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Patent Law Harmonization and the Draft SPLT

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I. Introduction

Thank you for the invitation to address this assembly on this important topic. I congratulate WIPO on its efforts to organize this deep and thorough look at the patent harmonization process from a balanced perspective and with due regard to the interests of all the stakeholders. If we can view this Forum as a product of WIPO's recent efforts to accommodate a more development friendly agenda,¹ it bodes well for the future of world intellectual property law, indeed.

Under the aegis of WIPO's Standing Committee on the Law of Patents (SCP), the Draft Substantive Patent Law Treaty (SPLT)² represents an attempt "to pursue a 'deep harmonization' of both the law and practice" concerning not just the drafting, filing and examination of patent applications, but also "cornerstone requirements of patentability, such as novelty, non-obviousness, sufficiency of description, and drafting and interpretation of claims."³ Several speakers this morning have already explained the potential importance of this initiative, and I will not review the case for "deep harmonization" they have ably articulated.⁴

Because time is short, let me clarify from the start what most of you know already. I am

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¹ On October 4th, 2004, the General Assembly of the World Intellectual Property Organization agreed to adopt a proposal presented by the so-called Group of Friends of Development (namely: Argentina and Brazil), for the establishment of a Development Agenda for WIPO, (document WO/GA/31/11). Since then, many other proposals have been presented and discussed. *See also* James Boyle, *A Manifesto on WIPO and the Future of Intellectual Property*, 2004 DUKE L. & TECH. REV. 9 (2004).

² Standing Committee on the Law of Patents, (SCP), Draft Substantive Patent Law Treaty (SPLT), 10th Sess., May 10-14, 2004, WIPO doc. SCP/10/2, 30 Sept. 2003.

³ Karen M. Hauda [Office of Legislative and International Affairs, USPTO], *The Role of the United States in World-Wide Protection of Industrial Property*, in *THE FUTURE OF INTELLECTUAL PROPERTY IN THE GLOBAL MARKET OF THE INFORMATION SOCIETY* (F. Gotzen, ed., Brylant, Brussels, 2003), 91, 97 [hereinafter *FUTURE OF IP*]. "This approach was adopted in an attempt to avoid the controversial hurdles to agreement that were found in the past." *Id.* *See also* Philippe Baechtold [Head Patent Law Section, Patent Policy Department, WIPO], *The Future Role of WIPO, in the Area of Industrial Property*, in *FUTURE OF IP, supra*, 139, 142-43 (stressing need to cover other topics such as patentable subject matter, the requirement of technical character of an invention, exceptions from patentability, novelty grace period and issue of equivalents).

⁴ Mr. Kenji Kamata Japan Intellectual Property Association, Tokyo; Mr. Jonathan Zuck, President, Association for Competitive Technology, Washington, D.C.; Mr. Daeshik Jeh, Director, Patent Examination Policy Team, Korean Intellectual Property Office, Daejeon.

deeply skeptical of the Draft SPLT, and believe that it is both unwise and premature to undertake another major substantive patent harmonization exercise barely ten years from the TRIPS Agreement,⁵ which already produced a revolutionary advance in the state of world patent law.⁶ Today, I would like first to reiterate the reasons why such an exercise would be bad for all developing countries, whatever their relative technological capacities may be. Then, I would like to argue a much more controversial claim, namely, that premature harmonization of patent laws would be bad, and indeed extremely counterproductive for developed countries, including those very countries who are most aggressively (and in my view erroneously) pressing for yet another round of multilateral intellectual property negotiations.

II. Adverse Impact on Developing Countries

If we look briefly at the developing countries, we see that they have just begun to absorb the social costs of higher standards of intellectual property protection under TRIPS, and they are greatly challenged by the need to adjust their development strategies to the new legal realities.⁷ Their ability to reverse engineer up-to-date foreign technologies has been significantly reduced; their rights to produce generic drugs without regard to pharmaceutical patents was completely eliminated in 2006 (for example, India);⁸ and their efforts to acquire high-tech goods on open markets to make their domestic firms more competitive in export markets has reportedly been hampered by refusals to deal and by demands for increased rent extraction by foreign manufacturers who enjoy immunity from reverse-engineering under the TRIPS norms.⁹ While the full extent of these anti-competitive barriers has been insufficiently studied, it seems that high-tech manufacturers in developed countries must prefer selling to wholly-owned foreign subsidiaries than to potential competitors in developing countries,¹⁰ and that when sales are made to third parties, the net welfare gains from technology installation may often be offset by the

⁵ Marrakesh Agreement Establishing the World Trade Organization (WTO), Annex 1C, Agreement on Trade-Related Aspects of Intellectual Property Rights [TRIPS Agreement] (1994).

⁶ See, e.g., Keith E. Maskus & Jerome H. Reichman, *The Globalization of Private Knowledge Goods and the Privatization of Global Public Goods*, in INTERNATIONAL PUBLIC GOODS AND TRANSFER OF TECHNOLOGY UNDER A GLOBALIZED INTELLECTUAL PROPERTY REGIME (K. E. Maskus & J. H. Reichman, eds., Cambridge U. Press, 2005), 1-45; J. H. Reichman, *Universal Minimum Standards of Intellectual Property Protection under the TRIPS Component of the WTO Agreement*, in INTERNATIONAL PROPERTY AND INTERNATIONAL TRADE – THE TRIPS AGREEMENT (C. M. Correa & A. A. Yusuf, eds., Kluwer 1998).

⁷ See, e.g., Commission on Intellectual Property Rights (CIPR), *Integrating Intellectual Property Rights and Development Policy* (2002).

⁸ See, e.g., Frederick M. Abbott, *Managing the Hydra: The Herculean Task of Ensuring Access to Essential Medicines*, in INTERNATIONAL PUBLIC GOODS AND TRANSFER OF TECHNOLOGY UNDER A GLOBALIZED INTELLECTUAL PROPERTY REGIME, *supra* note 6, 393-424.

⁹ See, e.g., Carlos M. Correa, *Can the TRIPS Agreement Foster Technology Transfer to Developing Countries?*, in INTERNATIONAL PUBLIC GOODS AND TRANSFER OF TECHNOLOGY UNDER A GLOBALIZED INTELLECTUAL PROPERTY REGIME, *supra* note 6, at 227. 229-32; Carlos Correa, *Trends in Technology Transfer – Implications for Developing Countries*, 21 SCI & PUB. POL'Y 369 (1994). See also Keith E. Maskus, *Encouraging International Technology Transfer*, (Draft Report, UNCTAD/ICTSD 2003).

