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Harmonization without Consensus: Critical Reflections on Drafting a Substantive Patent Law Treaty

JEROME H. REICHMAN
Duke University - School of Law

ROCHELLE COOPER DREYFUSS
New York University School of Law

HARMONIZATION WITHOUT CONSENSUS: CRITICAL REFLECTIONS ON DRAFTING A SUBSTANTIVE PATENT LAW TREATY

JEROME H. REICHMAN†

ROCHELLE COOPER DREYFUSS††

ABSTRACT

In this Article, we contend that the World Intellectual Property Organization's proposed Substantive Patent Law Treaty (SPLT) is premature. Developing countries are struggling to adjust to the heightened standards of intellectual property protection required by the TRIPS Agreement of 1994. With TRIPS, at least, these countries obtained side payments (in the form of trade concessions) to offset the rising costs of knowledge products. A free-standing instrument, such as the SPLT, would shrink the remaining flexibilities in the TRIPS Agreement with no side payments and no concessions to the catch-up strategies of developing countries at different stages of technological advancement.

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† Bunyan S. Womble Professor of Law, Duke University School of Law. The author presented an early version of this Article at the World Intellectual Property Organization's Open Forum on the Draft Substantive Patent Law Treaty (SPLT), International Conference Center (ICC), Geneva, Switzerland, March 1–3, 2006, and at the Intellectual Property & Communications Law Conference, Michigan State University College of Law, April 8, 2006. He would like to thank Professor Peter Yu and the participants at the latter conference for their comments and suggestions, as well as his research assistants, Dr. Emanuela Arezzo, S.J.D. Candidate, Duke University School of Law, and Samantha Jameson, J.D., Duke University School of Law, 2006. The author gratefully acknowledges the support of the National Human Genome Research Institute and the Department of Energy (CEER Grant P50 HG003391, Duke University, Center of Excellence for ELSI Research).

†† Pauline Newman Professor of Law, New York University School of Law. The author wishes to thank the Filomen D'Agostino and Max E. Greenberg Research Fund for its financial support.

More controversially, we argue that a deep harmonization would boomerang against even its developed country promoters by creating more problems than it would solve. There is no vision of a properly functioning patent system for the developed world that commands even the appearance of a consensus. The evidence shows, instead, that the worldwide intellectual property system has entered a brave new scientific epoch, in which experts have only tentative, divergent ideas about how best to treat a daunting array of new technologies. The proposals for reconciling the needs of different sectors, such as information technology and biotechnology, pose hard, unresolved issues at a time when the costs of litigation are rising at the expense of profits from innovation. These difficulties are compounded by the tendency of universities to push patenting up stream, generating new rights to core methodologies and research tools. As new approaches to new technologies emerge in different jurisdictions, there is a need to gather empirical evidence to determine which, if any, of these still experimental solutions are preferable over time.

Our argument need not foreclose other less intrusive options and measures surveyed in the Article that can reduce the costs of delaying harmonization. However, the international community should not rush to freeze legal obligations regarding the protection of intellectual property. It should wait until economists and policymakers better understand the dynamics of innovation and the role that patent rights play in promoting progress and until there are mechanisms in place to keep international obligations responsive to developments in science, technology, and the organization of the creative community.

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INTRODUCTION

Proposals to further harmonize domestic patent laws at the international level[1] have understandably attracted considerable attention.[2] As intellectual property continues to grow as a component of global trade, the costs of worldwide protection and enforcement have soared.[3] Patent holders accordingly seek ways to acquire and maintain their exclusive rights more efficiently in an integrated world marketplace.[4] They are also increasingly frustrated by the need to pursue multiple actions for infringement in cross-border disputes.[5] Under the bedrock principle of territoriality, successive litigations can trigger different applications of domestic and international patent norms to the same set of facts and can lead to conflicting judgments and arguably irreconcilable outcomes.[6]

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1. *See* World Intellectual Prop. Org. (WIPO), Standing Comm. on the Law of Patents, Report, at 1–2, WIPO Doc. SCP/10/11 (June 1, 2005); WIPO, Standing Comm. on the Law of Patents, *Information on Certain Recent Developments in Relation to the Draft Substantive Patent Law Treaty (SPLT)*, at 2–3, WIPO Doc. SCP/10/8 (Mar. 17, 2004); WIPO, Standing Comm. on the Law of Patents, *Draft Substantive Patent Law Treaty (SPLT)*, at 2, WIPO Doc. SCP/10/2 (Sept. 30, 2003).

2. *See generally* WIPO, Open Forum on the Draft Substantive Patent Law Treaty (SPLT), Geneva, Switz., Mar. 1–3, 2006 [hereinafter WIPO Open Forum], *available at* http://www.wipo.int/meetings/en/2006/scp_of_ge_06/scp_of_ge_06_inf1.html (hosting the presentation of papers, lectures, and speeches on the international harmonization of patent law).

3. *See* Gretchen Ann Bender, *Clash of the Titans: The Territoriality of Patent Law vs. The European Union*, 40 IDEA 49, 53 (2000); Erwin F. Berrier, Jr., *Global Patent Costs Must Be Reduced*, 36 IDEA 473, 473 (1996).

4. *See infra* notes 8–19 and accompanying text.

5. *See, e.g.*, Int'l Ass'n for the Prot. of Intellectual Prop. (AIPPI), Question Q174—Jurisdiction and Applicable Law in the Case of Cross-border Infringement of Intellectual Property Rights, 2003/I Y.B. 827–28, Oct. 25–28, 2003, *available at* http://www.aippi.org/reports/resolutions/Q174_E.pdf (recognizing the need for a fairer and more efficient method of resolving cross-border controversies); European Max-Planck Group for Conflict of Laws in Intellectual Prop., *Exclusive Jurisdiction and Cross-Border IP (Patent) Infringement: Suggestions for Amendment of the Brussels I Regulation*, *in* 29(5) EUR. INTELL. PROP. REV. 195, 195–96 (2007) (suggesting the need to amend the Brussels Regulation on Jurisdiction and Enforcement of Judgments in Civil and Commercial Matters, EC Regulation No 44/2001, to improve the efficiency of transnational dispute resolution).

6. *See*, *e.g.*, David Perkins & Garry Mills, *Patent Infringement and Forum Shopping in the European Union*, 20 FORDHAM INT'L L.J. 549, 550 (1996) (observing that "the English and German courts reached opposite conclusions in parallel litigation in the two countries" (citing Improver Corp. v. Remington Prods. Inc., 21 IIC 572 (1990), 24 IIC 838 (1993), [1993] GRUR Int. 242 (F.R.G.), and Improver Corp. v. Remington Consumer Prods. Ltd., [1990] F.S.R. 181 (Eng. Ch. 1989))). On the validity and infringement of the patent protecting Fosamax, see *Merck & Co., Inc. v. Teva Pharmaceuticals USA, Inc.*, 395 F.3d 1364, 1377 (Fed. Cir. 2005), holding that the patent is invalid because it was obvious, and *Merck & Co. Inc.'s Patents*, [2003] EWCA (Civ) 1545, [1]–[73] (Eng.), holding that the patent is invalid because it was both

Governments have responded to the upswing in patent applications by searching for techniques that would allow them to share examination responsibilities and costs.[7] The Patent Cooperation Treaty[8] and various regional agreements, such as the Convention on the Grant of European Patents, embody many important procedural advances.[9] These instruments, however, are seldom the product of true harmonization exercises, in part because the outcome of examinations conducted within these frameworks is typically a set of individual national patents that remain separately enforceable under local laws.[10] In 1994, the Agreement on Trade-Related Aspects of

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obvious and lacked novelty. On the importance of allocating a jurisdiction for a patent dispute, see generally Rochelle C. Dreyfuss & Jane C. Ginsburg, *Draft Convention on Jurisdiction and Recognition of Judgments in Intellectual Property Matters*, 77 CHI.-KENT L. REV. 1065 (2002), and Mariano Municoy, Symposium, *Allocation of Jurisdiction on Patent Disputes in the Models Developed by the Hague Conference in Private International Law: Asymmetric Countries and the Relationship of Private Parties*, 4 CHI.-KENT J. INTELL. PROP. 342 (2005), and see also Case C-593/03, Roche Nederland BV v. Primus, [2007] F.S.R. 5 (E.C.J. 2006) (questioning whether conflicting national judgments of validity or infringement should be considered "irreconcilable").

In the United States, the Court of Appeals for the Federal Circuit seems torn by the tension between territoriality and the global exercise of patent rights. *Compare*, *e.g.*, Voda v. Cordis Corp., 476 F.3d 887, 898 (Fed. Cir. 2007) (holding that "considerations of comity, judicial economy, convenience, fairness, and other exceptional circumstances constitute compelling reasons to decline [supplemental] jurisdiction under [28 U.S.C.] § 1367(c)" over foreign patents), *with* AT&T Corp. v. Microsoft Corp., 414 F.3d 1366, 1370–71 (Fed. Cir. 2005) (endorsing de facto extraterritorial application of domestic software patents to conduct occurring in countries that reject software patents), *rev'd*, 127 S. Ct. 1746 (2007).

7. Bruce A. Lehman, *Addressing the Crisis of the Global Patent System*, JAPAN ECON. CURRENTS, Jan. 2005, at 5, 5–6, *available at* http://www.keidanren-usa.org/publications/currents/docs/JEC_Jan05_132K.pdf.

8. Patent Cooperation Treaty, June 19, 1970, 28 U.S.T. 7645, 1160 U.N.T.S. 231.

9. Convention on the Grant of European Patents, Oct. 5 1973, 1065 U.N.T.S. 255. In addition, the European Community (EC) is considering the development of a region-wide community patent. *See* John H. Barton, *Issues Posed by a World Patent System*, 7 J. INT'L ECON. L. 341, 343 (2004); Hanns Ullrich, *National, European and Community Patent Protection: Time for Reconsideration* 14–22 (European Univ. Inst., Dep't of Law, EUI Working Papers, LAW No. 2006/41, 2006), *available at* http://papers.ssrn.com/sol3/papers.cfm?abstract_id=963759. Other nations are contemplating or have enacted similar measures. *See* Agreement Revising the Bangui Agreement of March 2, 1977, on the Creation of an African Intellectual Property Organization, tit. I, Feb. 24, 1999, *available at* http://www.oapi.wipo.net/doc/en/bangui_agreement.pdf; Protocol on Patents and Industrial Designs within the Framework of the African Regional Intellectual Property Organization (ARIPO), 2, § 1, Dec. 10, 1982, *available at* http://www.aripo.org/Documents/Protocols/harare_agreement.pdf (last amended Aug. 13, 2004); Marcelo J. Vernengo, Kees de Joncheere & Enrique Fefer, *Advances in Pharmaceutical Market Integration in Mercosur and Other Latin American Countries*, 32 DRUG INFO. J. 831, 834–35 (1998).

