. Ben Parr, *Vladimir Putin Orders Russian Government to Switch to Free Software by 2015*, MASHABLE.COM (Dec. 27, 2010), http://mashable.com/2010/12/27/vladimir-putin-free-software-by-2015/.

436. *See* GOVERNMENT OF THE RUSSIAN FEDERATION, *supra* note 406, at point 7.

437. *Id.* at point 15.

438. *See Linux Distribution*, WIKIPEDIA, http://en.wikipedia.org/wiki/Linux_distribution.

439. *See* GOVERNMENT OF THE RUSSIAN FEDERATION, *supra* note 406, at point 6.

440. *See, e.g.*, Steve Gutterman & Gleb Bryanski, *Putin Praises START Treaty, Warns on WTO*, REUTERS (Dec. 29, 2010, 4:05 PM), http://www.reuters.com/article/2010/12/29/uk-russia-putin-usa-idUKLDE6BS0Z520101229; Steve Gutterman, *Russia's*

fact, it is arguable that Mr. Putin's quest for indigenous Russian innovation already runs counter to the global focus and spirit of the Yaroslavl Roadmap[442] (specifically, Steps 5-7 and 10-11)[443] delivered to President Dmitry Medvedev in early September 2010.[444] That roadmap is intended to guide Russia along the optimal path to "accelerate the creation of a knowledge-based economy" in light of international "best practices."[445] Indeed, Mr. Putin's indigenous innovation gambit and protectionist tendencies could undermine political efforts initiated by Mr. Medvedev to follow the Yaroslavl Roadmap and secure WTO accession.[446] In particular, President Medvedev has endeavored to establish industrial strategic alliances, a free trade zone, and scientific, technological, and educational cooperation with the E.U. and the U.S. for the ultimate purpose of securing badly needed private and public western know-how[447] and investment capital (foreign direct investment).[448] President

Putin Sees 2011 WTO Entry Despite Questions, REUTERS (Dec. 29, 2010, 12:19 PM), http://www.reuters.com/article/2010/12/29/russia-wto-putin-idUSLDE6BS19720101229.

441. *See, e.g., American Lobbyists Against Open Standards, Faced with Opposition from the Free Software Foundation*, CNEWS SOFT (Oct. 21, 2010, 1:46 AM), http://soft.cnews.ru/news/softbox/10555/.

442. *See* Karin Ezbiansky Pavese, Christopher Hayter, Daniel M. Satinsky, Ben Levitan & Christopher Cooke, *Yaroslavl Roadmap 10-15-20, International Experience and the Path Forward for Russian Innovation Policy*, THE NEW YORK ACAD. OF SCI. (Aug. 20, 2010), http://www.nyas.org/yaroslavlroadmap.

443. Step 5 emphasizes the need to "[u]nderstand international and domestic markets". Step 6 emphasizes the need to "[s]timulate internal demand through world-class standards, regulation, and procurement protocols". Step 7 emphasizes the need to "[e]stablish a balance between large and small companies and between multinational and domestic companies with the understanding that all are necessary drivers for a successful innovation system." Step 10 emphasizes the need to "[e]stablish clear IP ownership rules for government-funded research." Step 11 emphasizes the need to "[e]stablish trusted and complete IP law." *Id.* at 106–10.

444. *See* Adrienne Burke, *Academy Executives Present Roadmap for Innovation to Russian Leaders*, Inside the Academy, THE N.Y. ACAD. OF SCI. (Sept. 13, 2010), http://www.nyas.org/membercenter/AcademyNews.aspx?cid=af15db02-5ce0-4fe5-93bc-ab58b9242ae8.

445. *See* Daniel Satinsky, *A Global Context for Russian Innovation Policy*, MODERN RUSSIA (Dec. 1, 2010), http://www.modernrussia.com/content/global-context-russian-innovation-policy.

446. *See, e.g.*, Craig Pirrong, *A Putin Torpedo Fired at the WTO?*, SEEKING ALPHA (Dec. 31, 2010), http://seekingalpha.com/article/244316-a-putin-torpedo-fired-at-the-wto (discussing in part how Putin's recent provocative remarks about justifiable protectionism may reflect an indirect effort to "undermin[e] the WTO" with the goal of weakening Medvedev and his clout).