¹⁰ See, e.g., Lee L. Branstetter, *Do Stronger Patents Induce More Local Innovation?* in INTERNATIONAL PUBLIC GOODS AND TRANSFER OF TECHNOLOGY UNDER A GLOBALIZED INTELLECTUAL PROPERTY REGIME, *supra* note 6, at 309. 317-20.

costs of increased rent extraction.¹¹

Of far greater importance is the fact that the developing countries stand to lose most of the flexibilities they retained under the TRIPS Agreement by engaging in the SPLT process. Consider, for example, the eligibility requirement of an inventive step (nonobviousness). If the United States now applies an extremely low standard of nonobviousness, which has elicited sustained criticism,¹² and if developing countries would benefit from a higher, more pro-competitive eligibility requirement,¹³ the latter cannot benefit from a single uniform standard because U.S. negotiators lack authority to change or elevate most of their domestic norms and practices.

More generally, there is a risk that virtually every pro-competitive option still left open to developing countries under their domestic patent laws—from exceptions to patentability to limitations on exclusive rights and the possibility of imposing compulsory licenses¹⁴ – would likely issue more circumscribed from the SPLT negotiations than before, because the industrialized countries only want higher standards. Consider, for example, the U.S. delegate’s response at a recent conference, when a WIPO representative noted the need to reflect on positions concerning “patentable subject matter, including the requirement of technical character of invention, [and]...exceptions from patentability:”¹⁵

[T]he U.S. delegation has made it clear that it cannot accept any ‘technical effect’ requirement.¹⁶

As regards other issues concerning “patent eligible subject matter” and “exceptions to patentability for health, the environment or protection of genetic resources, and traditional knowledge...[t]he U.S. delegation saw the inclusion of many of these provisions as being against a deep harmonization approach.”¹⁷

In a word, the developed countries have little to trade for protectionist concessions and little room to negotiate offsetting compensation for the other adverse effects of still higher levels of rent extraction from developing countries. At least in the bilateral and regional Free Trade Agreements, there is an appearance of compensatory market access opportunities, whatever the economic realities may turn out to be.¹⁸ Of course, even in those negotiations, USTR’s only

¹¹ *Id.*, at 319. See also *supra* note 9.

¹² See, e.g., A. B. JAFFE & J. LERNER, *INNOVATION AND ITS DISCONTENTS* 35 (Princeton Univ. Press, 2004); Rebecca Eisenberg, *Obvious to Whom? Evaluating Inventions from the Perspective of PHOSITA*, 19 BERKELEY TECH. L. J. 885 (2004); John Barton, *Non-Obviousness*, 43 IDEA 475 (2003).

¹³ See, e.g., CIPR, *supra* note 7; J. H. Reichman, *From Free Riders to Fair Followers: Global Competition under the TRIPS Agreement*, 29 N.Y.U. J. INT’L L. & POL. 11 (1997).

¹⁴ See generally, UNCTAD/ICTSD, *RESOURCE BOOK ON TRIPS AND DEVELOPMENT*, CAMBRIDGE, UNIVERSITY PRESS, 2005.

¹⁵ Baechtold, *supra* note 3, at 143.

¹⁶ Hauda, *supra* note 3, at 97.

¹⁷ *Id.*, at 97-98.

¹⁸ Martin Khor, *Bilateral/Regional Free Trade Agreements: An Outline Of Elements, Nature And Development Implications*, THIRD WORLD NETWORK, September 2005; Jean-Frédéric Morin, *Tripping Up Trips Debates IP and Health In Bilateral Agreements*, 2005; Frederick M. Abbott, *Intellectual Property Provisions of Bilateral and Regional Trade Agreements in Light of U.S. Federal Law*, ICTSD UNCTAD, January 2006. All articles are on file with the author.

mandate is to impose United States intellectual property norms,¹⁹ and they actually promote only a version of United States law endorsed by certain big companies that are also politically powerful.

What developing countries need most is a period of calm and stability in which to devise intellectual property strategies consistent with both the TRIPS Agreement and the needs of their own emerging national and regional systems of innovation. This is a lengthy, arduous, and difficult task in its own right. It is hard for governments and civil society to interact in devising innovation policies that will maximize the use of local assets, minimize the social costs of high international minimum standards of intellectual property protection, and preserve an optimal supply of public goods that are as essential to long-term development prospects as legal incentives to innovate. They cannot succeed if, at the international level, a new round of multilateral intellectual property negotiations threatens to raise the technological ladder once again, before they even get a solid foothold on it.²⁰

III. Likely Adverse Effects on Developed Countries

Rather than dwelling on the present plight of the developing countries, however, let us consider the contrary argument that, what is good for the developed countries must sooner or later trickle down to benefit the developing countries, once they begin to climb the technological innovation ladder. If only we can proceed to legislate a smoothly working worldwide patent system, the argument goes, over time all countries will profit from the lower transaction costs, greater legal certainty, and myriad other benefits, as they increase their technological skills.²¹

There are several fallacies with this argument. One is the false hope that, by adopting uniform standards now, we can somehow avoid the need to readjust and rebalance public and private interests tomorrow when new technological challenges arise once again. In reality, what we lack is any agreed “legitimizing governance process”²² to undertake a continuous process of accommodating all our intellectual property laws to changing technological realities at the international level.²³ Without a proper governance mechanism truly focused on managing what Maskus and I have called the “incipient transnational system of innovation,”²⁴ any premature attempt to freeze the law will likely represent merely partisan special interests. The end result could make both competition and innovation harder by a skewed re-regulation of the world

¹⁹ In 2002, US Congress enacted the Trade Promotion Authority stating that any “agreement governing intellectual property rights that are entered into by the United States [must] reflect a standard of protection similar to that found in United States law” (Trade Act of 2002, section 2102).

²⁰ See Maskus & Reichman, *supra* note 6, at 35-41.

²¹ Cf. John H. Barton, *Issues Posed by a World Patent System*, in INTERNATIONAL PUBLIC GOODS AND TRANSFER OF TECHNOLOGY UNDER A GLOBALIZED INTELLECTUAL PROPERTY REGIME, *supra* note 6, at 617, 621-28 (stressing need to accommodate developing countries’ problems).

²² Maskus & Reichman, *supra* note 6, at 19.