10. *See, e.g.*, Convention on the Grant of European Patents, *supra* note 9. The Agreement Revising the Bangui Agreement of March 2, 1977, on the Creation of an African Intellectual

Intellectual Property Rights (TRIPS Agreement or TRIPS),[11] which incorporated the 1967 text of the Paris Convention for the Protection of Industrial Property,[12] took a major step toward substantive patent law harmonization. It established a set of minimum international standards of protection for some 150 participating countries.[13] Yet the Agreement, which did not attempt to create a uniform or deeply harmonized global patent regime, left ample room for national variations and approaches, which are often collectively deemed "the TRIPS flexibilities."[14]

The effort by the World Intellectual Property Organization (WIPO) to organize a thorough exploration of the possibilities for further harmonization is therefore a welcome development to much of the patent community.[15] Under the aegis of WIPO's Standing Committee on the Law of Patents (SCP), the Draft Substantive

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Property Organization, *supra* note 9, however, does grant a regional patent. A draft European Patent Litigation Agreement is also under consideration. Draft Agreement on the Establishment of a European Patent Litigation System, Feb. 16, 2004, *available at* http://www.european-patent-office.org/epo/epla/pdf/agreement_draft.pdf.

11. Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, LEGAL INSTRUMENTS—RESULTS OF THE URUGUAY ROUND vol. 31, 33 I.L.M. 81 (1994) [hereinafter TRIPS Agreement].

12. Paris Convention for the Protection of Industrial Property, Mar. 20, 1883, 21 U.S.T. 1583, 828 U.N.T.S. 305 (as revised at Stockholm on July 14, 1967); TRIPS Agreement, *supra* note 11, art. 2.1.

13. *See* TRIPS Agreement, *supra* note 11, arts. 27–34.

14. *See id.*, art. 1.1; *see also* John Sulston, Presentation Before the WIPO, Open Forum on the Draft Substantive Patent Law Treaty (SPLT): International Patent Law Harmonization, Development and Policy Space for Flexibility (Mar. 3, 2006), *available at* http://www.wipo.int/meetings/en/2006/scp_of_ge_06/scp_of_ge_06_inf1.html (discussing the TRIPS flexibilities). S*ee generally* CARLOS M. CORREA, TRADE RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS: A COMMENTARY ON THE TRIPS AGREEMENT (2007); UNCTAD-ICTSD, RESOURCE BOOK ON TRIPS AND DEVELOPMENT (2005) [hereinafter UNCTAD-ICTSD, RESOURCE BOOK] (providing background and technical information on the TRIPS Agreement); J.H. Reichman, *Universal Minimum Standards of Intellectual Property Protection under the TRIPS Component of the WTO Agreement*, *in* INTELLECTUAL PROPERTY AND INTERNATIONAL TRADE: THE TRIPS AGREEMENT (C. M. Correa & A. A. Yusuf eds., 1998).

15. *See, e.g.*, Daeshik Jeh, Director, Patent Examination Policy Team, Korean Intellectual Property Office, Presentation Before the WIPO, Open Forum on the Draft Substantive Patent Law Treaty (SPLT): International Patent Law Harmonization and Development: The Experience of the Republic of Korea (Mar. 1, 2006), *available at* http://www.wipo.int/meetings/en/2006/scp_of_ge_06/scp_of_ge_06_inf1.html (discussing the benefits and desirability of harmonization); Kenji Kamata, Japan Intellectual Property Association, Presentation Before the WIPO, Open Forum on the Draft Substantive Patent Law Treaty (SPLT): The Rationale and Benefits of Patent Law Harmonization (Mar. 1, 2006), *available at* http://www.wipo.int/meetings/en/2006/scp_of_ge_06/scp_of_ge_06_inf1.html (same).

Patent Law Treaty (SPLT)[16] 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 the cornerstone requirements of patentability.[17] Ideally, member states would agree to adopt identical rules concerning what constitutes a novel and useful invention, when a technical advance meets the requirement for an "inventive step" (nonobviousness), and how much information must be revealed by the patent disclosure. "Deep harmonization" would also entail agreement on priority of inventorship (whether a patent is awarded to the first to invent or the first to file) and whether inventors will be accorded a grace period permitting publication for some period prior to filing.[18] Notably, through the efforts of the so-called Group of Friends of Development,[19] this initiative is being tested against the drive for a more development-friendly agenda at WIPO, with a view to ensuring

16. WIPO, Standing Comm. on the Law of Patents, *Draft Substantive Patent Law Treaty (SPLT)*, *supra* note 1.

17. Karen M. Hauda, *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 89, 97 (Frank Gotzen ed., 2003).

18. *Id.* ("This approach was adopted in an attempt to avoid the controversial hurdles to agreement that were found in the past."); *see also* Philippe Baechtold, *The Future Role of WIPO in the Area of Industrial Property*, *in* THE FUTURE OF INTELLECTUAL PROPERTY IN THE GLOBAL MARKET OF THE INFORMATION SOCIETY, *supra* note 17, at 139, 143 ("[T]here are other issues that require further reflection . . . [including] the question of patentable subject matter, . . . the requirement of technical character of the invention, the exceptions from patentability, the introduction of some form of grace period and the issue of equivalents.").

19. In the Fall of 2004, the General Assembly of the World Intellectual Property Organization invited comment on a proposal presented by the Group of Friends of Development (led by Argentina and Brazil) for the establishment of a Development Agenda for WIPO. WIPO, Gen. Assembly, *Proposal by Argentina and Brazil for the Establishment of a Development Agenda for WIPO*, WO/GA/31/11 (Aug. 27, 2004), *available at* http://www.wipo.int/documents/en/document/govbody/wo_gb_ga/pdf/wo_ga_31_11.pdf. Since then, many other proposals have been presented and discussed. *E.g.*, WIPO, Provisional Comm. on Proposals Related to a WIPO Development Agenda, *Report of the Third Session*, at 1, PCDA/3/3 (June 11, 2007), *available at* http://www.wipo.int/edocs/mdocs/mdocs/en/pcda_3/pcda_3_3.pdf; WIPO, Provisional Comm. on Proposals Related to a WIPO Development Agenda, *Proposal for a Decision of the PCDA on the Establishment of a WIPO Development Agenda*, PCDA/2/2 (June 23, 2006), *available at* http://www.wipo.int/edocs/mdocs/mdocs/en/pcda_2/pcda_2_2.pdf; *see also* James Boyle, *A Manifesto on WIPO and the Future of Intellectual Property*, 2004 DUKE L. & TECH. REV. 9, at 3–4 (2004), *available at* http://www.law.duke.edu/journals/dltr/articles/pdf/2004DLTR0009.pdf (criticizing the "one size fits all" approach of WIPO and the TRIPS agreement).

consideration of the needs of all nations, whatever their technological capacities may be.[20]

Despite the promise such an effort holds, we believe that it is unwise to move to deep substantive harmonization so quickly after the TRIPS Agreement elevated patent standards universally.[21] These standards challenged the technological catch-up strategies of all the developing countries and saddled them with social costs they are struggling to absorb.[22] As the endless controversies surrounding pharmaceutical patents demonstrate,[23] higher standards of global protection—whatever their incentive effects[24]—also generate severe and unintended distributional consequences for the developing

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20. WIPO, Provisional Comm. on Proposals Related to a WIPO Development Agenda, *Proposal for a Decision of the PCDA on the Establishment of a WIPO Development Agenda*, *supra* note 19; WIPO, Provisional Comm. on Proposals Related to a WIPO Development Agenda, *Report of the Third Session*, *supra* note 19, at 1.

21. For developing countries, the patent standards (articles 27–34) of the TRIPS Agreement became generally operational on January 1, 2000. TRIPS Agreement, *supra* note 11, art. 65.2; J.H. Reichman, *The TRIPS Agreement Comes of Age: Conflict or Cooperation with the Developing Countries?*, 32 CASE W. RES. J. INT'L L. 441, 444 (2000). Developing countries, however, that did not previously allow product patents on pharmaceutical and agricultural chemical products were given another five years to cover them, subject to a "mail-box" provision for patents arising in the meantime. TRIPS Agreement, *supra* note 11, arts 65.4, 70.8–70.9 (mailbox and minimum exclusive marketing rights).

22. *See* COMM'N ON INTELLECTUAL PROP. RIGHTS, INTEGRATING INTELLECTUAL PROPERTY RIGHTS AND DEVELOPMENT POLICY 159–62 (2002), *available at* http://www.iprcommission.org/papers/pdfs/final_report/CIPRfullfinal.pdf [hereinafter CIPR]; CARLOS M. CORREA, INTELLECTUAL PROPERTY RIGHTS, THE WTO AND DEVELOPING COUNTRIES: THE TRIPS AGREEMENT AND POLICY OPTIONS 5–44 (2000); Reichman, *supra* note 14, at 77–92.

23. *See, e.g.*, Janice M. Mueller, *Taking TRIPS to India—Novartis, Patent Law, and Access to Medicines*, 356 NEW ENG. J. MED. 541, 541 (2007) (discussing Novartis's effort to patent Gleevec); Robert Steinbrook, *Thailand and the Compulsory Licensing of Efavirenz*, 356 NEW ENG. J. MED. 544–46 (2007) (noting Merck's objection to Thailand's compulsory licensing of an antiretroviral medication). *See generally* 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 394, 408–10 (Keith Maskus & Jerome H. Reichman eds., 2005) (discussing how patents function as obstacles both to prevent generic products from entering the market and to prevent competition that may lower costs).

24. *See, e.g.*, Ashish Arora, Andrea Fosfuri & Alphonso Gambardella, *Markets for Technology, Intellectual Property Rights and Development*, *in* INTERNATIONAL PUBLIC GOODS AND TRANSFER OF TECHNOLOGY UNDER A GLOBALIZED INTELLECTUAL PROPERTY REGIME, *supra* note 23, at 321, 325–26 ("Strong patent protection provides incentives to codify and organize new knowledge in ways that are meaningful and useful to others."); Alan O. Sykes, *TRIPS, Pharmaceuticals, Developing Countries, and the Doha "Solution,"* 3 CHI. J. INT'L L. 47, 48 (2002) ("The ultimate wisdom of measures that relax intellectual property protection for pharmaceuticals in developing countries turns on complex matters, including empirical issues about which one can only hazard an educated guess.").

world.[25] A further round of harmonization will likely aggravate these and other unresolved problems without producing any offsetting user rights or concessions for these countries. On the contrary, the dynamics of TRIPS and the post-TRIPS trade agreements teach that even a development-sensitive negotiation process is likely to produce an instrument that furthers the interests of developed countries at the expense of poorer, less powerful participants.[26]

More controversially, we contend that higher levels of harmonization will harm even the developed countries, including those that are most aggressively pressing for yet another round of multilateral intellectual property negotiations. The domestic patent laws as currently practiced were largely formulated for the inventions of the Industrial Revolution,[27] and these laws still reflect the technological premises and concepts of the creative sectors as they were then structured. Yet in this postindustrial information age, with knowledge-intensive inventions emerging from new kinds of research institutions, creative entities are organized nonhierarchically and along continuously changing lines.[28] New players, such as universities and scientific research organizations, routinely patent their output, and whole new sectors, including biotechnology and information

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25. *See, e.g.*, Margaret Chon, *Intellectual Property and the Development Divide*, 27 CARDOZO L. REV. 2821, 2832 (2006) ("Over-reliance on utility maximization ignores distributional consequences . . . but intellectual property globalization has made these aspects of the provision of basic knowledge goods increasingly difficult to ignore."); Peter M. Gerhart, *Distributive Values and Institutional Design in the Provision of Global Public Goods*, *in* INTERNATIONAL PUBLIC GOODS AND TRANSFER OF TECHNOLOGY UNDER A GLOBALIZED INTELLECTUAL PROPERTY REGIME, *supra* note 23, at 69, 72 ("[A]lthough institutions like the World Trade Organization (WTO) and World Intellectual Property Organization (WIPO) promote an efficient system of global trade and investment, we have found no way to tax those who benefit from the efficiency of the global system in order to support those who do not."); Joseph E. Stiglitz, Lecture, *Economic Foundations of Intellectual Property Rights*, 57 DUKE L.J. (forthcoming 2007), *available at* http://www.law.duke.edu/webcast.