447. *See, e.g.*, *Joint Statement by the Presidents of the United States of America and the Russian Federation on a Strategic Partnership in Innovation*, THE WHITE HOUSE (June 25, 2010), http://www.whitehouse.gov/the-press-office/us-russia-joint-statements; *Deliverables for U.S.-Russia Innovation Dialogue, U.S.-Russia Innovation Dialogue*, EMBASSY OF THE UNITED STATES, MOSCOW, RUSSIA (Feb. 2010), http://moscow.usembassy.gov/rustechdel022510.html; *EU–Russia Cooperation on Innovation: INNO-Views Publishes the Summary Outcomes of Two Policy Workshops and the First EU-Russia*

Medvedev has also encouraged international participation in ambitious innovation projects such as the Skolkovo Center,[449] a high tech innovation hub modeled after California's Silicon Valley.[450] Its existence was largely made possible only by Russia's adoption of WTO-consistent legislation modeled after U.S. intellectual property, technology transfer, and public-private partnership laws.[451] Therefore, those western companies possessing valuable patents, trade secrets, and other intangible assets that have already pledged funds and technical cooperation to such projects should remain especially vigilant to ensure that such laws are actually implemented as written.[452] While it is possible that Mr. Putin's expected return to the

Innovation Forum, PRO INNO EUROPE (July 22, 2010, 11:54 PM), http://www.proinno-europe.eu/inno-views/newsroom/eu-russia-cooperation-innovation-inno-views-publishes-summary-outcomes-two-policy. Indeed, Point 22 of Executive Order No 2299-p provides that the Russian government should "investigat[e] . . . possible forms (methods) and the prospects for state support to Russian software developers *involved in international projects* for developing free software that can be used for purposes of federal executive bodies." GOVERNMENT OF THE RUSSIAN FEDERATION, *supra* note 406 (emphasis added).

448. *See* Alexander Kolyandr, *Russia Moves to Draw in More Foreign Investors*, WALL ST. J., Dec. 29, 2010, at A7; Gleb Bryanski, *Putin Wants Russia to Ease Foreign Investor Rules*, REUTERS (Dec. 28, 2010, 5:08 PM), http://www.reuters.com/article/idUSTRE6BR3RP20101228; Chris Weafer, *Economic Glasnost*, THE MOSCOW TIMES (Dec. 20, 2010), *available at* http://www.themoscowtimes.com/opinion/article/economic-glasnost/427178.html.

449. *See* Alexey Drujinin, *Russia, EU Must Cooperate in Innovation—Putin*, RIA NOVOSTI (Nov. 25, 2010, 9:43 AM), http://en.rian.ru/world/20101125/161489372.html.

450. *Cf.* Simon Shuster, *Russia Plans a Silicon Valley*, TIME MAGAZINE (Apr. 19, 2010), http://www.time.com/time/magazine/article/0,9171,1978772,00.html.

451. *See, e.g.*, Evgeniy Krasowski, *The New Russian Technology Transfer Legislation: An Overview Of Federal Law No. 217-FZ*, BFW NEWS (July 6, 2010), http://www.beyondthefirstworld.com/?page_id=1958; Lawrence A. Kogan, *Taking Advantage of IP Protection to Advance Russian Biotech*, presentation at the *First EurasiaBIO International Congress for Biotechnology, Bioenergy and Bioeconomy*, YU. A. OVCHINNIKOV RUSSIAN SOC'Y OF BIOTECHNOLOGISTS AND NAT'L BIOFUEL ASSOC. (Apr. 25, 2008), *available at* http://www.itssd.org/Programs/KoganPresentationEurasiaBIOMoscowConferenceApril2008.ppt; Yelena M. Bakulina & Lawrence A. Kogan, *How Market-Based Policies Could Spur Biotechnology Growth in Russia*, 23 WASH. LEGAL FOUND.—LEGAL BACKGROUNDER (Mar. 21, 2008), *available at* http://www.wlf.org/upload/03-21-08balukina.pdf.

452. *See GE in Russian Joint Ventures*, ZACKS INV. RESEARCH (Dec. 29, 2010), http://www.zacks.com/stock/news/45283/GE+in+Russian+Joint+Ventures; *Skolkovo Attracts Foreign Companies*, THE VOICE OF RUSSIA (Dec. 14, 2010, 8:23 PM), http://english.ruvr.ru/2010/12/14/36849246.html; Olga Razumovskaya, *Siemens Plans Pilot Projects*, THE ST. PETERSBURG TIMES (Dec. 14, 2010), *available at* http://www.times.spb.ru/index.php?action_id=2&story_id=33272; Svetlana Katmykova, *Russia May Take Lead in Innovations by 2017*, THE VOICE OF RUSSIA (Dec. 13, 2010, 5:47 PM), http://english.ruvr.ru/2010/12/13/36758465.html; Tom Washington, *Skolkovo Cash Goes to Russian Energy Giants*, THE MOSCOW NEWS (Dec. 13, 2010), http://themoscownews.com/business/20101213/188274658.html?referfrommn; Andrey Goltsblat, *Skolkovo Innovation*