²³ See, e.g., Graeme B. Dinwoodie and Rochelle Cooper Dreyfuss, *WTO Dispute Resolution and the Preservation of the Public Domain of Science under International Law*, in INTERNATIONAL PUBLIC GOODS AND TRANSFER OF TECHNOLOGY UNDER A GLOBALIZED INTELLECTUAL PROPERTY REGIME, *supra* note 6, at 861-83.

²⁴ Maskus & Reichman, *supra* note 6, at 34-35.

market and by excessive privatization of global public goods.²⁵

The typical response to such arguments is that we should avoid pessimism and at least move forward to codify basic aspects of the domestic patent law – or so-called “best practices” – that would provide a solid foundation for transnational harmonization.²⁶ That viewpoint, of course, rests on the assumption that we actually possess such best practices and really know, at some fundamental level, what are the right solutions to be codified. This is the biggest fallacy of them all.

A. When “Rational Ignorance” is Hardly Bliss²⁷

The sad truth is that no one in the developed world at the moment really knows what a proper functioning patent system for the twenty-first century should look like. There are as many different proposals and solutions on the table as there are thinkers and investigators; and the only thing they have in common at the moment—besides the irreconcilable differences of their prescriptions is that the United States patent system is in a dreadful mess and badly needs reform.

True, there is still a handful of judges on the United States Court of Appeals for the Federal Circuit who disagree with this conclusion, and perhaps one law professor who usually tells them they are doing the best possible job in the best of all possible worlds.²⁸ But to be fair, many other judges on the Federal Circuit are reportedly concerned and perplexed about the direction that the court has lately taken.²⁹ Meanwhile the critical clamor³⁰ has grown louder and louder, and now includes a painstaking study by the National Academies,³¹ another by the Federal Trade Commission,³² and by a ferocious exposé by two highly respected conservative economists, Jaffe and Lerner, with the provocative subtitle “How Our Broken Patent System Is Endangering Innovation and Progress and What to Do About It.”³³

²⁵ *Id.*, at 19 (stressing lobbying role of “knowledge cartel,” which pushes “governments to regulate the global market in ways that lock in temporary competitive advantages without necessarily advancing the global public interest in innovation, competition or the provision of complementary public goods” and noting that “representatives of the global public interest are unlikely to be seated at the table where hard-law negotiations take place.”).

²⁶ Hauda, *supra* note 3, at 97.

²⁷ For the term “Rational Ignorance,” see Mark A. Lemley, *Rational Ignorance at the Patent Office*, 95 NORTHWESTERN U.L. REV. 1 (2001) (suggesting that poor patent office examination procedures may save overall resources because so few patents are actually licensed or litigated).

²⁸ See M. ADELMAN, PERSPECTIVES ON PATENTS.

²⁹ Interview with Professor Rochelle Cooper Dreyfuss, N.Y.U. School of Law.

³⁰ See, e.g., Maskus & Reichman, *supra* note 6, at 24 nn. 85-88 (citing critical articles by Professors Rai, Kesan, Thomas, Leung, Quillen & Ogden, Baird, Merges, Lemley, Heller & Eisenberg, Barton and others).

³¹ NATIONAL RESEARCH COUNCIL, A PATENT SYSTEM FOR THE 21ST CENTURY, The National Academies, Washington D.C., (2004).

³² To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy, a Report by the Federal Trade Commission, October 2003, available at <http://www.ftc.gov/os/2003/10/innovationrpt.pdf>.

³³ See JAFFE & LERNER, INNOVATION AND ITS DISCONTENTS, *supra* note 12. In reality, Jaffe & Lerner are more optimistic than they sound, because they think the problems stem from how the patent law is

Of course, it should surprise no one that new technologies, and new modes of producing them, constantly raise hard new questions that cannot simply be answered by routine tinkering with a patent paradigm launched at Venice in the fourteenth century and refined by the United Kingdom in the seventeenth century. There are major new challenges for which our past experiences give only untested and untrustworthy hypotheses, with no convincing empirical studies on the horizon to resolve our doubts. You can see this clearly by examining emerging differences and tensions among developed countries with regard to just a few basic issues under the SPLT, such as the novelty, nonobviousness, and utility standards, or the research exemption, not to mention growing differences regarding the treatment of compulsory licenses. There are also critical attacks on the institutional infrastructure governing administrative matters and the procedures or granting and re-examining patented inventions.

For example, the National Academies' Report criticized the reluctance of the Federal Circuit to defer to the examination guidelines that USPTO applies to new technologies, while applying unrealistic standards of their own that ignore what people skilled in the art actually know as well as the concerns of knowledgeable economists.³⁴ Professors Rai and Cooper Dreyfuss have questioned the broad powers vested in the Federal Circuit, specialized court, and its penchant for reviewing *de novo* even the facts of PTO and district court patent decisions, while a distracted Supreme Court ignored patent policy.³⁵

Virtually the entire literature condemns the general trend in the United States towards low and relaxed standards of novelty and nonobviousness,³⁶ including articles in both prestigious scientific reviews and the popular press.³⁷ For example, Jaffe and Lerner complain that we have started handing out patents "to pretty much anyone who asked for one, despite the legal tests of novelty and nonobviousness," a trend that "now undermines rather than fosters the crucial process of technological innovation."³⁸ They conclude that

[T]he intense pathology of the current system arises from the combination of stronger patent protection, a decline in the standards for granting patents, and the emergence of broad [yet questionable] patents in particular industries undergoing rapid technological change.³⁹

This trend is particularly acute with regard to both biotechnology and software patents, where scholars also point out that the eligibility standards are applied differently depending on the

applied and not from what it provides. See Rochelle Cooper Dreyfuss, [Review Article] (criticizing them in this regard).

³⁴ See NAS Report, *supra* note 31. *But see* Mark A. Lemley, *supra* note 27.

³⁵ See, e.g., Arti K. Rai, *Engaging Facts and Policy: A Multi-Institutional Approach to Patent System Reform*, 103 COLUM. L. REV. 1035, (2003); A. K. Rai, *Allocating Power over Fact-Finding in the Patent System*, 19 BERKELEY TECH. L. J. 907, (2004); Rochelle Cooper Dreyfuss, WVU L.J. [article criticizing specialized courts].

³⁶ See, e.g., Eisenberg, *supra* note 12; Barton, *supra* note 12; FTC Report, *supra* note 32 (stressing dangers of proliferation of "weak patents").