26. *See, e.g.*, Peter K. Yu, *Five Disharmonizing Trends in the International Intellectual Property Regime*, *in* 4 INTELLECTUAL PROPERTY AND INFORMATION WEALTH 73, 73–74 (Peter K. Yu ed., 2007) (discussing the tensions between developed and less-developed countries with respect to the TRIPS Agreement).

27. *See generally* CHRISTOPHER MAY & SUSAN K. SELL, INTELLECTUAL PROPERTY RIGHTS: A CRITICAL HISTORY (2006).

28. *See* Yochai Benkler, *An Unhurried View of Private Ordering in Information Transactions*, 53 VAND. L. REV. 2063, 2077–78 (2000); James Boyle, *The Second Enclosure Movement and the Construction of the Public Domain*, 66 LAW & CONTEMP. PROBS. 33, 39–40, 44–46 (Winter/Spring 2003); Charlotte Hess & Elinor Ostrum, *Ideas, Artifacts, and Facilities: Information as a Common-Pool Resource*, 66 LAW & CONTEMP. PROBS. 111, 133–34 (Winter/Spring 2003).

technology, have emerged.[29] Until the operations of these and other new technical communities are better understood, there is a greater need for legal experimentation at the substantive level than for harmonization. In the absence of any international governance infrastructure capable of interpreting and amending the law (rather than freezing it prematurely), a compelling case can be made for delaying deep harmonization until other methods for improving the efficiency of a global patent system have been fully explored.[30]

Part I of this Article surveys the implications of deep harmonization for developing countries, and Part II does likewise for developed countries. Part III suggests that the appropriate goal for the progressive development of world intellectual property law after TRIPS is to nurture an "incipient transnational system of innovation,"[31] which can, in turn, provide the appropriate template for validating global patent norms over time.

I. THE LIKELY ADVERSE IMPACT ON DEVELOPING COUNTRIES

Before moving to the more controversial claim that harmonization could boomerang against its developed-country advocates, we stress that even a cursory look at the results of the TRIPS Agreement reveals the problems harmonization of the type envisioned by the SPLT pose for the developing world. Although TRIPS specifically leaves room for nations to tailor their laws to their internal needs and pace of intellectual advancement,[32] experience shows that emerging economies are, in fact, greatly challenged by the costs and hardship associated with adjusting their development

29. *See* Graeme B. Dinwoodie & Rochelle C. Dreyfuss, *International Intellectual Property Law and the Public Domain of Science*, 7 J. INT'L ECON. L. 431, 433 (2004); Arti K. Rai & Rebecca S. Eisenberg, *Bayh-Dole Reform and the Progress of Biomedicine*, 66 LAW & CONTEMP. PROBS. 289, 291 (Winter/Spring 2003).

30. *See* 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, *supra* note 23, at 3, 17–20.

31. *Id.* at 44.

32. TRIPS Agreement, *supra* note 11, art. 1.1 (leaving Members "free to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice"); *id.* at arts. 7–8 (stressing objectives of promoting innovation and transfer of technology "to the mutual advantage of producers and users of technological knowledge" and "the public interest in sectors of vital importance to [Members'] socio-economic and technological development"). *See generally* UNCTAD-ICTSD, RESOURCE BOOK, *supra* note 14 (discussing "flexibilities" within the TRIPS regime).

strategies to new legal realities and that successive rounds of negotiations tend to reduce the flexibilities available for nations to tailor intellectual property law to their own needs.[33]

A. The Social Costs of the TRIPS Patent Standards

In principle, higher standards of patent protection under the TRIPS Agreement will provide needed incentives to invest in the innovative sectors of some developing economies,[34] to make high-technology products available to local industries, and to promote new licensing agreements and direct foreign investments.[35] In practice, however, their different national and regional capabilities, institutions, and endowments limit the developing countries' absorptive capacities and reduce the potential benefits of open markets for knowledge goods. This "technology divide" is further widened by the high rents exacted by technology exporters.[36]

Whether they fall into the high-, medium-, or low-income brackets, all the developing countries—except for a small group of Least Developed Countries (LDCs)—that seek to become suppliers of knowledge goods must compete on roughly the same normative terms and conditions that govern advanced industrialized countries.[37]

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33. *See, e.g.*, CIPR, *supra* note 22, at 8–9, 21–27; Maskus & Reichman, *supra* note 30, at 4–15; Ruth L. Okediji, *Public Welfare and the Role of the WTO: Reconsidering the TRIPS Agreement*, 17 EMORY INT'L L. REV. 819, 839–42 (2003). For a more optimistic view, see Joseph Straus, *The Impact of the New World Order on Economic Development: The Role of Intellectual Property Rights System*, 6 J. MARSHALL REV. INTELL. PROP. 1, 3 (2006).

34. *See* Straus, *supra* note 33, at 4.

35. *See, e.g.*, KEITH E. MASKUS, INTELLECTUAL PROPERTY RIGHTS IN THE GLOBAL ECONOMY 109–42 (2000); Keith E. Maskus, Kamal Saggi & Thitima Puttitanun, *Patent Rights and International Technology Transfer Through Direct Investment and Licensing*, *in* INTERNATIONAL PUBLIC GOODS AND TRANSFER OF TECHNOLOGY UNDER A GLOBALIZED INTELLECTUAL PROPERTY REGIME, *supra* note 23, at 265, 265. *But see* Daniel C.K. Chow, *The Role of Intellectual Property in Promoting International Trade and Foreign Direct Investment*, *in* 4 INTELLECTUAL PROPERTY AND INFORMATION WEALTH, *supra* note 26, at 187, 187 (stressing China's ability to attract foreign direct investment despite weak intellectual property rights).

36. *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 23, at 227, 229–32 [hereinafter Correa, *Can the TRIPS Agreement Foster Technology Transfer to Developing Countries?*]; Carlos M. Correa, *Trends in Technology Transfer: Implications for Developing Countries*, 21 SCI. & PUB. POL'Y 369, 377–79 (1994) [hereinafter Correa, *Trends in Technology Transfer*]; *see also* KEITH E. MASKUS, UNCTAD-ICTSD, ENCOURAGING INTERNATIONAL TECHNOLOGY TRANSFER 2 (2004).

37. *See, e.g.*, TRIPS Agreement, *supra* note 11, art. 27.1 (requiring that "patents shall be available for any inventions, whether products or processes, in all fields of technology" if they

Although some developing countries have demonstrated considerable capacity in certain technological sectors,[38] all are struggling to cope with the limits TRIPS places on their ability to reverse engineer up-to-date foreign technologies that were previously unpatented in their territories. For example (and especially problematical), the ability to produce generic drugs without regard to pharmaceutical patents was completely eliminated in 2005.[39] For an economy like that of India, where the generic drug industry is a significant source of income and a key locus of technological development, "fair following" by honest means of reverse engineering had been an important strategic option.[40]

Whether they engage in the production of knowledge goods for local consumption or for export purposes, developing countries must internalize the TRIPS-mandated intellectual property standards in ways that stimulate potentially innovative industrial sectors without legally discriminating against foreign competitors.[41] They must also avoid undermining those less-advanced sectors of their own economies that meet local needs for knowledge goods at affordable prices. India's new patent law, for example, reflects the tensions between efforts to stimulate the nation's research-based

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meet specified eligibility criteria); *id.* arts. 65–66. As regards pharmaceutical products in particular, see World Trade Organization, Ministerial Conference, Declaration on the TRIPS Agreement and Public Health, WT/MIN(01)/DEC/2 (Nov. 14, 2001) [hereinafter Doha Declaration]; Decision by the Council for TRIPS of 27 June 2002, *Extension of the Transition Period under Article 66.1 of the TRIPS Agreement for Least-Developed Country Members for Certain Obligations with Respect to Pharmaceutical Products*, WT/IP/C/25 (July 1, 2005).

LDCs may postpone implementation of other TRIPS obligations, including the duty to provide patent protection for products other than pharmaceuticals, until 2013. *See* Decision of the Council for TRIPS of 29 November 2005, *Extension of the Transition Period under Article 66.1 for Least-Developed Country Members*, WT/IP/C/40 (Nov. 30, 2005). During these transition periods, LDCs must continue to respect national treatment and Most Favored Nation (MFN) obligations under articles 3–4 of the TRIPS Agreement. *See id.* para. 5.

38. *See* Janice M. Mueller, *The Tiger Awakens: The Tumultuous Transformation of India's Patent System and the Rise of Indian Pharmaceutical Innovation*, 68 U. PITT. L. REV. (forthcoming 2007) (manuscript at 3), *available at* http://ssrn.com/abstract=923538 ("India became a world leader in high-quality generic drug manufacturing."); Straus, *supra* note 33, at 6–8.

39. *See* sources cited *supra* note 37.

40. *See* Mueller, *supra* note 38, at 4, 28, 55. *See generally* 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) (evaluating "the impact of the TRIPS Agreement on [developing countries'] capacity to acquire the knowledge and skills they need to compete on the market for technologically advanced products and processes").

41. TRIPS Agreement, *supra* note 11, arts. 3–4.

pharmaceutical sector and efforts to preserve its well-developed capacity to supply low-cost drugs for the needy in both domestic and foreign markets.[42]

At the same time, the foreign technology suppliers' demands for increased rent extraction—combined with refusals to work, refusals to deal, and various forms of unchecked anticompetitive conduct—hamper the efforts of developing-country entrepreneurs to acquire high-technology goods on open markets at prices that preserve their own comparative advantages.[43] These practices also frustrate their governments' ability to attract foreign direct investment and to build the infrastructure needed to move to a more competitive position on the technological frontier.[44] Although the full extent of these barriers has been insufficiently studied, it seems that high-tech manufacturers in developed countries prefer selling to wholly owned foreign subsidiaries rather than to potential competitors in developing countries. When sales are made to third parties, the net welfare gains from technology installation may be offset by the costs of increased rent extraction.[45]

Moreover, all the developing countries, even those not engaged in the production of knowledge goods, must maintain patent offices and create mechanisms that enable foreign patent owners to enforce their rights—a costly and burdensome operation.[46] How they accomplish this task will seriously affect their internal development

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42. *See* Mueller, *supra* note 23, at 541–43; Mueller, *supra* note 38, at 55–61.

43. *See* John Barton, *Integrating IPR Policies in Development Strategies*, *in* TRADING IN KNOWLEDGE 57, 61 (Christophe Bellmann et al. eds., 2003) (stressing the difficulties of entry—"compounded by the international IP system"—into markets "dominated by multinational oligopolies"); Paul Champ & Amir Attaran, *Patent Rights and Local Working under the WTO TRIPS Agreement: An Analysis of the U.S.-Brazil Patent Dispute*, 27 YALE J. INT'L L. 365, 369–70 (2002) (discussing differing opinions on local work requirements between developed and developing countries); *cf.* Ruth L. Okediji, *Sustainable Access to Copyrighted Digital Information Works in Developing Countries*, *in* INTERNATIONAL PUBLIC GOODS AND TRANSFER OF TECHNOLOGY UNDER A GLOBALIZED INTELLECTUAL PROPERTY REGIME, *supra* note 23, at 142, 145 (suggesting that similar problems arise in connection with copyrighted scientific and educational works).