Russian Presidency in 2012 would present additional risks to foreign ICT and other investments, it is not yet certain.[453]

e. South Africa

While having only very recently become a member of the BRICS nations,[454] South Africa is "[t]he leader of information and communication technology (ICT) development in Africa" and has become "the 20th largest consumer of IT products and services in the world . . . [T]he country's ICT and electronics sector [is recognized] as an increasingly important contributor to South Africa's gross domestic product (GDP)."[455]

Center Update: Rules for Aspirations: Fueling Inspiration or Regulating It?, *GBLP in the Press*, GOLDSBLAT BLP (Dec. 2, 2010), http://www.gblplaw.com/news/articles/47092/; Rajorshi Roy, *Skolkovo Initiative: Russia's Drive Towards Modernization*, *IDSA COMMENT*, INSTITUTE FOR DEFENCE STUDY AND ANALYSES (Nov. 26, 2010), http://www.idsa.in/idsacomments/SkolkovoInitiativeRussiasDriveTowardsModernization_rroy_261110; Derek Anderson, *Nokia Agrees to Join Skolkovo Center*, THE MOSCOW TIMES (Nov. 18, 2010), *available at* http://www.themoscowtimes.com/business/article/nokia-agrees-to-join-skolkovo-center/423593.html; Goldie Blumenstyk, *In New Project, Russian Universities Tap American Expertise in Tech Transfer*, THE CHRONICLE OF HIGHER EDUCATION (Sept. 30, 2010), *available at* http://chronicle.com/article/In-New-Project-Russian/124657/.

453. *See* Andrew E. Kramer, *For Investors, Russia's Putin Is Good for Business*, N.Y. TIMES (Sept. 27, 2011), *available at* http://www.nytimes.com/2011/09/28/business/global/new-putin-presidency-seen-as-good-for-business-in-russia.html ("A consensus is emerging among bankers, economists and companies that evaluate market risk that the return of Vladimir V. Putin as Russia's president will be a net positive for foreign investors—regardless of whether they support the politics of it. . . . According to this analysis, the reunification of power in the Russian president in both title and practice—*even one, like Mr. Putin, who has a track record of abrogating contracts*—creates a more predictable long-term outlook for companies like Exxon Mobil, which has just agreed to a major oil exploration deal in the Russian Arctic. This investment argument in favor of more stable, less pluralistic politics in Russia seems also to reflect the reality that rapid economic development has been achieved in a number of post-Communist countries that never transitioned to democracy, like China. . . . Other analysts note that companies and investors will now be able to price in political risks whose contours are not likely to change much, as Mr. Putin is poised to remain in power until 2024." (emphasis added)). *See also* 5 *Reasons for Investors to Cheer Putin's Return*, Editorial, The Moscow Times (Sept. 26, 2011) *available at* http://www.themoscowtimes.com/mobile/article/444280.html ("If Putin has proved anything during his 11 years in power, it is that he is a strong leader interested in bringing stability to Russia. His means of ushering in stability and maintaining it have bred corruption and raised worries about the state of democracy and civil society. But at the same time, *the investment climate has markedly improved from the chaotic 1990s, with, among other things, the passage of key legislation and regulations that allow investors to work within an understandable—if often violated—legal framework*, a demonstrably greater effort by the authorities to consider and act on investors' concerns, and a steady increase in the standard of living that has led to growing consumer demand." (emphasis added)).

454. *See* GLOBAL POST, *supra* note 116; SOUTHAFRICA.INFO, *supra* note 116.

455. *See ICT and Electronics in South Africa, Key Sectors*, SOUTHAFRICA.INFO (Oct. 2008), http://www.southafrica.info/business/economy/sectors/icte-overview.htm.