³⁷ See, e.g., Heller & Eisenberg, *SCIENCE*; James Gleick, *Patently Absurd*, NEW YORK TIMES MAGAZINE, Mar. 12, 2004, at 44.

³⁸ JAFFE & LERNER, *supra* note 12 at 35.

³⁹ *Id.*, at (19?).

industrial sector at issue.⁴⁰ As regards software and business method patents, the *Alappat*⁴¹ and *State Street Bank*⁴² decisions confirmed the test of a “concrete, tangible and useful result,” which combined a low standard of utility with a relatively low standard of nonobviousness, though one that seems paradoxically higher than that used in the biotech cases. The protectionist thrust of these and other decisions is further fanned by an inadequate knowledge of the prior art and by a quirky judicial requirement that pre-existing references cannot be read together absent a showing of objective motivation to combine. This approach validates patents on slivers of small-scale software innovation, with dubious demonstrations of utility that are then used to challenge and block later applications of the same basic idea or algorithm.

In DNA patenting, instead, the Federal Circuit has been clinging to analogies with chemical compounds that require relatively little differentiation from the prior art and little showing of specific utilities. Traditionally, if two chemical compounds were deemed functionally similar, there was a presupposition of nonpatentability. In evaluating DNA patents, however, the Federal Circuit focuses on structure, not functionality; and it treats the routine practitioner skilled in the art as a scientific nincompoop, far more dimwitted than his counterpart in computer-related technologies.⁴³

Translated to DNA patents, this approach tends to view every new isolated variant of DNA as both novel and nonobvious, no matter how limited the known useful applications may be. Moreover, because scientific publications seldom or never discuss the common technical processes underlying procedures for isolating specific genetic materials, the patent specifications tend to create a false appearance of difference between each new molecule or protein seen in isolation from their common production techniques. Applying the “motivation” test to end molecules without regard to these common production techniques also makes little sense. As a result, small variants of pre-existing molecules receive strong patent protection, with few known uses, and these dubious patents may then disrupt uses discovered later on analogy to chemical compounds.⁴⁴

A new study by Jensen and Murray of M.I.T. shows that twenty per cent of human gene DNA sequences have already been patented, especially genes dealing with health and disease, and some genes are patented as many as twenty times.⁴⁵ This array of strong patents on small variant molecules tends to create thickets of rights and blocking or anticommons effects, and as with software patents, they generate endless and costly litigation. While the Federal Circuit has recently, and somewhat reluctantly, stiffened its test of utility to require at least one concrete use of such molecules,⁴⁶ the Court’s “contorted logic” regarding novelty and nonobviousness (to use

⁴⁰ Dan Burk & Mark A. Lemley, *Is Patent Law Technology Specific?* 17 BERKELEY L.J. 1155 (2002).

⁴¹ *In re Kuriappan P. Alappat*, 33 F. 3d 1526, 31 U.S.P.Q. 2d 1545 (Fed. Cir. Fed. Cir. 1994).

⁴² *State Street Bank & Trust Co. v. Signature Financial Group Inc.*, 149 F.3d 1368 (Fed. Cir. 1998).

⁴³ See, e.g., Andrew Chin, *Artful Prior Art and the Quality of DNA Patents* (2005) (unpublished article on file with the authors); Samantha Jameson, *Biotechnology Patents in the United States and the European Communities* (Draft, January 2006) (unpublished article on file with the authors); Burk & Lemley, *supra* note 40.

⁴⁴ See generally Chin, *supra* note 43.

⁴⁵ Kyle Jensen & Fiona Murray, *Intellectual Property Landscape of the Human Genome*, 310 SCIENCE (Oct. 14, 2005).

⁴⁶ *In re Fisher* (CAFC 2006)

Prof. Rai's phrase) ensures that these practices will continue.⁴⁷

One line of resistance is a growing trend to defensive patenting in some quarters,⁴⁸ which, however, Professor Rai says only further blurs the line between what competitors can freely use and what is protected, and also deters new entrants.⁴⁹ A more aggressive attack has been launched by Prof. Andrew Chin of the University of North Carolina, who recently published a compilation of all the standard techniques for isolating supposedly variant DNA molecules, with a view to showing the Patent Office all the technical common denominators surrounding these claimed DNA "inventions," whose differences shrink from this perspective.⁵⁰ Chin's Registry has already been cited in twenty-five cases, and could change the facts on the ground by producing prior art for novelty and nonobviousness tests that the PTO can no longer ignore. Unfortunately, his registry only applies to post 2005 filings, whereas many weak but previously filed DNA patents are likely to issue because his data cannot be retroactively applied.

Another related problem has to do with the tendency to issue patents on biotechnology inventions that subsequently become necessary for the conduct of further scientific research.⁵¹ Arguably, this trend might produce a good kind of problem if the nonobviousness standard were high enough to ensure that only major contributions to the art survived the examination process.⁵² Even then, some experts shudder to think what might have happened if certain crucial discoveries in biotechnology had been patented in the past or been made available only under exclusive licenses.⁵³ As matters stand, the eligibility standards are low, "one person's research tool is another person's research" (as Prof. Eisenberg shrewdly observed),⁵⁴ and there are mounting concerns about potential obstacles to research at all levels, including government funded research at universities.

At the same time, the pernicious effects of so much upstream patenting on experimental science have proved difficult to measure. We now have four or five empirical studies claiming serious disruptions of biotech research efforts due to patent thickets, anticommons effects, and refusals to share research data or materials.⁵⁵ There is also one study by my colleague at Duke, Professor Wesley Cohen, which tends to contradict some of the results of these other studies.⁵⁶

⁴⁷ Rai, *supra* note 35 at

⁴⁸ Carl Shapiro, *Navigating the Patent Thicket: Cross Licenses, Patent Pools, and Standard-Setting*, (March 2001). in INNOVATION POLICY AND THE ECONOMY, Adam Jaffe et al., eds., Nat'l Bureau of Econ., 2001.

⁴⁹ Rai, *supra* note 35 at

⁵⁰ Chin, *supra* note 43.

⁵¹ Rebecca Eisenberg [in Oxford book, Dreyfuss et al eds.][Research tool literature]

⁵² Interview with Prof. Rochelle Cooper Dreyfuss.

⁵³ See [author in Dreyfuss book]. Dr. Robert Cook-Deegan is constructing a biotech intellectual property history at Duke under a major NIH grant, to help focus attention on the potential dangers of these trends.

⁵⁴ Rebecca Eisenberg cite.