44. *See* MASKUS, *supra* note 35, at 119–35; Barton, *supra* note 43, at 373–74; Correa, *Can the TRIPS Agreement Foster Technology Transfer to Developing Countries?*, *supra* note 36, at 229–32; Correa, *Trends in Technology Transfer*, *supra* note 36, at 371–72.

45. *See, e.g.*, Lee G. Branstetter, *Do Stronger Patents Induce More Local Innovation?*, *in* INTERNATIONAL PUBLIC GOODS AND TRANSFER OF TECHNOLOGY UNDER A GLOBALIZED INTELLECTUAL PROPERTY REGIME, *supra* note 23, at 309, 317–20 (finding increased rent extraction following patent strengthening).

46. CIPR, *supra* note 22, at 114.

strategies along with their ability to supply such essential public goods as education, public health, environmental safety, scientific advancement, and a soundly competitive marketplace for goods and services.[47]

These tensions are linked with, but not necessarily determined by, problems of wealth distribution. For example, the TRIPS Agreement made assumptions about technological self-sufficiency that proved inaccurate and contributed directly to a health crisis over much of the globe.[48] Although the subsequent Doha Round remedied the problem by permitting countries to issue compulsory licenses to meet the health needs of nations unable to produce locally needed medicines, the Doha Agreement took several years to negotiate and its efficacy is yet to be demonstrated.[49]

Admittedly, TRIPS gives its Members some leeway to tailor their laws to local needs. For example, states can presumably supply their own definitions of "inventive step" and determine for themselves the technological scope of patent protection.[50] They can refuse to patent diagnostic, surgical, and therapeutic methods;[51] they can exclude from

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47. Maskus & Reichman, *supra* note 30, at 33–35; *cf.* Chon, *supra* note 25, at 28–49 (describing the nation-state as the "best guardian of the domestic welfare bargain" upon which the international trading system should not unduly intrude); Peter K. Yu, *Reconceptualizing Intellectual Property Interests in a Human Rights Framework*, 40 U.C. DAVIS L. REV. 1039, 1090 (2007) (comparing material interests in intellectual creations and protections to human rights interests, such as health, education and free expression).

48. *See* Doha Declaration, *supra* note 37, para. 6; TRIPS Agreement, *supra* note 11, art. 31(f). The TRIPS Agreement allowed compulsory licensing of patented products in the domestic market. TRIPS Agreement, *supra* note 11, art. 31. Members lacking the capacity to manufacture pharmaceuticals locally, however, could not effectively use compulsory licensing or obtain exports under a double compulsory licensing regime. *Id.*, art. 31(f); Doha Declaration, *supra* note 35, para. 6. For a description of the difficulties in providing access to essential medicines, see generally Frederick M. Abbott, *The WTO Medicines Decision: World Pharmaceutical Trade and the Protection of Public Health*, 99 AM. J. INT'L L. 317 (2005).

49. *See* FREDERICK M. ABBOTT & JEROME H. REICHMAN, EUROPEAN PARLIAMENT COMMITTEE ON INTERNATIONAL TRADE, ACCESS TO ESSENTIAL MEDICINES: LESSONS LEARNED SINCE THE DOHA DECLARATION ON THE TRIPS AGREEMENT AND PUBLIC HEALTH, AND POLICY OPTIONS FOR THE EUROPEAN UNION 13 (2007); Abbott, *supra* note 48, at 317 ("Nongovernmental organizations (NGOs) concerned about access to medicines were disappointed by the complexity of the [Doha Declaration's implementation], arguing that it would be unworkable in practice.").

50. *See* TRIPS Agreement, *supra* note 11, arts. 27(1), 28. Article 27(1) lists an "inventive step" as one of the requirements for patentable subject matter but does not define the term. *Id.* art. 27(1). Article 28 defines scope in terms of the nature of the rights conferred, but the Agreement does not set out the breadth of technological terrain a patent right must cover. *Id.* art. 28.

51. *Id.* art. 27(3)(a).

patentability inventions required to protect *ordre public*, morality, and human health;[52] and they can grant limited exceptions to the exclusive rights conferred.[53] They also have increasing power to order compulsory licenses.[54] These flexibilities allow developing countries considerable policy space in which to maximize the benefits and minimize the social costs of adopting the international minimum standards. But addressing these flexibilities is expensive and requires a sophisticated legal infrastructure. Taken together with the costs of complying with the obligations TRIPS mandates, the burden on developing countries is formidable.[55] To make matters worse, these same countries must increasingly also deal with pressures to provide the higher, TRIPS-plus levels of intellectual property protection embodied in bilateral or regional trade agreements.[56]

B. Shrinking the TRIPS Flexibilities

Against this background, any form of deep harmonization through the SPLT that is likely to win the support of the developed countries seems certain to erode whatever flexibilities the developing countries still retain under the TRIPS Agreement and under subsequently negotiated TRIPS-plus Free Trade Agreements (including their Most Favored Nation implications[57]). Consider, for example, the eligibility requirement of an inventive step (nonobviousness).[58] The standard of inventiveness is intimately tied to a nation's economic goals, and especially to its citizens' technological

52. *Id.* art. 27(2).

53. *Id.* art. 30.

54. *See id.* art. 31; *see also* ABBOTT & REICHMAN, *supra* note 49, at 13 (noting that the proposed amendment to the TRIPS agreement, already accepted by WTO members on December 6, 2005, would permit expansion of compulsory licensing for pharmaceutical products).

55. *See, e.g.*, UNCTAD-ICTSD, RESOURCE BOOK, *supra* note 14, at 135–214, 358–61 (describing flexibilities in the TRIPS Agreement); SISULE F. MUSUNGU, SUSAN VILLANUEVA & ROXANA BLASETTI, UTILIZING TRIPS FLEXIBILITIES FOR PUBLIC HEALTH PROTECTION THROUGH SOUTH-SOUTH REGIONAL FRAMEWORKS 23–34 (2004); Reichman, *supra* note 40, at 28–29.

56. *See* Frederick M. Abbott, *Intellectual Property Rights in a Global Trade Framework: IP Trends in Developing Countries*, 98 AM. SOC'Y INT'L L. PROC. 95, 97–98 (2004).

57. *See* TRIPS Agreement, *supra* note 11, art. 4 (establishing MFN treatment).

58. *Id.* art. 27.1 (requiring patents to be made available for inventions that are "new, involve an inventive step and are capable of industrial application"). Footnote 5 equates the terms "inventive step" and "capable of industrial application" with "nonobvious" and "useful." *Id.* n.5.

potential and to the types of creativity it can hope to foster.[59] Even within one nation, determining the right standard can be difficult. In the United States, for example, the threshold of nonobviousness has varied widely at different periods,[60] and it remains a contentious issue.[61]

Perhaps for these reasons, TRIPS leaves the height of the inventive step to national law. Presumably, deep harmonization requires convergence on a single standard. Yet finding one that would suit countries at different levels of technological sophistication and for all kinds of intellectual advances could easily prove impossible.[62] Whatever standard is chosen will, at best, represent a mediate position—one that will differ from the optimum for many developing countries.

More generally, there is a risk that virtually every procompetitive 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 licenses[63]—would shrink or disappear in the SPLT. After all, if experience is any guide, on virtually all of these issues, the advanced industrialized countries will tend to demand higher protectionist standards than those favored by policymakers in developing countries. The United States, for example, has shown little willingness to limit the scope of patentable subject matter by adopting the "technical effect" requirement found in other countries' patent statutes.[64] The United States—indeed developed countries

59. Rochelle Cooper Dreyfuss & Andreas F. Lowenfeld, *Two Achievements of the Uruguay Round: Putting TRIPS and Dispute Settlement Together*, 37 VA. J. INT'L L. 275, 300–01 (1997); *see* CIPR, *supra* note 22, at 7.

60. *See* ADAM B. JAFFE & JOSH LERNER, INNOVATION AND ITS DISCONTENTS 35 (2004).

61. *See id.*; John H. Barton, *Non-Obviousness*, 43 IDEA 475, 508 (2003); Rebecca S. Eisenberg, *Obvious to Whom? Evaluating Inventions from the Perspective of PHOSITA*, 19 BERKELEY TECH. L.J. 885, 887 (2004). Indeed, despite more than two-hundred years of experience with a patent system, the standard of nonobviousness was just the subject of another Supreme Court case, *KSR International Co. v. Teleflex, Inc.*, 127 S. Ct. 1727 (2007). *KSR*'s effect on patent issuances remains to be seen, but it appears to have once again raised the standard of nonobviousness.

62. For example, although the standard in the United States is currently low, *see, e.g.*, JAFFE & LERNER, *supra* note 60, at 34–35, the standard in India is high, *see* Mueller, *supra* note 38, at 86–89.

63. *See* UNCTAD-ICTSD, RESOURCE BOOK, *supra* note 14, at 351–57.

64. *Compare* Convention on the Grant of European Patents, *supra* note 9, arts. 52–53, 57 (requiring patents to be capable of having an "industrial application," defined by the EPO as requiring the ability to be used in any kind of industry), *and* European Patent Office,

generally—has resisted the inclusion of exceptions to patentability for health, the environment, or the protection of genetic resources and traditional knowledge.[65] In fact, the United States appears to be taking the position that any agreement reached must reflect the standards of protection found in U.S. law.[66] Such intransigence does not bode well for the kind of compromising required to produce an instrument that truly accommodates diverse needs.

Of course, the TRIPS Agreement adopted some relatively high standards, and various bilateral and regional free trade agreements impose even higher ones.[67] But in those negotiations, there is, at least theoretically, the prospect that advanced industrialized countries will exchange higher intellectual property standards for trade concessions in other areas which fosters some degree of equity. The rents to be extracted from a highly protectionist intellectual property regime would thus be offset (to some extent) by new market access opportunities. In the context of a free-standing patent agreement, such as the SPLT, no such compensation is possible. There is little in the way of offsetting doctrinal concessions that private stakeholders would permit developed-country negotiators to offer developing countries in return for adopting a patent regime that the latter regard as suboptimal. Such a bargaining stalemate, indeed, is precisely what caused the failure of the Diplomatic Conference to Revise the Paris Convention in 1985 and led the technology-exporting countries to

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Computer-Implemented Inventions, http://www.epo.org/focus/issues/computer-implemented-inventions.html (last visited Oct. 4, 2007) (requiring patents for computer-implemented inventions to make a technical contribution), *with* State St. Bank & Trust Co. v. Signature Fin. Group, Inc., 149 F.3d 1368, 1373 (Fed. Cir. 1998) (requiring only that mathematical inventions have a "useful, concrete and tangible result"(quoting *In re* Alappat, 33 F.3d 1526, 1544 (Fed. Cir. 1994))).

65. DANIEL GERVAIS, THE TRIPS AGREEMENT: DRAFTING HISTORY AND ANALYSIS 228–34 (2d ed. 2003); *cf.* Dawson Chem. Co. v. Rohm and Haas Co., 448 U.S. 176, 215 & n.21 (1980) (noting resistance to the adoption of compulsory licensing provisions in U.S. patent law).

66. *See generally* Hauda, *supra* note 17.