"The South African Ministry of Trade and Industry (DTi) has identified ICT and electronics among 11 priority sectors that have the highest growth and investment potential in South Africa."[456]

It is therefore not surprising that the South African government, a leading member of the WIPO DAG, released its own national *e*Government ICT interoperability framework during 2007. Like the interoperability frameworks previously discussed in this Article, the South African framework broadly defines open standards "as standards containing specifications that are "documented, *freely implementable* and available to the public at large."[457] The MIOS is applicable to all existing as well as legacy government systems used by South African national, provincial, and local government departments and agencies, and covers all intra-government agency, government-to-citizen, government-to-employee and government-to-third party interactions consisting of the exchange of data and information access.[458] The South African government also recommends that MIOS be implemented "in all public sector procurements and major upgrades to . . . departmental legacy systems . . . [even for] systems that fall outside the scope and mandate" of MIOS.[459]

And, as in the case of some other national governments' frameworks, South Africa has drawn a strong correlation between ICT interoperability and "open standards" largely for economic competitiveness and "public interest" reasons. While acknowledging the different "definitions of open standards which emphasize different aspects of openness, including of the resulting specification, the openness of the drafting process, and the ownership of rights in the standard," the framework nevertheless sets forth a list of mandatory criteria for a standard to be considered "open." Among other things, for example, "the intellectual property rights required to implement the standard (e.g., essential patent claims) [must be] irrevocably available without any royalties attached" and there must be "no reservations regarding reuse of the standard."[460] Perhaps corporate innovators and investors may derive some comfort from the South African

456. *State of Victoria, Emerging ICT Market Strategy: South Africa*, DEP'T OF INNOVATION, INDUS. & REG'L DEV., 6 (2007), *available at* http://www.mmv.vic.gov.au/Assets/606/1/MMVSthAfricaStrategyNov2007.pdf.

457. MINIMUM INTEROPERABILITY STANDARDS (MIOS) FOR INFORMATION SYSTEMS IN GOVERNMENT (VERSION 4.1) (2007), at §§ 2.2–.3 (S. Afr.) (emphasis added), *available at* http://www.sita.co.za/standard/MIOSv4.12007.pdf.

458. *Id.* at §§ 1.2.1–33.

459. *Id.* at § 1.2.4.

460. *Id.* at § 2.3.1.

government's willingness, for reasons of pragmatism, to adopt other than fully "open" standards as so defined. For example, it may "take into account . . . the degree of openness . . . when selecting an appropriate standard [that does] not necessarily conform to being open in all respects,"[461] as in the case where a fully open royalty-free standard is unavailable or is unsupported by the market and an otherwise compatible FRAND, royalty-based specification is.

IV. CONCLUSION

Multinational businesses possessing unique scientific and technological know-how should be concerned with the issues raised and findings revealed in this Article. National and regional governments, in both emerging and developing countries, are actively pursuing 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. In the process, these governments have intentionally or unwittingly increased the already high level of legal and economic uncertainty and associated risks currently borne by companies operating in the pharmaceutical and biotech, medical devices, clean and renewable energy technologies, clean technology services, and ICT sectors, as well as their investors. As a result, unless such companies endeavor to mitigate these risks through available public and private means, investors may ultimately decide to modify their investment strategies such that capital funds previously committed and 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.

A. Public Law Opportunities to Mitigate Such Risks

1. International Trade Agreements and the WTO State-to-State Proceedings

The international trade agreements that fall under the auspices of the World Trade Organization (WTO) acknowledge that proposed or enacted regulatory changes in one country can and often do affect the investment, trade, and regulatory landscapes in another. Such regulatory changes also aim to prevent one member country's laws and regulations from creating non-tariff-related trade and investment barriers that impede the

461. *Id.*

flow of goods and services offered for sale and 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 such measures may engender.

Consequently, consistent with the mutual concessions made by each WTO member state at the Uruguay Round of trade negotiations, 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 enacting proposed legislative and regulatory measures that could potentially affect the property and due process rights of citizens engaged in the international trade of goods and services.[462] This obligation applies as well to WTO Member State laws and regulations that may possibly impair the exploitation by WTO member citizens of validly held intellectual property (patent and trade secret) rights and trade in high technology goods in which such IP rights are embedded.[463] In addition, it also applies to WTO Member State laws and regulations that may "condition[] the approval of [patent-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.[464]

462. *See* Art. 12.4 (relating to *Administration*) and Annex B (relating to *Transparency Of Sanitary and Phytosanitary Regulations*) of the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS), Apr. 15, 1994, 1867 U.N.T.S. 493.; 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 Agreement on Technical Barriers to Trade (TBT), Apr. 15, 1994, 1868 U.N.T.S. 120.