⁵⁵ [cites, include Hilfiger I, Hilfiger II, and JAMA study]. See generally Jerome H. Reichman and Paul F. Uhler, *A Contractually Reconstructed Research Commons for Scientific Data in a Highly Protectionist Intellectual Property Environment*, 66 LAW & CONTEMP. PROBS. ____ (2003).

⁵⁶ W.M. Cohen, J.P. Walsh, Charlene Cho, *Views from the Bench: Patents and Materials Transfers*, SCIENCE, vol. 309, 23 September 2005.

Two brand new studies, however, cast doubt on Professor Cohen's more optimistic findings. In one, Stern and Murray present fresh evidence of growing anti-commons effects.⁵⁷ In another, the respected economists, James Bessen and Michael Meurer, find that these and similar problems pervade the entire U.S. patent system, and are not confined to biotechnology.⁵⁸ Bessen and Meurer show that in many industries, patents are actually decreasing the incentive to invest in innovation. They argue that this has happened because the law has changed to make patents less like property. For example, in many areas it is hard to know what the boundaries of patent claims are, which discourages licenses and encourages disputes and litigation.⁵⁹ As a result, the amount of litigation has tripled from 1987 to 1997, and the costs of patent litigation now outweigh the value of patents to owners by about two per cent. This deficit constitutes a tax on overall research and development investment.

Even Professor Cohen's study shows that scientists at United States universities have experienced difficulties in obtaining access to biological materials developed by other scientists, despite the sharing ethos that nominally applies. University scientists also tend to ignore patent constraints on research,⁶⁰ including the very narrow research exemption that the Federal Circuit has recently established in *Madey v. Duke*.⁶¹ It is hardly comforting to learn that the vast system of government-funded university research in the United States is now conducted in a lawless manner, and that it could be disrupted at any moment by some disgruntled company that has breaks relations with a particular university.

Fix the problem, you will say, by adopting a better research exemption. Yet, after two years of trying, there is not a single standard or proposal likely to win agreement among the different stakeholders in the U.S. alone. Good luck at the international level!

Indeed, the difficulties in agreeing on any domestic standard for a research exemption are paralleled by failures to agree on any of the serious patent reform proposals that have been pending before Congress for two years or more. According to recent reports, action on reform bills has stalled because different industries are deadlocked on the various proposals and none can gain a consensus of all the major stakeholders.⁶² These divisions mirror a deeper intuition by Burk and Lemley about the increasingly inconsistent standards that U.S. courts apply to evaluate patents emanating from different industries.⁶³ While some experts appear dismayed⁶⁴ to hear that "while patent law is technology-neutral in theory, it is technology-specific in application,"⁶⁵

⁵⁷ Scott Stern & Fiona Murray, *Do Formal Intellectual Property Rights Hinder the Free Flow of Scientific Knowledge? An Empirical Test of the Anti-Commons Hypothesis*, NBER Working Paper No. W11465. Available at SSRN: <http://ssrn.com/abstract=755701>.

⁵⁸ James Bessen, *The Empirical Evidence on Patents: Do They Work Like Property?* Lecture at Duke University School of Law, February 27, 2006).

⁵⁹ *Id.*, See also Rochelle Cooper Dreyfuss (antitrust article SSRN).

⁶⁰ W.M. Cohen *et al.*, see *supra*, note 56.

⁶¹ *Madley v. Duke University*, 307 F. 3d 1351 (Fed. Cir. 2002).

⁶² [Lost citation]

⁶³ Burk & Lemley, *supra* note 40.

⁶⁴ See *e.g.*, Kappos, SOFTIC SYMPOSIUM (2005).

⁶⁵ See Burk & Lemley, *supra* note 40 at :

Of late, however, we have noticed an increasing divergence between the rules themselves and the application of the rules to different industries. The best examples are biotechnology and computer software. In biotechnology cases, the Federal Circuit has bent over backwards to find biotechnological inventions nonobvious, even if the prior art demonstrates a clear plan for

Burk and Lemley suggest that modern patent law might be better served by industry-specific, tailor-made judicial strategies than by across-the-board neutral standards.

For the purposes of this Forum, the question is not whether they are right or not. The real question is, if they are right, how would we ever manage to avoid even more intractable problems than those we already face by prematurely freezing the patent law on an entirely different and possibly outdated conceptual basis?

Observe, by the way, that in the U.S. system, there is always the possibility that the United States Supreme Court will intervene to reshape any particular configuration of the patent law that seemed firmly entrenched, as it has periodically done throughout history. These interventions seem to follow cyclical swings back and forth from more protectionist moods to greater emphasis on competition,⁶⁶ and there are signs that the Supreme Court may have embarked upon a more pro-competitive campaign once again.⁶⁷ Consider that the Court has recently granted certiorari in three potentially important patent cases⁶⁸ and several more petitions are pending;⁶⁹ that the new Chief Justice Roberts is knowledgeable about patents; and that some experts think that the Court may be about to rebuke the Federal Circuit or at least to impose some changes on existing law, particularly the much-criticized eligibility standards.⁷⁰ Whether or not this occurs, Professor Dreyfus has soundly criticized the whole experiment with specialized federal courts,⁷¹ and Professor Rai thinks it would be better to abolish the Federal Circuit altogether and replace it with more specialized lower courts that would be subject to control by generalist appellate courts.⁷²

We should never forget that, over time, the U.S. Supreme Court has contributed significantly to the development of domestic patent law, from the construction of the nonobviousness standard in 1967,⁷³ to the acceptance of biotechnology as patentable subject matter in 1980,⁷⁴ to a narrow

producing the invention. On the other hand, the court has imposed stringent enablement and written description requirements on biotechnology patents that do not show up in other disciplines. In computer software cases, the situation is reversed. The Federal Circuit has essentially excused software inventions from compliance with the enablement and best mode requirements, but has done so in a way that raises serious questions about how stringently it will read the nonobviousness requirements. As a practical matter, it appears that while patent law is technology-neutral in theory, it is technology-specific in application.

⁶⁶ Contrast e.g., the *Sears-Compco* decisions of 1964 and related decisions with *Goldstein v. California* (1974).

⁶⁷ Cf, e.g., *Wal-Mart v. Samara* (U.S. 2000); *Traffix*.