67. *See, e.g.*, Australia-United States Free Trade Agreement, U.S.-Austl., art. 17.4.7(e)(i), May 18, 2004, 118 Stat. 919, *available at* http://www.dfat.gov.au/trade/negotiations/us_fta/final-text/index.html (prohibiting parallel importation, even though the issue is left open by article 6 of the TRIPS Agreement). *See generally* Carlos M. Correa, *Bilateralism in Intellectual Property: Defeating the WTO System for Access to Medicines*, 36 CASE W. RES. J. INT'L L. 79, 80 (2004) (elaborating "on the bilateralism in [intellectual property rights] standard setting, using as an example the substantial elevation of [intellectual property rights] standards in the Central American Free Trade Agreement . . . in relation to pharmaceutical test data . . . and the new requirement . . . linking patent protection to the registration of a pharmaceutical product").

bring intellectual property within the Uruguay Round of Multilateral Trade Negotiations in 1986.[68]

The counterargument is that the benefits of a smoothly working worldwide patent system will ultimately trickle down to developing countries and help them climb the technological innovation ladder.[69] Such a system would, in theory, lower transaction costs, produce greater legal certainty, and permit emerging economies to invest in building the technological skills of their population, secure in the knowledge that technology transfer and foreign direct investment will follow.[70]

However, the counterargument has many defects. One is that no one knows the exact contours of a system that would produce these results, and a good case can be made for quite divergent approaches. For example, one of us has taken the Indian example to heart and argued that developing countries would benefit from a patent system that makes it easy to acquire protection.[71] The theory is that such a regime would encourage innovation at the level at which it can be realistically elicited, and that the resulting patents would produce "buy in" in the form of an appreciation for the wealth that intellectual property protection creates.[72] Conversely, the other author has suggested exactly the opposite: that the need to build competitive markets mandates that the acquisition of full patent rights should be

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68. *See* World Trade Organization, Ministerial Declaration of 20 September 1986, MIN(86)/W/19, 25 I.L.M. 1623 (1986), *available at* http://www.sice.oas.org/trade/Punta_e.asp; *see also* SUSAN K. SELL, PRIVATE POWER, PUBLIC LAW: THE GLOBALIZATION OF INTELLECTUAL PROPERTY RIGHTS 96–120 (2003) ("In effect, twelve corporations made public law for the world."). *See generally* Frederick M. Abbott, *Protecting First World Assets in the Third World: Intellectual Property Negotiations in the GATT Multilateral Framework*, 22 VAND. J. TRANSNAT'L L. 689 (1989) (addressing "industrialized countries' growing concerns over technology transfer and their efforts to obtain protection of intellectual property rights under the General Agreement on Tariffs and Trade"); Peter K. Yu, Symposium, *Currents and Crosscurrents in the International Intellectual Property Regime*, 38 LOY. L.A. L. REV. 323 (2004) (demonstrating "that the international intellectual property regime is an ongoing project that provides opportunities and crises for both developed and less developed countries, as well as for rights holders and individual end users").

69. *See* Maskus et al., *supra* note 35, at 265 (noting that developing countries rely on foreign technology to spark economic growth).

70. 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 23, at 617, 622 (proposing ways to limit the costs of a global patent system for developing countries).

71. Dreyfuss & Lowenfeld, *supra* note 59, at 300.

72. *Id.*

made relatively difficult.[73] On this view, governments should rely on second-tier regimes—such as utility model laws or "compensatory liability regimes" (liability rules)—to stimulate investment in locally attainable adaptations or improvements of foreign technology, and in "cumulative and sequential innovation" generally.[74] In the absence of empirical evidence either way, experimentation makes more sense than freezing the law prematurely.

Trumping all of these substantive and strategic considerations, moreover, is the fact that what developing countries most need 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 and arduous task in its own right. It is difficult 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.[75] Developing countries cannot succeed if, at the international level, a new round of multilateral intellectual property negotiations threatens to raise the technological ladder once again, before these countries even get a solid foothold on it.[76]

II. THE LIKELY ADVERSE IMPACT ON DEVELOPED COUNTRIES

However cogent the concerns of developing countries might be, one must nonetheless weigh them against the supposed benefits of deep harmonization.[77] If lower transaction costs, increased legal certainty, and greater economies of scale and scope prove as remunerative as the advocates of harmonization contend, one could

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73. Reichman, *supra* note 40, at 31.

74. Maskus & Reichman, *supra* note 30, at 3, 39–41; *see also* Jerome H. Reichman & Tracy Lewis, *Using Liability Rules to Stimulate Local Innovation in Developing Countries: Application to Traditional Knowledge*, *in* INTERNATIONAL PUBLIC GOODS AND TRANSFER OF TECHNOLOGY UNDER A GLOBALIZED INTELLECTUAL PROPERTY REGIME, *supra* note 23, at 337, 340–42 (arguing that a liability rule which promotes small-scale innovation in the developing world would stimulate investment by local entrepreneurs).

75. Margaret Chon, for example, highlights the problem of providing school children with affordable textbooks. Chon, *supra* note 25, at 2894–95.

76. *See* Maskus & Reichman, *supra* note 30, at 37–39.

77. *See* Baechtold, *supra* note 18, at 142–43. *See generally* Hauda, *supra* note 17; Jeh, *supra* note 15.

envision a compromise scheme that achieves these ends on behalf of developed economies, but permits developing countries to reject such changes if, on balance, they are not as helpful to them as pursuing a slower track. Developing countries could be further placated with selected concessions[78] and compensatory side payments.[79]

The sad truth, however, is that no one has managed to put forward a vision of a properly functioning patent system for the *developed* world that commands even the appearance of a consensus. There are as many different proposals on the table as there are thinkers and investigators. With its relatively experienced patent office, excellent trial courts, specialized appellate court, and a Supreme Court poised to add a generalist perspective, the United States uniquely possesses the kind of institutional infrastructure needed to build and maintain a strong patent law system.[80] Even so, all that the proponents for change in that country can agree on is that the patent law badly needs reform. The risk and cost of litigation is rising rapidly, which creates a drag on innovation and imposes disincentives to invest in creative production.[81] Two studies by the National Academies[82] and another by the Federal Trade

78. Concessions might include greater harmonization of international patent law with the Convention on Biological Diversity, with imposition of certificates of origin and prior consent for inventions making use of developing country resources and with some recognition of traditional knowledge in international intellectual property law. *See* Thomas Cottier & Marion Panizzon, *Legal Perspectives on Traditional Knowledge: The Case for Intellectual Property Protection*, 7 J. INT'L ECON. L. 371, 372, 376 (2004); Graham Dutfield, *Legal and Economic Aspects of Traditional Knowledge*, *in* INTERNATIONAL PUBLIC GOODS AND TRANSFER OF TECHNOLOGY UNDER A GLOBALIZED INTELLECTUAL PROPERTY REGIME, *supra* note 23, at 495, 505–06.

79. Robert O. Keohane, *Comment: Norms, Institutions, and Cooperation*, *in* INTERNATIONAL PUBLIC GOODS AND TRANSFER OF TECHNOLOGY UNDER A GLOBALIZED INTELLECTUAL PROPERTY REGIME, *supra* note 23, at 65, 67.

80. *See* Rochelle C. Dreyfuss, *The Federal Circuit: A Case Study in Specialized Courts*, 64 N.Y.U. L. Rev. 1 (1989).

81. *See* James Bessen & Michael J. Meurer, *Patent Failure: How Judges, Bureaucrats, and Lawyers Put Innovators at Risk* (Sept. 19, 2007) (unpublished manuscript at 14, on file with the *Duke Law Journal*) (suggesting that the costs of litigation are beginning to overtake the monetary rewards of the patent system, at least in certain technological sectors); Michael J. Meurer & James Bessen, *The Patent Litigation Explosion* 1 (Am. L. & Econ. Ass'n 15th Annual Meeting, Working Paper No. 57, 2005), *available at* http://law.bepress.com/alea/15th/art57; Scott Stern & Fiona Murray, *Do Formal Intellectual Property Rights Hinder the Free Flow of Scientific Knowledge? An Empirical Test of the Anti-Commons Hypothesis* 9–10 (Nat'l Bureau of Econ. Research, Working Paper No. 11465, 2005), *available at* http://ssrn.com/abstract=755701.

82. NAT'L RESEARCH COUNCIL, REAPING THE BENEFITS OF GENOMIC AND PROTEOMIC RESEARCH: INTELLECTUAL PROPERTY RIGHTS, INNOVATION, AND PUBLIC HEALTH (2006) (considering the effects of patenting and licensing practices in the fields of genomics and

Commission,[83] and criticism from numerous legal and economics scholars[84] and a variety of judges[85] have offered various diagnoses of the problems and assorted, often contradictory, prescriptions for change. Indeed, even the goals of the patent system are the subject of debate: although patents may still protect inventors from free riders, scholars have suggested that in many new industries, patents serve signaling, financing, and allocating functions,[86] which arguably could be performed in ways that have fewer adverse effects on the public interest.[87]

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protemics and steps that the NIH can take to promote productivity and innovation); NAT'L RESEARCH COUNCIL, A PATENT SYSTEM FOR THE 21ST CENTURY (2004) (offering seven criteria for evaluating the present patent system and seven recommendations for designing a more effective patent system).

83. FED. TRADE COMM'N, TO PROMOTE INNOVATION: THE PROPER BALANCE OF COMPETITION AND PATENT LAW AND POLICY (2003), *available at* http://www.ftc.gov/os/2003/10/innovationrpt.pdf (recommending policies for maintaining the proper balance between patent law and competition law and policy).

84. *See, e.g.*, JAFFE & LERNER, *supra* note 60, at 35 (contending that patents are now available "to pretty much anyone who ask[s] for one, despite the legal tests or novelty and non-obviousness," arguing that the trend "now undermines rather than fosters the crucial process of innovation"); Rochelle Dreyfuss, *Pathological Patenting: The PTO as Cause or Cure*, 104 MICH. L. REV. 1559, 1578 (2006) ("[A] strong argument can be made that the observed problems are not caused merely by the *implementation* of the law, but also by its *articulation*: by an institutional failure to keep patent law and policy abreast with developments at the technological frontier."); Maskus & Reichman, *supra* note 30, at 24 nn.85–88 (citing critical articles by Professors Rai, Kesan, Merges, Lemley, Heller & Eisenberg, Barton and others); Robert P. Merges, *As Many as Six Impossible Patents before Breakfast: Property Rights for Business Concepts and Patent System Reform*, 14 BERKELEY TECH. L.J. 577, 615 (1999) (proposing "common-sense starting points to deal with the problem of business concept patents"). In reality, Professors Jaffe and Lerner are more optimistic than they sound, because they think the problems stem from how the patent law is applied and not from what it provides. JAFFE & LERNER, *supra* note 60, at 5–6.

85. *See, e.g.*, *In re* Fisher, 421 F.3d 1365, 1379–80 (Fed. Cir. 2005) (Rader, J., dissenting) (disagreeing with the majority's position on utility standards); Univ. of Rochester v. G.D. Searle & Co., 358 F.3d 916, 919–30 (Fed. Cir. 2004) (considering and rejecting Rochester's position on the written description requirement); Integra Lifesciences I, Ltd. v. Merck KGaA, 331 F.3d 860, 863–64 n.2 (Fed. Cir. 2003) (disagreeing with the dissent's position on the scope of infringement liability), *vacated*, 545 U.S. 193 (2005).