463. Art. 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]." *Notifications Under the TRIPS Agreement*, WTO, http://www.wto.org/english/tratop_e/trips_e/intel7_e.htm (last visited July 25, 2010). *See also WTO Trade Related Investment Measures (TRIMs) Agreement*, TRADE POLICY DIRECTORATE (Aug. 2001), *available at* http://webarchive.nationalarchives.gov.uk/tna/+/http://www.berr.gov.uk/files/file22992.pdf. In particular, TRIMS Article 6 relates to *Transparency*. *See* Agreement on Trade Related Investment Measures (TRIMs), Apr. 15, 1994, 1868 U.N.T.S. 186.

464. For example, governments may not adopt measures to promote the "public interest" of securing technological development and tech transfer at the expense of foreign patent and trade secret rights holders. *See* TRIPS, Article 8.1. Nor may governments

Furthermore, the obligations to ensure "national treatment" and transparency to prevent "like" product discrimination or the creation of "unnecessary obstacles" to (disguised restrictions on) international trade[465] 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.[466]

Consequently, a government's decision to issue a de jure or de facto compulsory license against foreign-owned software or other ICT patents or to enact a mandatory ICT interoperability framework has the same effect on ICT patent rights as do WTO implications may have on a compulsory license. WTO liability may be triggered if such rules favor domestic nonproprietary software and communications technology developers operating pursuant to a "software-as-a-service" business model at the expense of foreign proprietary software, or communications technology developers operating pursuant to a royalty-based business model. For example, substantive *as well as* procedural measures could potentially fall within WTO Agreement provisions intended to prevent discrimination between different types of intellectual property rights (patents versus copyrights or patents versus trade secrets) or between different types of ICTs.[467] Or, both types of measures[468] could conceivably fall within WTO Agreement provisions intended to prevent otherwise nondiscriminatory government measures from creating unnecessary obstacles to trade if it can be shown that they impede a foreign owner's

adopt measures to prevent "abuse" of IP rights to prevent anti-competitive practices and practices that prevent technology transfer that unduly restrict or abrogate the right holder's enjoyment of IP rights in violation of the TRIPS Agreement. *See* TRIPS, Article 8.2.

465. *See also* TRIPS, Art. 41.1; TBT, Art. 2.2–2.3.

466. *See* Agreement on Government Procurement art. VI.1, Apr. 15, 1994 Marrakesh Agreement Establishing the World Trade Organization, 1915 U.N.T.S. 103; URUGUAY ROUND TRADE AGREEMENTS, TEXTS OF AGREEMENTS, IMPLEMENTING BILL, STATEMENT OF ADMINISTRATIVE ACTION, AND REQUIRED SUPPORTING STATEMENTS, H.R. DOC. NO. 103–316 (1994). *See also* Arts. III.1(a) and (b), XIX and XXIII.2 of the Agreement on Government Procurement, *supra*.

467. *See* TRIPS, Art. 27.1, which provides that ". . . patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced." *Id.*

468. "Procedures concerning the acquisition or maintenance of intellectual property rights . . . [shall be] . . . reasonable . . . [and like] . . . procedures concerning the enforcement of intellectual property rights[,] shall be fair and equitable. They shall not be unnecessarily complicated or costly, or entail unreasonable time-limits or unwarranted delays . . . [And, they] shall be applied in such a manner as to avoid the creation of barriers to legitimate trade and to provide for safeguards against their abuse." *See* TRIPS, Arts. 41.1–41.2, 62.1, and 62.4.

exercise of its IP rights[469] when other less trade restrictive alternatives are available to fulfill a legitimate public policy objective.[470]

Arguably, the inquiry and analysis that national and 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. The inquiry should entail a broad examination of the domestic and cross-border *purposes* and *effects* of the particular measure(s) in question. The following inquiries should be made:

- 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)?

469. *See* TRIPS, Art. 31, which sets conditions for the issuance of compulsory licenses.

470. A WTO dispute panel recently explained the requirements imposed by TBT, Art. 2.2, which are arguably analogous to those contained in TRIPS, Art. 41.1. While such decision is not binding, it may be viewed as persuasive for purposes of interpreting TRIPS, Art. 41.1. *See United States-Measures Concerning the Importation, Marketing and Sale of Tuna and Tuna Products, Report of the Panel (US–Tuna II) WT/DS381/R*, WTO (Sept. 15, 2011), http://www.worldtradelaw.net/reports/wtopanels/us-tunamexico(panel).pdf. "The first sentence of Article 2.2 translates this general objective into a positive obligation by requiring Members to ensure that their technical regulations are not prepared, adopted or applied with a view to, or with the effect of, creating unnecessary obstacles to international trade." *Id.* at ¶ 7.385. "[T]he second sentence of Article 2.2 of the TBT Agreement establishes two requirements that technical regulations must comply with in order not to constitute unnecessary obstacles to international trade . . . Technical regulations must pursue a legitimate objective; and They must not be more trade-restrictive than necessary to fulfill that legitimate objective, taking into account the risks non-fulfilment would create." *Id.* at ¶ 7.387. "Similarly under Article 2.2 of the TBT Agreement, which also relies on the notion of 'legitimate objective' pursued by the measures, the burden is on the complainant . . . to establish the existence of a violation of this provision, including that the measures are 'more trade-restrictive than necessary to fulfill a legitimate objective,' and this necessarily involves a determination of what such objective is and its legitimacy within the meaning of Article 2.2." *Id.* at ¶ 7.392.