⁶⁸ *Laboratory Corp. of America Holdings v. Metabolite Laboratories*, 370 F.3d 1354, 71 U.S.P.Q.2d 1081 (Fed.Cir. 2004), Inc. 126 S.Ct. 601; *E-Bay Inc. v. MercExchange, L.L.C.* 401 F.3d 1323, 74 U.S.P.Q.2d 1225 (Fed.Cir. 2005), 126 S.Ct. 733; *Medimmune, Inc. v. Genetech, Inc. et al*, 427 F.3d 958, 76 U.S.P.Q.2d 1914, cert. grant., ___ S.Ct. ___, (2006).

⁶⁹ [Cite pending cert. petitions, two with the Solicitor General(?)]

⁷⁰ See e.g., *Wegner*, SOFTIC 2005.

⁷¹ Rochelle Cooper Dreyfus, N.Y.U.L. Rev. study.

⁷² Prof. Rai explains that Although abolishing the Federal Circuit would most likely be a “political nonstarter”, the Federal Circuit could, and should, be subject to sustained generalist review that forces it to evaluate, in a serious and neutral fashion, questions of innovation policy. Arti Rai, *Engaging Facts and Policy*, *supra* note 35, at 1103 and ff.

⁷³ *Graham v. John Deere Co.*, 383 U.S. 1, 86 S.Ct. 684 (1966).

⁷⁴ *Diamond v. Chakrabarty*, 447 U.S. 303, 100 S.Ct. 2204 (1980).

shaping of the doctrine of equivalents in recent years.⁷⁵ Shall we now preclude our Supreme Court – and yours, your ECJ and equivalents elsewhere – from offering their contributions in the future? Shall we tell them that, in 2006, the SCP, in its wisdom knew exactly what standards were needed for all time, and they should henceforth keep out?

To ask that question is to answer it. We need their wisdom – the evolving wisdom of courts facing real world conditions – more now than ever, for the empirical light it casts, a light that ill-conceived SPLT standards might prematurely dim.

B. Rational Divergence at the EPO

Finally, just to get the full picture, we see the EPO moving away from these U.S. models and increasingly developing its own approach. Let us disregard the EU Parliament’s rejection of software patents, and of business method patents in particular.⁷⁶ The EPO insists on a higher standard of nonobviousness than U.S. courts based on a showing of a “technical contribution” palpably beyond the state of the art.⁷⁷

With regard to DNA patents, moreover, the EPO – after the European Directive on Biotechnology,⁷⁸ which it attempts to follow – seems to be breaking away from the “chemical compound” analogy to which the U.S. Federal Circuit obstinately clings. Instead, growing evidence shows that the EPO has begun to treat DNA patents as information products, whose eligibility tests should turn on the quality and industrial applicability of the information revealed.⁷⁹ While it is too soon to evaluate the results, this approach seems more promising than the model emerging in the United States, both with respect to the quality of patents and to a likely, more circumscribed scope of protection, with fewer blocking effects.

Even so, some EU member governments remain dissatisfied with the pace of developments at the EPO and seem either unwilling to fully implement the Biotech Directive,⁸⁰ or wish to strike out in new directions of their own. The German government, in particular, has enacted a new law on gene patents, which reportedly limits or eliminates the possibility of exclusive rights to the gene as such.⁸¹ Rather, product patents covered by the new law appear limited to specific uses of the gene, a solution that will displease some patent experts but could be of interest to

⁷⁵ Warner-Jenkinson Company Inc. v. Hilton Davis Chemical Co., 520 U.S. 17, 117 S.Ct. 1040, (1997); Festo Corp. v. Shoketsu Kogyo Kabushiki Co., 535 U.S. 722, 122 S.Ct. 1831 (2002).

⁷⁶ cites

⁷⁷ E. Panagiotidou, *The Patentability of Computer Programs, According to the Commission’s New Proposal for a Directive and to EPO Boards of Appeal Decisions*, 9 COMPUTER AND TELECOMMUNICATION L.R. 126 (2003); W. Tauchert, *Patent Protection for Computer Programs – Current Status and New Developments*, 31 IIC 812 (2000); T. Hoeren, *European Union Commission and Recent Trends in European Information Law*, 29 RUTGERS COMPUTER AND TECH. L.J. 4 (2003).

⁷⁸ Directive 98/44/EC of The European Parliament and of the Council of 6 July 1998 on the Legal Protection of Biotechnological Inventions, OJ L 213/13, 30 July 1998.

⁷⁹ R.J. Alerts, *The Industrial Applicability and Utility Requirements for the Patenting of Genomic Inventions: A Comparison Between European and US Law*, 26 EUR. INTELL. PROP. REV. 349, (2004); Samantha Jameson, *Biotechnology Patents in the United States and the European Communities*, January 2006 (unpublished paper on file with the author),

⁸⁰ The recalcitrant EU Member States have all implemented the Directive by the end of 2005. More information can be found at http://www.europa.eu.int/comm/internal_market/indprop/docs/invent/state-of-play_en.pdf.

⁸¹ [Cite]

many other countries, particularly developing countries.

Note in passing that most European patent laws formally recognize a compulsory license for dependent patents on improvements, in order to reduce blocking effects, which is perfectly consistent with the TRIPS Agreement,⁸² and that at least one country, Italy, makes extensive use of these licenses.⁸³ Moreover, the EU Biotechnology Directive added a new compulsory license to facilitate interaction between infringing plant breeders and biotech patents.⁸⁴ Yet, United States law recognizes no compulsory licenses for dependent patents and it remains prepared to tolerate bargaining to impasse, whatever the social costs.⁸⁵ There is no chance of harmonization on this matter, unless the European Union renounces one of the few built-in antilocking provisions available from its domestic patent laws.

C. Alternative Regimes

I suspect, moreover, that if we seriously began to reflect upon the mounting reports of patent thickets and anticommons effects, we should examine the need to supplement the patent system with new kinds of intermediate or second-tier protection systems more attuned to present-day technological realities than either full patent protection or utility model laws. Consider that a strong property rights system, such as the patents law, presupposes clear boundaries between different rights holders and the ability of first inventors to know how best to develop their inventions for applications purposes.⁸⁶ In reality, we are confronted more and more with unclear boundaries – with cumulative and sequential innovation – in which each new contribution is totally dependent on others; and increasingly we see that it is the market itself – ingenious second comers – who best know how to develop the first comer's cumulative and sequential contribution for both scientific and commercial purposes.⁸⁷

In these circumstances, by insisting on patents at all costs, we are desperately trying artificially to divide that which is inherently indivisible, and we are breeding high litigation costs and needlessly decreasing the optimum rate of innovation.⁸⁸ If so, I suspect that a different kind of regime – which I call “compensatory liability rules” – may have much to offer by protecting first comers against wholesale duplication while enabling second-comer improvers who must, however, give a healthy share of the potential gains to those same first comers.⁸⁹ Note that I am

⁸² See TRIPS Agreement, *supra* note 5, art. 31(1); J.H. Reichman with Cathy Hasenzahl, *Non-Voluntary Licensing of Patented Inventions: Historical Perspective, Legal Framework under TRIPS, and an Overview of the Practice in Canada and the United States of America*, UNCTAD-ICTSD, Geneva, 2003.