86. *See generally* Bronwyn H. Hall & Rosemary Ham Ziedonis, *The Patent Paradox: An Empirical Study of Patenting in the U.S. Semiconductor Industry, 1979–1995*, 32 RAND J. ECON. 101, 102 (2001) (examining the "'patent paradox' in the semiconductor industry, where the gap between the relative ineffectiveness of patents . . . and their widespread use is particularly striking"); Clarisa Long, *Patent Signals*, 69 U. CHI. L. REV. 625, 627 (2002) ("The ability to convey information credibly to observers at low cost is a highly valuable role of patents that has been completely overlooked."); Ronald J. Mann, *Do Patents Facilitate Financing in the Software Industry?*, 83 TEX. L. REV. 961 (2005) (analyzing the role patents play in fostering investments).

87. For example, Dirk Czarnitzki and his coauthors demonstrate a positive correlation between patenting rate and publication rate, which suggests that publications could serve as

In Europe, similar uncertainty exists. In a publication entitled *Scenarios for the Future*,[88] the European Patent Office (EPO)[89] has frankly recognized the uncertain future of the worldwide patent system. It has outlined four different scenarios that could emerge in response to different interest groups seeking to influence domestic and international policymaking forums.

The first scenario envisions the tightening of worldwide patent standards under an international treaty, such as the SPLT, a position championed by many multinational corporations.[90] A second scenario envisions the evolution of a variegated system in which developing countries—especially emerging economies—gradually reshape the existing patent system to suit their own comparative advantages.[91] A third scenario envisions a shift toward second-tier regimes, possibly sounding in liability rules rather than exclusive rights, which would specifically address the problems posed by cumulative and sequential innovation.[92] The fourth scenario envisions a re-elaboration of the

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signals of technological competence. Dirk Czarnitzki, Wolfgang Glänzel & Katrin Hussinger, *An Empirical Assessment of Co-Activity Among German Professors* 17 (ZEW Ctr. for European Econ. Research, Discussion Paper No. 06-080, 2006), *available at* ftp://ftp.zew.de/pub/zew-docs/dp/dp06080.pdf. Eric Brousseau and coauthors have investigated the use of contracts to govern relationships among innovators in the high-tech sector. Eric Brousseau, Régis Coeurderoy & Camille Chaserant, *The Governance of Contracts: Empirical Evidence on Technology Licensing Agreements*, 163 J. INSTITUTIONAL & THEORETICAL ECON. 205, 205 (2007). Paul David's work looks at the role of publication rates in allocating research resources in science. Paul A. David, *Positive Feedbacks and Research Productivity in Science: Reopening Another Black Box*, *in* ECONOMICS OF TECHNOLOGY 65, 69–70 (O. Granstrand ed., 1994).

88. EUROPEAN PATENT OFFICE (EPO), SCENARIOS FOR THE FUTURE—HOW MIGHT IP REGIMES EVOLVE BY 2025? WHAT GLOBAL LEGITIMACY MIGHT SUCH REGIMES HAVE? (2007) [hereinafter SCENARIOS FOR THE FUTURE].

89. The EPO is not an organ of the European Communities. Rather, it was established by the Convention on the Grant of European Patents (EPC). *Id.* at inside cover. The EPO, which acts as a regional patent office for the member states, is the executive body of the treaty members. There is also an administrative council, which operates as a de facto legislative body. Revisions of the EPC are undertaken by an intergovernmental diplomatic conference for the contracting states. *Id.*

90. *See id.* at 30–47. With "[b]usiness as the dominant driver," this scenario tells "[t]he story of consolidation in the face of a system that has been so successful that it is collapsing under its own weight; Power and Global Jungle are the major driving forces." *Id.* at 29.

91. *See id.* at 48–65. With "[g]eopolitics as dominant driver," this scenario tells "the story of conflict in the face of changing geopolitical balances and competing ambitions, where Power and Global Jungle are the major driving forces, but in contrast to the business-led scenario, the states are the key players." *Id.* at 29.

92. *See id.* at 95–96. With "[t]echnology as dominant driver," this scenario tells "[t]he story of differentiation in the face of global systemic crises, where Pace of Change, Systemic Risks and Knowledge Paradox (as the nature of knowledge changes) are the major driving forces." *Id.* at 29; *see also* J.H. Reichman, *Of Green Tulips and Legal Kudzu: Repackaging Rights in*

basic patent paradigm that would give much greater weight to the provision of public goods and "access to knowledge" in general, at the expense of private incentives to innovate.[93] Although the EPO takes no position on which of these scenarios it favors, its publication demonstrates that policymakers responsible for the future evolution of the patent system will be constrained to take account of the divergent interests underlying each of these remarkably prescient scenarios.

It should, indeed, surprise no one that routine tinkering with a patent paradigm launched in Venice in the fifteenth century and refined by the United Kingdom in the seventeenth century cannot answer the hard questions raised by new technologies and the new modes of producing them.[94] There are major challenges for which past experiences give only untested and untrustworthy hypotheses, with no convincing empirical studies on the horizon to resolve the doubts. These problems affect all aspects of patent protection. Not only are there discordant views on how high the inventive step should be, there are also disagreements on virtually every substantive topic under discussion in connection with the SPLT: novelty and utility standards, the research exemption, compulsory licenses—along with standards for analyzing infringement and awarding relief.[95]

Subpatentable Innovation, *in* EXPANDING THE BOUNDARIES OF INTELLECTUAL PROPERTY: INNOVATION POLICY FOR THE KNOWLEDGE SOCIETY 23, 24 (Rochelle Dreyfuss et al. eds., 2001) [hereinafter Reichman, *Of Green Tulips and Legal Kudzu*] (proposing a "compensatory liability regime" for incremental innovation); J.H. Reichman, *Legal Hybrids Between the Patent and Copyright Paradigms*, 94 COLUM. L. REV. 2432, 2447 (1994) [hereinafter Reichman, *Legal Hybrids between the Patent and Copyright Paradigms*] (suggesting that a liability regime would increase investment in cumulative and sequential technologies while avoiding market failure with fewer anticompetitive effects).

93. *See* SCENARIOS FOR THE FUTURE, *supra* note 88, at 72. With "[s]ociety as the dominant driver," this scenario tells, "[t]he story of erosion [of patent law] in the face of diminishing societal trust, where Power (from the bottom up) and societal fear of Pace of Change and Systemic Risks—and Knowledge Paradox (in terms of access and control)—are the major driving forces." *Id.* at 29; *see also* Amy Kapczynski, *The Access to Knowledge Movement*, 117 YALE L.J. (forthcoming 2008) (describing the development of groups opposing restrictive rights and promoting greater public access).

94. *See* MAY & SELL, *supra* note 27, at 203–18 ("Only by understanding the long history of intellectual property can the problems of its contemporary global governance be properly assessed."). *See generally* John F. Duffy, *Harmony and Diversity in Global Patent Law*, 17 BERKELEY TECH. L.J. 685 (2002) (discussing the diversity of patent law and the potential costs of harmonization).

95. *See, e.g.*, Request for Comments on the International Effort to Harmonize the Substantive Requirements of Patent Law, 66 Fed. Reg. 15,409, 15,409–11 (Mar. 19, 2001) (listing seventeen differences between U.S. patent law and the law of other developed countries); *see*

Furthermore, there are a multitude of open procedural questions—including questions about the level of scrutiny that patent offices give to applications,[96] the standards for reexamining issued patents, as well as the availability of avenues to challenge patents administratively (through opposition procedures)[97] and judicially (through, for instance, declaratory judgment actions).[98] The National Academies' Report criticized the reluctance of the Court of Appeals for the Federal Circuit to defer to the examination guidelines that the U.S. Patent Office applies to new technologies, while applying unrealistic standards of its own that ignore what those skilled in the art actually know.[99] Others have questioned vesting powers over patent law in a single specialized court, pointing to the Federal Circuit's penchant for *de novo* review,[100] its apparent lack of interest in economics or patent policy,[101] and its insulation from criticism.[102]

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also James Gleick, *Patently Absurd*, N.Y. TIMES MAG., Mar. 12, 2000, at 44, 44 (describing the proliferation of patent infringement claims in e-commerce).

96. *See* Mark A. Lemley, *Rational Ignorance at the Patent Office*, 95 NW. U. L. REV. 1495, 1495–96 (2001).

97. *See* JAFFE & LERNER, *supra* note 60, at 181, 192 (discussing opposition procedures and standards of proof).

98. For U.S. examples, see the various proposals for patent reform, including the Patent Reform Act of 2007, H.R. 1908, S. 1145, 110th Cong. (2007); the Patent Reform Act of 2005, H.R. 2795, 109th Cong. (2005), which proposed opposition procedures, including varying standards of proof on the question of validity; and the ruling in *MedImmune, Inc. v. Genentech, Inc.*, 127 S. Ct. 764, 775–76 (2007), in favor of standing to challenge patent validity in a declaratory judgment action. *Cf.* Paul Edward Geller, *An International Patent Utopia?*, 25 EUR. INTELL. PROP. REV. 515, 516 (2003) (advocating instant disclosure of all patent applications via the Internet).

99. *See* NAT'L RESEARCH COUNCIL, A PATENT SYSTEM FOR THE 21ST CENTURY, *supra* note 82, at 87–95.

100. *See, e.g.*, Samantha A. Jameson, Note, *The Problems of the Utility Analysis in Fisher and its Associated Policy Implications and Flaws*, 56 DUKE L.J. 311, 311 (2006) (questioning whether the PTO is equipped to deal with policy and criticizing the decision in *Fisher*).

101. *Cf. In re* Fisher, 421 F.3d 1365, 1378 (Fed. Cir. 2005) ("[W]e observe that the government and its amici express concern that allowing EST patents without proof of utility would discourage research, delay scientific discovery, and thwart progress in the 'useful Arts' and 'Science.' . . . [These] are public policy considerations which are more appropriately directed to Congress as the legislative branch of government, rather than this court as a judicial body responsible simply for interpreting and applying statutory law."). *See generally* Rochelle C. Dreyfuss, *The Federal Circuit: A Continuing Experiment in Specialization*, 54 CASE W. RES. L. REV. 769 (2004) (surveying the effects of "specializing the adjudication of patent disputes by channeling patent appeals to a single court").

102. *See, e.g.*, Dreyfuss, *supra* note 84, at 1567–70; Arti K. Rai, *Allocating Power over Fact-Finding in the Patent System*, 19 BERKELEY TECH. L.J. 907, 913 (2004); Arti K. Rai, *Engaging Facts and Policy: A Multi-Institutional Approach to Patent System Reform*, 103 COLUM. L. REV. 1035, 1035 (2003); Craig Allen Nard & John F. Duffy, *Rethinking Patent Law's Uniformity*

This Article cannot explore all of the problems with which the system is grappling. Our purpose is to demonstrate how promulgating substantive law in the absence of either a normative consensus or an authority competent (in both the cognitive and juridic sense) to administer and revise it will interfere with the emergence of new industries, with scientific advancement, and with the development of new approaches to encouraging and supporting innovation.

A. Emerging Industries

Although there is broad dissatisfaction with domestic patent systems, many of the complaints—at least in the United States—are based on law developed for emerging sectors, principally information technology and biotechnology.[103] These issues merit a deeper look.