- Were less intrusive and trade restrictive alternatives available other than those selected?

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 or 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—"[mechanisms that are other than] the least trade-restrictive alternative[s] available to satisfy a legitimate national policy objective."[471]

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 or enforcement of government policy preferences 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.[472] 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 or proprietary-free services.[473] In this regard, the findings contained in the

471. *See* Precis of ITSSD WIPO Side-Bar Event, *supra* note 277, at 13.

472. *See* Lawrence A. Kogan, *Discerning the Forest from the Trees: How Governments Use Ostensibly Private and Voluntary Standards to Avoid WTO Culpability*, 2 GLOBAL TRADE AND CUSTOMS J., No. 9, 2007 at 319, *available at* http://www.itssd.org/GTCJ_03-offprints%20KOGAN%20-%20Discerning%20the%20Forest%20from%20the%20Trees.pdf.

473. For a more detailed discussion of the WTO implications of emerging voluntary, compulsory and/or industry standards directly and indirectly impairing the exercise of exclusive patent rights, see Kogan, The Complementarity of Patents and Standards, *supra* note 235, at pp. 30-41.

Report of the Panel on Canada—Certain Measures Affecting the Automotive Industry[474] are quite instructive, as they acknowledge that government action can involve a demand, request, or the imposition of a condition, but need not carry a particular connotation with respect to the legal form in which such government action is taken.[475] Consequently, when evaluating "situations involving actions by private parties, it is necessary to take into account that there is a broad variety of forms of government action that can be effective in influencing the conduct of private parties."[476]

2. International Investment Agreements and Investor-State Arbitration

The international trade agreements administered by the WTO provide for state-to-state procedures that focus on either the removal or withdrawal of state measures that interfere with an investor's exercise of private property rights, including patents and trade secrets, or the bringing of such measures into compliance or conformity with the relevant WTO Agreement (e.g., TRIPS).[477] In addition to such state-to-state procedures,

474. *See Report of the Panel on Canada—Certain Measures Affecting the Automotive Industry*, WT/DS139/R, WT/DS142/R (Feb. 11, 2000), http://www.wto.org/english/tratop_e/dispu_e/6100d.pdf.

475. "We note that several GATT and WTO Panel Reports have found that actions by private parties can constitute 'requirements' within the meaning of Article III:4." *Id.* ¶ 10.102. "While these cases are instructive in that they confirm that both legally enforceable undertakings and undertakings accepted by a firm to obtain an advantage granted by a government can constitute 'requirements' within the meaning of Article III:4, *we do not believe that they provide support for the proposition that either legal enforceability or the existence of a link between a private action and an advantage conferred by a government is a necessary condition in order for an action by a private party to constitute a 'requirement.'* To qualify a private action as a 'requirement' within the meaning of Article III:4 means that in relation to that action a Member is bound by an international obligation, namely to provide no less favourable treatment to imported products than to domestic products." *Id.* at ¶ 10.106 (emphasis added).

476. *Id.* at ¶¶ 10.106–10.107. "A determination of whether private action amounts to a 'requirement' under [GATT] Article III:4 must therefore necessarily rest on a finding that there is a nexus between that action and the action of a government such that the government must be held responsible for that action. We do not believe that such a nexus can exist only if a government makes undertakings of private parties legally enforceable, as in the situation considered by the Panel on *Canada—FIRA*, or if a government conditions the grant of an advantage on undertakings made by private parties, as in the situation considered by the Panel on *EEC—Parts and Components*." *Id.* at ¶ 10.107.

477. *See* Christopher Gibson, *A Look at the Compulsory License in Investment Arbitration: the Case of Indirect Expropriation*, *supra* note 81, at 417, referencing The DSU, Article 3.7. For a text of the DSU, panel and Appellate Body reports, and information

there exist a myriad of international investment agreements (IIAs) which a foreign IP investor could invoke in an investor-state arbitration proceeding.