⁸³ Interview with Prof. Gustavo Ghidini, Luiss University, Rome, Italy.

⁸⁴ See EU Biotech Directive, *supra* note 78, art. 12.

⁸⁵ See *e.g.*, Merges & Lemley, (U. TEXAS L. REV.)

⁸⁶ See *e.g.*, Bessen, *supra* note 58; Rochelle Cooper-Dreyfuss, Unique Works/Unique Challenges at the Intellectual Property/Competition Law Interface, in EUROPEAN COMPETITION LAW ANNUAL 2005: THE RELATIONSHIP BETWEEN COMPETITION LAW AND INTELLECTUAL PROPERTY LAW, Hart Publ., Oxford, C-D Ehlermann and I. Atanasiu, eds. (forthcoming 2006).

⁸⁷ See *e.g.*, J. H. Reichman, *Of Green Tulips and Legal Kudzu; Repackaging Rights in Subpatentable Innovation*, 53 VANDERBUILT L. REV. 1743 (2000).

⁸⁸ See *e.g.*, J. H. Reichman, *Saving the Patent Law from Itself*, in PERSPECTIVES ON PROPERTIES OF THE HUMAN GENOME PROJECT 289-304 (F. Scott Kief, ed., Elsevier Academic Press, 2003).

⁸⁹ See *e.g.*, Reichman, *Green Tulips*, *supra* note 87; Jerome H. Reichman & Tracy Lewis, *Using Liability Rules to Stimulate Local Innovation in Developing Countries: Application to Traditional Knowledge*,

not talking about *ex post* compulsory licenses but *ex ante* entitlements. These entitlements could even be voluntarily adopted by industrial sectors⁹⁰ or by government agencies to resolve blocking effects pertaining to research tools and other publicly funded research outcomes.⁹¹

Of course, if I am wrong about the benefits that greater resort to liability rules might entail, then nothing is lost by further expansion of the international patent space at the expense of every other alternative. Yet economists have showed increasing interest in liability rules.⁹² What if I am right in thinking that all innovation systems might benefit from supplementary liability rules (just as the European Union now benefits from a supplementary form of liability rule in design protection law that people scoffed at when it was first proposed in the 1980s)? Rather than closing the door, what we need now is more knowledge and empirical data about different kinds of regimes – including both “open source” or collaborative modes of production and liability rules – not hasty permanent international measures premised on obsolete theories for which no positive empirical evidence has been collected.

IV. Nurturing an Incipient Transnational System of Innovation

What the foregoing survey portrays is hardly a picture of a developed world waiting for enlightened lawgivers in Geneva to harmonize its patent laws at the international level. It reveals, instead, that we have entered a brave new technological epoch, in which experts have only tentative, divergent ideas about how to treat business methods, software patents, DNA patents, bioinformatics and small molecule compounds, microarrays, and diverse other novel technologies. We operate at best with a set of rudimentary working hypotheses that different countries are putting to the test, and we should be focusing on the need for experimentation and new empirical findings, based on the TRIPS standards, exactly as occurred at the end of the nineteenth century, when the Paris and Berne Conventions were first established. We need, in short, a period of open-minded experimentation and of searching for best practices, not a closed-minded, premature adoption of standards based largely on ignorance and power politics that would in effect “export...a dysfunctional system to the rest of the world.”⁹³

What the integrated world economy really needs at the moment is not a harmonized patent system so much as an “incipient transnational system of innovation” that will gradually enable innovators in all countries to reach the world market by means that are geared to their different national and regional capabilities and endowments.⁹⁴ The trouble is, we have no trusted governance system for balancing public and private interests in this emerging transnational system; we have no clear idea about which standards will work best over time; or about how best

in INTERNATIONAL PUBLIC GOODS AND TRANSFER OF TECHNOLOGY UNDER A GLOBALIZED INTELLECTUAL PROPERTY REGIME, *supra* note 6, at 337-366.

⁹⁰ *Cf.*, e.g., The Semiconductor Chip Protection Act of 1985, art. ___ (x year period of protection against duplication *unregistered* integrated circuit designs); *cf. also* EC Design Regulation, art. ___ (two years of protection against wholesale duplication of *unregistered* industrial designs).

⁹¹ See Reichman, Rai, Uhlir & Crossman, *Novel Intellectual Property Solutions to the Small Molecule Puzzle*, (Project for the NIH-CEER Grant, Duke University, 2006).

⁹² See e.g., Ian Ayres; Lewis & USC scholar; others].

⁹³ Maskus & Reichman, *supra* note 6, at 23; see also John F. Duffy, *Harmony and Diversity in Global Patent Law*, 17 BERKELEY TECH. L.J. 685, 709-25 (2002).

⁹⁴ *Id.*, at 33-35 (stressing that “[a]ll countries could benefit from a functionally efficient transnational system of innovation if low barriers to entry enabled entrepreneurs everywhere to invest in the production and distribution of knowledge goods.”).

to maintain the supply of knowledge as a global public good; and the last thing we want to do is leave this governance in the hands of a few multinational corporations who are not all that creative to begin with⁹⁵ or to rush in where angels fear to tread, as the EU did with its Database Directive,⁹⁶ which is now under attack from all directions.⁹⁷

For these reasons, Maskus and Reichman have elsewhere called for a “moratorium on stronger intellectual property standards,” with a possible exception for interim minimalist arrangements that may or may not become demonstrably necessary to deal with egregious cases of market destructive behavior:⁹⁸

Any gains in efficiency of operations and lower transaction costs...[from] greater harmonization...are likely to be offset by losses of sovereign power to control the single states’ own innovation policies; by a shrinking public domain; by still higher costs of technological inputs and reverse engineering; and by growing thickets of rights that will make transfer of technology harder for those operating outside patent and IP pools...⁹⁹

With every rise in international intellectual property standards, moreover, “there will likely be a corresponding loss of flexibility under the TRIPS Agreement,” and new risks of encountering claims of nonviolation acts of nullification and impairment that such higher standards may engender.¹⁰⁰

Of course, a moratorium would not necessarily check the spread of TRIPS-plus or TRIPS-minus provisions inserted into bilateral and regional trade agreements,¹⁰¹ unless it stiffened the backs of pliant central administrations in relevant developing countries.¹⁰² These provisions ignore the larger public interest in the countries concerned, and they are creating a serious political backlash, both in those countries and even in the United States. But those bilateral and regional processes will not likely be stopped by the multilateral SPLT process; and even if it were, the demanders of a multilateral process would then attempt to lock in all the misguided, untested, or excessive standards being pursued at the bilateral and regional levels.