1. *Information Technology (IT).* With regard to the IT sector, there is considerable debate about the need for exclusive rights to promote development of software and business methods and whether patent protection is the appropriate regime to use. Unlike copyrights and contractual rights, patents create claims that are good even against independent inventors. For cumulative technologies or in instances where interoperability is an important goal, the need to sift through prior patents and negotiate rights arguably creates a high tax on innovation and a drag on development.[104]

Other untoward consequences may flow from the decision to permit patenting in this area. For example, the risk of debilitating suits motivates participants to acquire multiple patents, hoping that with enough potential counterclaims, they can fend off or negotiate their way out of difficulty. The result is a vicious cycle: thickets of rights that are expensive (or nearly impossible) to clear, requiring an ever-larger arsenal of defensive protection.[105] Furthermore, many IT products involve multiple inventions and, accordingly, multiple

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Principle 5 (George Washington Univ. Legal Studies Research Paper No. 225), *available at* http://ssrn.com/abstract=928498.

103. *See, e.g.*, Dan Burk & Mark A. Lemley, *Is Patent Law Technology-Specific?*, 17 BERKELEY TECH. L.J. 1155, 1155–56 (2002).

104. *See* Pamela Samuelson, Randall Davis, Mitchell D. Kapor & J.H. Reichman, *A Manifesto Concerning the Legal Protection of Computer Programs*, 94 COLUM. L. REV. 2308, 2422 (1994). Many of these problems were identified well before patents on software were issued. *Id.* at 2361.

105. *See* JAFFE & LERNER, *supra* note 60, at 59.

licenses.[106] In that environment, holdout possibilities are numerous and, as the Blackberry case[107] nearly demonstrated, can potentially undermine the investments of producers, other patentees, and the public.[108] All of this patenting activity fosters so many potential lawsuits that, as economists James Bessen and Michael Meurer have concluded, the cost of litigation has begun to exceed the profits from patents by all measures in this sector.[109]

In addition, some IT products are characterized by strong network effects and standard setting, which may make switching costs high and lock consumers into inferior products.[110] Those holding patent rights in products toward which a market has tipped receive awards out of proportion to the technical contributions of the inventors. When these patents also dominate their fields, they allow right holders to prevent entry by competitors.[111]

Commentators further criticize the way the law has been administered. To some, the European approach, which looks for a technical effect, is superior because it greatly limits the kinds of information technology that can be protected.[112] Others note that, because courts assume the level of skill in the art to be high, they relieve patentees of the obligation to disclose the underlying code.

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106. Hall & Ziedonis, *supra* note 86, at 109–10 (discussing semiconductors).

107. NTP, Inc. v. Research in Motion, Ltd., 418 F.3d 1282 (Fed. Cir. 2005).

108. *See* Jeremiah Chan & Matthew Fawcett, *Footsteps of the Patent Troll*, 10 INTELL. PROP. L. BULL. 1, 5 (2005).

109. Bessen & Meurer, *supra* note 81 (manuscript at 13, on file with the *Duke Law Journal*) (noting that "annual worldwide profits from software patents are only $0.69 billion, far less than litigation costs").

110. *See* Michael L. Katz & Carl Shapiro, *Network Externalities, Competition, and Compatibility*, 75 AM. ECON. REV. 424, 424 (1985); Christopher R. Leslie, *The Anticompetitive Effects of Unenforced Invalid Patents*, 91 MINN. L. REV. 101, 124 (2006).

111. *See, e.g.*, Rochelle Dreyfuss, *Unique Works/Unique Challenges at the Intellectual Property/Competition Law Interface*, *in* EUROPEAN COMPETITION LAW ANNUAL 119, 121–23 (2005) (noting that the dominance factor exists especially in fields such as biotechnology); Carl Shapiro, *Navigating the Patent Thicket: Cross Licenses, Patent Pools, and Standard-Setting*, 1 INNOVATION POL'Y & ECON. 119, 119 (2001) ("In several key industries, including semiconductors, biotechnology, computer software, and the Internet, our patent system is creating a *patent thicket:* an overlapping set of patent rights requiring that those seeking to commercialize new technology obtain licenses from multiple patentees.").

112. *See* Rochelle Dreyfuss, *Are Business Method Patents Bad for Business?*, 16 SANTA CLARA COMPUTER & HIGH TECH. L.J. 263, 278–79 (2000) (advocating an approach that asks whether "a patent incentive is actually required to promote investment in innovation"); John R. Thomas, *The Patenting of the Liberal Professions*, 40 B.C. L. REV. 1139, 1179–84 (1999) (stating that "the European Patent Convention presents the most fulsome articulation of the industrial applicability standard").

These patents can be very broad and, because they fail to enable, they deprive the public of disclosure, which is one of the significant benefits of the patent system.[113] Moreover, because monetary damages are calculated based on the value of the product and not of the patent that has been infringed, this sector attracts "trolls," who are in the business of making money though litigation rather than through product development.[114]

2. *Biotechnology*. The burgeoning field of biotechnology is experiencing a different set of problems. Here, courts and the PTO consider the level of skill quite low,[115] which leads to narrow patents and the danger of an "anticommons effect."[116] When that occurs, property rights cannot be aggregated efficiently to create, for example, effective methods for assembling and screening new molecules or to realize the ambitions of personalized medicine, which would require whole-genome sequencing.

Because U.S. courts tend to conceptualize DNA as molecules rather than information products,[117] manufacturers and researchers can easily evade patent rights in some cases by—essentially—paraphrasing the information covered by the patent.[118] As a result, the patent may yield insufficient incentives to support research in a given area.[119] Paradoxically, there is also a growing number of patents in this

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113. *See* 35 U.S.C. § 112 (2000) (requiring a "written description of the . . . manner and process of making and using [the invention], in such full, clear, concise, and exact terms as to *enable* any person skilled in the art . . . to make and use the same" (emphasis added)); Dan L. Burk & Mark A. Lemley, *Policy Levers in Patent Law*, 89 VA. L. REV. 1575, 1689 (2003).

114. *See* Amy L. Landers, *Let the Games Begin: Incentives to Innovation in the New Economy of Intellectual Property Law*, 46 SANTA CLARA L. REV. 307, 307 (2006); *cf.* Patent Reform Act of 2007, S. 1145, 110th Cong., § 5(a)(2) (2007) (proposing a change in damages calculation based upon "the patent's specific contribution").

115. *See, e.g.*, *In re* Deuel, 51 F.3d 1552, 1558 (Fed. Cir. 1995) (refusing to find the subject of a patent "obvious" despite the fact the "the claimed molecules, their functions, and their general chemical nature may have been obvious from" prior research); *In re* Bell, 991 F.2d 781, 785 (Fed. Cir. 1993) ("[T]he combination of prior art references does not render the claimed invention obvious . . . .").

116. Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 SCIENCE 698, 699 (1998).

117. *See* Arti K. Rai, *Intellectual Property Rights in Biotechnology: Addressing New Technology*, 34 WAKE FOREST L. REV. 827, 833 (1999).

118. *See* Helen M. Berman & Rochelle C. Dreyfuss, *Reflections on the Science and Law of Structural Biology, Genomics, & Drug Development*, 53 UCLA L. REV. 871, 876 (2006) (noting that manufacturers could alter "protected nucleotide sequences" while generating a functionally similar product).

119. *See* Burk & Lemley, *supra* note 113, at 1676–80.

field—particularly patents on genes and certain proteins that are, at least for research purposes, so broad[120] that it is unlikely a patent holder could efficiently exploit the entire breadth of the claims. Meanwhile, the potential blocking effects appear increasingly serious.

3. *Reconciling the Needs of Different Sectors*. It is not clear that these problems will be easy to resolve. First, these quick sketches of two emerging sectors demonstrate that there is disagreement concerning the existence, scope, and nature of the problem. For example, despite the strong and persistent complaints about patents in the software industry, there is some empirical evidence that the patent system is not hurting—and may be helping—the development of this sector.[121] Patent reform is thus stalling at least in part because domestic stakeholders cannot even agree that reform will be worth the dislocations it will entail.

Second, there are disputes about how to handle the problems. For example, some economists claim that reengineering the law is not necessary. They argue that the system could be restored to order by simply improving the quality of the patents that issue (that is, by creating a mechanism for ensuring that patents issue only for inventions that are truly nonobvious).[122]

Third, it is proving so difficult to find common ground among the various patent industries that some have suggested sector-specific legislation.[123] If heeded, this approach could take patent law down untested pathways culminating in a set of clumsy, *sui generis* regimes.[124] Moreover, even if such an approach proved politically

120. *See* Kyle Jensen & Fiona Murray, *Intellectual Property Landscape of the Human Genome*, 310 SCIENCE 239, 239 (2005) (suggesting that sometimes a single gene can be associated with as many as twenty patents); Eileen M. Kane, *Splitting the Gene: DNA Patents and the Genetic Code*, 71 TENN. L. REV. 707, 711–12 & n.19 (2004); *see also* Andrew Chin, *Artful Prior Art and the Quality of DNA Patents*, 57 ALA. L. REV. 975, 977 (2006) (describing the shortcomings of the U.S. Patent Office registry approach in documenting prior art of genetic research, thus leading to "low-quality patents . . . issued on inventions that are already known or represent only an obvious advance in the field").

121. Mann, *supra* note 86, at 985–1012; Robert P. Merges, Patents, Entry and Growth in the Software Industry (Aug. 1, 2006) (unpublished manuscript, *available at* http://papers.ssrn.com/sol3/papers.cfm?abstract_id=926204).

122. JAFFE & LERNER, *supra* note 60, at 197–207.

123. Burk & Lemley, *supra* note 103, at 1202 (suggesting that industry-specific tailoring is "desirable").

124. *Cf.* Reichman, *Legal Hybrids Between the Patent and Copyright Paradigms*, *supra* note 92, at 2445 (examining "proliferating legal hybrids . . . [that] represent both a consequence of . . .

feasible in a domestic setting, it could elicit objections sounding in the TRIPS Agreement, which requires that "patents . . . be available and patent rights enjoyable without discrimination as to . . . the field of technology."[125] But TRIPS is only a minimum standard regime. Were the United States bound by an instrument that required complete substantive harmonization, resolving the issues that exist within emerging industries would not be feasible without endless rounds of entangling negotiations—and, if the system includes enforceable obligations, unsettling appeals.[126]

Moreover, the technology sectors are hardly the end of the line: science is sure to generate new and equally daunting innovation opportunities in the future. Synthetic biology represents one such development.[127] Because it utilizes both software and biotechnological advances, this field potentially suffers from the combined impact of

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growing incoherence and a cause of the incipient breakdown that is weakening the international intellectual property system from within").

125. TRIPS Agreement, *supra* note 11, art. 27(1); *see also* Panel Report, *Canada-Patent Protection of Pharmaceutical Products*, WT/DS114/R (Mar. 17, 2000) (distinguishing between permissible reconcilable "differentiation" attributable to needs of different product sectors and impermissible "discrimination"). *But see* Graeme B. Dinwoodie & Rochelle C. Dreyfuss, *Diversifying Without Discriminating: Complying with the Mandates of the TRIPS Agreement*, 13 MICH. TELECOMM. & TECH. L. REV. 445, 450 (2007) (arguing that "[d]iscrimination is not the same as differential treatment" and suggesting that some types of differentiating should withstand challenge).