Foreign investors generally can prevail in an IIA arbitration if they can show that a compulsory license (or government procurement interoperability rules requiring royalty-free ICTs to participate in *e*Government standards that are tantamount to a compulsory license) constitute(s) an indirect expropriation.[478] Unfortunately, there is no "mechanical formula" that can be employed to determine whether a given state act(s) rise(s) to the level of an actionable indirect expropriation, given the multitude of state measures that could potentially substantially curtail an investor's rights in its investment.[479]

According to one commentator who has adopted a single-step analysis, an indirect expropriation will be found to exist where an investor has suffered a deprivation of the use of its property right and such deprivation was "the result of the government reneging on a previous contractual commitment or authorization."[480] Another commentator embraces a two-step analysis to determine whether a state act(s) constitute(s) an indirect expropriation. First he focuses on whether "the nature or magnitude of the interference to the investor's property interests in its investment caused by" that measure(s) "amount[s] to a 'taking'".[481] Second he looks to whether such "interference rises to the level of an expropriation by reference to the relevant treaty standard . . . [taking into account] 'specific undertakings or representations' the state made to the investor and the 'legitimate reliance or expectations' of the investor which were subsequently disappointed by the state interference".[482] A third commentator has adopted a three-step analysis. He first "examines whether the level of deprivation constitutes a taking [and then] whether [it also] . . . rises to the level of an indirect expropriation. [He

on the WTO dispute process, *see* http://www.wto.org/english/tratop_e/dispu_e/dispu_e.htm.

478. *Id*. at 378.

479. *Id*. at 378–79.

480. *Id*. at 381–82, referencing Andrew Newcombe, *The Boundaries of Regulatory Expropriation in International Law*, 20 ICSID REV. FOR. INV. L.J. 1, 9–11 (2005), *available at* http://papers.ssrn.com/sol3/papers.cfm?abstract_id=703244&download=yes. "[Thus,a] state's decision to revoke a previously granted right [will be deemed similar] in its effects [to] the indirect appropriation or acquisition of that previously granted approval or authorization by the state." *See* Christopher Gibson, *A Look at the Compulsory License in Investment Arbitration: the Case of Indirect Expropriation*, *supra* note 81, at p. 382.

481. Christopher Gibson, *supra* note 81, at 382 (referencing Jan Paulsson & Zachary Douglas, *Indirect Expropriation in Investment Treaty Arbitrations*, *in* ARBITRATING FOREIGN INVESTMENT DISPUTES 145, 145–46 (Norbert Horn & Stefan Kröll eds., 2004).

482. *Id.*

then examines] the character of . . . and the regulatory purpose behind . . . the government action."[483]

Unlike the remedies available in WTO proceedings, which are purely prospective in nature, the remedies available in investor-state tribunals are purely compensatory in nature and would provide monetary damages "in the case of an indirect expropriation or other violation of the international investment agreement."[484] There are significant differences as well between the available enforcement mechanisms of the WTO and those of an IIA. WTO enforcement measures, which tend to be lengthy and non-tailored to particular investors, include "diplomatic pressure to withdraw the WTO-noncompliant measure or bring it into compliance, obtention of compensation (which is voluntary), or suspension of trade concessions as a form of retaliation."[485] By contrast, an award rendered under the ICSID (International Centre for Settlement of Investment Disputes) Convention[486] must be recognized as binding by each contracting state. Thus each must "enforce the pecuniary obligations imposed by that award within its territory as if it were a final judgment of a court in that State."[487] ICSID investor-state awards cannot be appealed administratively or otherwise challenged in court, "as is possible under the New York [UNCITRAL][488] Convention."[489] If successful, an investor will have the option of enforcing "an award in any country where the host state may hold funds" or it may be "required to avail itself of the domestic courts of the host state against whom such enforcement is sought."[490] Were an investor to take this latter course, it may encounter the