⁹⁵ See *id.*, at 18-20.

⁹⁶ Directive 96/9/Ec Of The European Parliament And Of The Council Of 11 March 1996 On The Legal Protection Of Databases, O.J. L-077, 27/03/1996, p. 20 – 28.

⁹⁷ Recently the Commission itself has published a report containing a critical evaluation of the practical impact of the database Directive: First Evaluation of Directive 96/9/Ec on The Legal Protection of Databases, Commission of The European Communities, Dg Internal Market And Services Working Paper, Brussels, 12 December 2005, available at http://www.europa.eu.int/comm/internal_market/copyright/docs/databases/evaluation_report_en.pdf. For further critiques on the database Directive: Bernt Hugenholtz, Stephen M. Maurer, Harlan J. Onsrud, Europe’s Database Experiment, *SCIENCE*, vol. 294, 26 October 2001, p. 790. See generally J.H. Reichman, *Database Protection in a Global Economy*, 2002 *REVUE INTERNATIONALE DE DROIT ECONOMIQUE* 455-503; J.H. Reichman & Pamela Samuelson, *Intellectual Property Rights in Data?*, 50 *VANDERBILT L. REV.* 51 (1997).

⁹⁸ Maskus & Reichman, *supra* note 6, at 36-39.

⁹⁹ *Id.*, at 27.

¹⁰⁰ *Id.*, at 27. See TRIPS Agreement, *supra* note 5, arts. 64.2, 64.3.

¹⁰¹ [Cite examples]

¹⁰² [Cite critiques of these treaties]

A moratorium on stronger intellectual property norms would not prevent WIPO from undertaking important work to improve the worldwide patent system from the bottom up rather than from the top down. On the contrary, it would keep WIPO from having to treat patents in isolation from, rather than as an integral component of, an incipient worldwide innovation system, in which there must be an appropriate balance between incentives to create and free competition, and between private interests and public goods. That is, indeed, the message implicit in the WIPO Development Agenda, which could move forward much more effectively in the absence of premature treaty negotiations.

There is much to be done in this context. For example, efficient measures to facilitate transnational dispute resolution based on local laws are badly needed, and new ideas are on the table. Professors Jane Ginsberg and Rochelle Cooper Dreyfuss are working with the American Law Institute on an ambitious set of proposals for resolving choice of law issues and for facilitating the recognition of foreign judgments in intellectual property cases.¹⁰³ A doctoral thesis by Yoav Oesterreicher, a former student at Duke University School of Law, takes a different, more minimalist position concerning these same issues,¹⁰⁴ which I find particularly promising. In any event, WIPO should certainly put this topic on its agenda.

Another important issue concerns the duplication of examination procedures under the domestic patent systems, which Judge Newman of the Federal Circuit reportedly condemns as a waste of the world's wealth.¹⁰⁵ She and others contend that great strides could be made in work-sharing programs between patent offices even under existing laws, without incurring the risks of premature harmonization.

Moreover, major efforts are underway in all developed countries to rethink the interaction between intellectual property laws and competition laws. The notion that competition law should operate only as a handmaiden of innovation laws (which displaced the earlier notion that competition laws should dominate the patent laws) is giving way to new theories of interaction in the larger public interest and to novel solutions being developed and tested, particularly in the European Union. I would advise WIPO not to leave the interface between intellectual property and antitrust to the competition authorities, but to incorporate it into the heart of its own agenda, particularly in view of the developing countries' pressing need for assistance in this area.

There are still many other issues that cry out for WIPO's attention, as the steward of a healthy worldwide intellectual property system. For example, governments everywhere are increasingly concerned to identify weak or bad patents, and this information needs to be widely distributed. There is a need for patent-mapping exercises that would identify key technologies in the public domain or their relative potential status in different countries. Also of growing concern at the moment are patents – especially so-called “submarine” patents – on technical standards. All stakeholders, including the large multinational companies would benefit from a WIPO initiative to promote disclosure and transparency with regard to such patents.

Yet another major topic concerns the possibilities for defensive patenting, which even big companies find necessary, in order to avoid undue restraints on research and development. Procedures are needed not only to accommodate such public interest initiatives, but also to facilitate open-source and similar collaborative undertakings where high fees may prevent patent

¹⁰³ [Cite ALI project, 3rd Report?].

¹⁰⁴ Oesterreicher cite.

¹⁰⁵ Interview with Prof. Dreyfuss.

holders from dedicating some of their rights to the public in a manner consonant with Creative Commons licenses in copyright law.

Above all, WIPO should begin systematically to identify and study different patent trends and practices that are emerging in both developed and developing countries, with a view to testing empirically the different approaches to critical new technologies I have briefly discussed above. This, indeed, was the message of various Doha Ministerial Declarations themselves, which stressed the need for local adaptations of international intellectual property standards.¹⁰⁶ WIPO should become the principal forum in which these trends are seriously studied by lawyers, economists, scientists, engineers and entrepreneurs from all over the world, so that we start to collect a centralized bank of empirical data that could inform more enlightened legislation later on.

In other words, the Open Forum that brings us together here today should become a model for a new direction in WIPO's future activities. The possibilities are immense. If we rise above our petty sectarian interests, and focus attention on nurturing the incipient transnational system of innovation that the TRIPS Agreement brought into being, we can stimulate research and innovation on a grander scale than ever before. But let us take the time and invest the efforts to get it right. Let us look for trustworthy, empirically supportable solutions that benefit humanity at large, and not those that lock in fleeting, competitive advantages of one group of stakeholders or another, at the expense of real innovators and dynamic entrepreneurs everywhere, whose interests will certainly be compromised by any movement favoring harmonization for its own sake.

¹⁰⁶ Doha cites.