483. Christopher Gibson, *supra* note 81, at 382–83.
484. *Id.* at 418.
485. "These measures may bring the investor the relief it desires, but the process may be lengthy and is not guaranteed to achieve a tailored outcome for the particular investor, even if some form of enforcement takes place." *Id.* at 419.
486. "ICSID is an autonomous international institution established under the Convention on the Settlement of Investment Disputes between States and Nationals of Other States [t]he primary purpose of [which] is to provide facilities for conciliation and arbitration of international investment disputes." *See* International Centre for Settlement of Investment Disputes, *available at* http://icsid.worldbank.org/ICSID/Index.jsp.
487. *See* ICSID Convention, Article 54(1), *available at* http://icsid.worldbank.org/ICSID/StaticFiles/basicdoc/CRR_English-final.pdf.
488. *See* U.N. Convention on the Recognition and Enforcement of Foreign Arbitral Awards [New York Convention] art. V, June 10, 1958, 330 U.N.T.S. 38, *available at* http://www.uncitral.org/pdf/english/texts/arbitration/NY-conv/XXII_1_e.pdf.
489. *See* Christopher Gibson, *supra* note 81, at 418–19.
490. *Id.* at 419.

doctrine of sovereign immunity which "may be used to impede execution of the award."[491]

Notwithstanding the apparent differences between WTO state-to-state and investor-to-state proceedings, it must be remembered that, in the end, the tribunal must maintain an "appropriate balance between the rights and responsibilities of investors and those of governments."[492] This means that while a foreign IP "investor is entitled to have its legitimate expectations with regard to the operation and return on its [patent and trade secret] investment[s] respected by the host state . . . the host state should [nevertheless] be able to pursue lawful regulatory goals [such as affordable *e*Government ICT interoperability] without risk of 'regulatory chill.'"[493] This will entail an additional level of complexity as the TRIPS compulsory licensing provisions are applied in an investor-state arbitration to assess the legality of the regulatory provisions in question.

> The possible reference to the WTO TRIPS Agreement demonstrates the second level of complexity: the compulsory license provides a case in point to show the intricate interplay between two different treaty-based regimes. *A compulsory license-based claim for indirect expropriation against a host state under an IIA may implicate several strands of public law that can be complimentary or competing, integrated or overlapping. International investment law, as channeled through the investment treaty, confronts intellectual property law as established through national law or the TRIPS Agreement.* The compulsory license brings this confluence of competing legal regimes into stark focus. If a foreign investor believes that a host state has improperly authorized a compulsory license with respect to its patent-based investment, it may face not only a choice of forum in which to vindicate its rights, but also complex choice of law issues in making out a claim of indirect expropriation. *Because investment agreements such as BITs stand side-by-side with the WTO multilateral trading system*, these different regimes may afford different levels of protection and different remedies to the foreign investor in a dispute where the investor's home state and the host state are both members of the WTO, or where the IIA itself makes reference to the TRIPS Agreement.[494]

Indeed, other legal commentators have also considered how general public international law, such as WTO and human rights law can influence international investment law.[495]

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491. "Nothing in Article 54 shall be construed as derogating from the law in force in any Contracting State relating to immunity of that State or of any foreign State from execution." *See* ICSID Convention, Article 55; *see* Christopher Gibson, *supra* note 81, at 419.

492. *Id.* at 420.

493. *Id.*

494. *Id.* at 421 (emphasis added).

495. *See* Jurgen Bering, Tillmann Rudolf Braun, Ralph Alexander Lorz, Stephan Schill, Christian Tams & Christian Jietje, *General Public International Law and International Investment Law—A Research Sketch on Selected Issues* 9–25 (The International Law Association German Branch, Subcommittee on Investment Law

B. Private Law Opportunities to Mitigate Such Risks

Beyond recourse to public international trade and investment law remedies, the innovator and investor community 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 are 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 intellectual property (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 access to or development of information pathways through credible sources, or reportage 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; construction of a flexible decision matrix to support a regime of identity or nonidentity to be associated with such efforts; and concentration and limitation of personnel therein to reduce possible leakage or other unwanted or unintended consequences. External considerations also include vigorous supply-chain enforced protocols for information exchange, conformity assessment and compliance with quality, performance, and integrity of

Working Group, Working Paper (2009)), *available at* http://www.50yearsofbits.com/docs/091 2211342_ILA_Working_Group_IIL_PIL.pdf (demonstrating, in part, how the abstract principle of "fair and equitable treatment" contained in most bilateral investment treaties has been addressed in the practices of arbitral tribunals and is influenced by public international law, and recommending an alternative approach that draws parallels to public law standards used in both domestic law and other international law regimes).

shipment standards, loss control, and verified real time reporting, among others.

Carefully crafted communications with individuals and organizations would preserve credibility and access, whether or not contracted for, gratuitous, or circumstantial. An external communications policy that conveys clear guidelines to all vetted personnel acting as representatives governed by an information regime designed to assess and ensure the identity, accuracy, and protection of relevant information must be established. 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.