126. The TRIPS dispute resolution experience is not an entirely happy one in this respect because WTO Settlement Panels have been ill equipped to deal with technical legal issues. *See, e.g.*, Dinwoodie & Dreyfuss, *supra* note 29, at 413 (identifying "interpretive approaches" to the TRIPS Agreement and raising "questions regarding the level of formalism" of the WTO dispute settlement process); Joost Pauwelyn, *WTO Dispute Settlement: Of Sovereign Interests, Private Rights and Public Goods*, *in* INTERNATIONAL PUBLIC GOODS AND TRANSFER OF TECHNOLOGY UNDER A GLOBALIZED INTELLECTUAL PROPERTY REGIME, *supra* note 23, at 817, 829 (examining "the tension between sovereign/government interests, private rights, and public goods" in the WTO dispute settlement process); Gregory Shaffer, *Recognizing Public Goods in WTO Dispute Settlement: Who Participates? Who Decides? The Case of TRIPS and Pharmaceutical Patent Protection*, *in* INTERNATIONAL PUBLIC GOODS AND TRANSFER OF TECHNOLOGY UNDER A GLOBALIZED INTELLECTUAL PROPERTY REGIME, *supra* note 23, at 884, 884 (focusing on disputes related to pharmaceutical patents and concerns about public goods including "the generation of new knowledge, the provision of public health, and the maintenance of rules fostering trade and competition").

127. Synthetic biology is an engineering field that utilizes artificially constructed DNA to construct/program useful "machines" (such as plants that produce fuel). *See generally* Philip Ball, *Starting from Scratch*, 431 NATURE 624 (2004) (describing synthetic biology and concerns about risks associated with the field).

patenting problems in both sectors.[128] Were the SPLT to be implemented, its adherents would have diminished capacity to adapt the legal order so that such new opportunities could flourish.

B. Scientific Advancement

The prospects for the future could become even more troubling. As patenting moves upstream to cover fundamental advances, existing dysfunctionalities within the system could impede scientific progress and reduce the chances of generating future opportunities for innovation. Drawing once again on the situation in the United States as an example, a reorganization underway within the scientific community has begun to pose hard and unresolved problems for patent law.

A major development was, undoubtedly, the wholesale entry of universities into the patent system. Since the passage of the Bayh-Dole Act in 1980,[129] which permits universities to patent the fruits of federally funded research, filings by the university sector have significantly increased.[130] Although the statute aimed mainly to encourage technology transfer, universities increasingly understand it as a funding mechanism, with many untoward consequences for science and education. Most obviously, work that once would have gone into the public domain for general and free use becomes privatized.[131]

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128. *See* Arti K. Rai & Sapna Kumar, *Synthetic Biology: The Intellectual Property Puzzle*, 85 TEX. L. REV. 1745, 1747 (2007) ("The manner in which the law has handled software on the one hand and biotechnology on the other may not bode well for synthetic biology.").

129. Bayh-Dole Act, Pub. L. No. 96-517, 94 Stat. 3015 (1980) (codified as amended at 35 U.S.C. §§ 200–212 (2000)).

130. The issue of cause and effect is itself a subject of dispute. Some claim that the Bayh-Dole Act created the university patenting phenomenon, whereas others contend that universities' desire to patent gave rise to the Act. *See* Mowery et al., *The Growth of Patenting and Licensing by U.S. Universities: An Assessment of the Effects of the Bayh-Dole Act of 1980*, 30 RES. POL'Y 99, 100 (2001).

131. *See, e.g.*, Rebecca S. Eisenberg, *Public Research and Private Development: Patents and Technology Transfer in Government-Sponsored Research*, 82 VA. L. REV. 1663, 1666 (1998) ("Only in exceptional circumstances does the statute acknowledge that there may be an affirmative case for putting a discovery in the public domain for the greater good."); Rai & Eisenberg, *supra* note 29, at 303 (discussing how increased patent opportunities may reduce the chance that technology will end up in the public domain); *see also* J.H. Reichman & Paul F. Uhlir, *A Contractually Reconstructed Research Commons for Scientific Data in a Highly Protectionist Intellectual Property Environment*, 66 LAW & CONTEMP. PROBS. 315, 342–43 (Winter/Spring 2003) (discussing the impact of the Bayh-Dole Act on university research and the public domain).

Moreover, because academia engages in fundamental research, university patenting tends to push upstream, which creates broad rights over core methodologies and research tools—rights that can dominate diverse research agendas.[132] Although there is some empirical evidence indicating that universities have begun to patent more selectively and license these opportunities more wisely,[133] horror stories abound in which universities reportedly signed over rights without any guarantee that their licensees would bring products to market. Indeed, sometimes universities appear to have licensed rights to institutions that had private reasons to stifle research and access.[134] Perhaps to counter this problem, the courts have begun to deploy various patent law theories to narrow the ambit of broad claims.[135] But overly narrow rights in "slivers of innovation" create problems of their own.[136]

Even if the universities' behavior were to improve, problems with their patenting practices could persist. Courts have decided that because universities are behaving as commercial actors, patent law should treat them as such. Accordingly, courts do not afford academic researchers special privileges to delay work on patentable subject matter, even when the delay arises from attempts to preserve

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132. *See, e.g.*, Rebecca S. Eisenberg, *Bargaining Over the Transfer of Proprietary Research Tools: Is This Market Failing or Emerging?*, *in* EXPANDING THE BOUNDARIES OF INTELLECTUAL PROPERTY: INNOVATION POLICY FOR THE KNOWLEDGE SOCIETY, *supra* note 92, at 223, 225 ("[T]here seems to be a widely-shared perception that negotiations over the transfer of proprietary research tools present a considerable and growing obstacle to progress in biomedical research and product development."). *See generally* Rebecca S. Eisenberg, *Reaching Through the Genome*, *in* PERSPECTIVES ON PROPERTIES OF THE HUMAN GENOME PROJECT at 209 (F. Scott Kieff ed., 2003) (discussing reach-through strategies, remedies, and mechanisms).

133. *See* David C. Mowery, Bhaven N. Sampat & Arvids A. Ziedonis, *Learning to Patent: Institutional Experience, Learning, and the Characteristics of U.S. University Patents after the Bayh-Dole Act, 1981–1992*, 48 MGMT. SCI. 73, 85–86 (2002).

134. *See* Avital Bar-Shalom & Robert Cook-Deegan, *Patents and Innovation in Cancer Therapeutics: Lessons from CellPro*, 80 MILBANK Q. 637, 661 (2002); Lorelei Ritchie de Larena, *The Price of Progress: Are Universities Adding to the Cost?*, 43 HOUS. L. REV. 1373, 1417–27 (2007).

135. *See, e.g.*, Univ. of Rochester v. G.D. Searle & Co., 358 F.3d 916, 929 (Fed. Cir. 2004) (finding that the University's patent was invalid for lack of an adequate description and stating that the Bayh-Dole Act "was not intended to relax the statutory requirements for patentability" for universities).

136. J.H. Reichman, *Saving the Patent Law from Itself*, *in* PERSPECTIVES ON PROPERTIES OF THE HUMAN GENOME PROJECT, *supra* note 132, at 289, 297; *see also supra* text accompanying note 116.

pedagogic opportunities for students.[137] This creates one of a series of new conflicts between a university's educational mission and its commercial goals; between a faculty member's research and teaching commitments; and between the academy's duties as honest brokers in science policy debates and its proprietary self-interest.

Far more worrisome is the judicial trend to deny academics engaged in scholarly inquiry any further research exemptions from infringement liability.[138] Fortunately, few infringement suits have been filed against universities to date, but if such cases were to proliferate unchecked, the cost of basic science would soar. Even in the absence of suits against scientists, an empirical study has uncovered evidence that university research is beginning to suffer from an anticommons effect.[139] Although some studies also claim that patents have little direct impact on university work, scholarship has documented the erosion of the Mertonian norms, with increased secrecy and a growing reluctance to share research materials.[140] Furthermore, patenting could easily come to affect scholarly agendas, shifting attention from the basic work that opens whole new fields of knowledge to applied research aimed narrowly at exploiting particular commercial markets. Again, the empirical evidence is mixed, but the effects of an increasing interest in patenting (and commerce) on the part of university faculty is alarming.[141]

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137. *See, e.g.*, Griffith v. Kanamaru, 816 F.2d 624, 626 (Fed. Cir. 1987) (finding no excuse for a university professor-inventor's inactivity when he claimed that his delay was due in part to the fact that he was waiting for a particular graduate student to begin work).

138. *See, e.g.*, Madey v. Duke Univ., 307 F.3d 1351, 1362 (Fed. Cir. 2002) ("[O]ur precedent does not immunize any conduct that is in keeping with the alleged infringer's legitimate business, regardless of commercial implications. For example, major research universities, such as Duke, often sanction and fund research projects with arguably no commercial application whatsoever. However, these projects unmistakably further the institution's legitimate business objectives, including educating and enlightening students and faculty participating in these projects. These projects also serve, for example, to increase the status of the institution and lure lucrative research grants, students and faculty.").

139. Stern & Murray, *supra* note 81, at 5.

140. Timothy Caulfield et al., *Evidence and Anecdotes: An Analysis of Human Gene Patenting Controversies*, 24 NATURE BIOTECHNOLOGY 1091, 1092 (2006); Wesley M. Cohen & John P. Walsh, *Real Impediments to Academic Biomedical Research*, *in* 8 INNOVATION POL'Y & ECON. (Adam B. Jaffe, Joshua Lerner & Scott Stern eds., forthcoming 2007); Wesley M. Cohen, John P. Walsh & Charlene Cho, *View from the Bench: Patents and Material Transfers*, 309 SCIENCE 2002, 2002 (2005). For an introduction to Mertonian norms, see ROBERT K. MERTON, *The Normative Structure of Science*, *in* THE SOCIOLOGY OF SCIENCE: THEORETICAL AND EMPIRICAL INVESTIGATIONS 267 (Norman W. Storer ed., 1973).

141. *See, e.g.*, Pierre Azoulay, Waverly Ding & Toby Stuart, *The Determinants of Faculty Patenting Behavior: Demographics or Opportunities?*, 63 J. ECON. BEHAV. & ORG. 599, 601

In theory, of course, legislation might remedy some of these problems. For example, Congress could enact a codified research exemption.[142] Patent applications from academics could be examined differently, and the scope of patents could be adjusted to deal with the anticommons effect. When necessary, compulsory licenses to unblock dependent patents and enable improvers to reach the market could also be enacted, a solution that remains fully consistent with the TRIPS Agreement.[143]

Yet, as Section A showed, there is substantial disagreement concerning the very existence of the problems and the wisdom of proposed legislative solutions.[144] Were the laws in question subject to substantive international obligations, it would compound these problems. Some economies may rely on the spillover benefits of basic research; others may see commercializing university work as an important source of funding. Another complicating factor is that universities do not participate equally in all commercial sectors. Consequently, arguments about technological neutrality would arise

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(2007) (suggesting that mid-career faculty, faculty associated with patent holders, and faculty employed by institutions holding many patents are more likely to patent); Mario Calderini, Chiara Fanzoni & Andrea Vezzulli, *If Star Scientists Do Not Patent: The Effect of Productivity, Basicness and Impact on the Decision to Patent in the Academic World*, 36 RES. POL'Y 303, 317 (2007) (suggesting that scientists engaged in applied research are more likely to patent than scientists engaged in basic research); Richard R. Nelson, *Observations on the Post Bayh-Dole Rise of Patenting at American Universities*, 26 J. TECH. TRANSFER 13, 15 (2001) (arguing that the rising number of patents suggests trouble down the road); Jerry G. Thursby & Marie C. Thursby, *Who Is Selling the Ivory Tower? Sources of Growth in University Licensing*, 48 MGMT. SCI. 90, 102 (2002) (showing that research agendas are not changing significantly, but instead universities are patenting discoveries that they would previously have made publicly available).

142. *See generally* Rochelle C. Dreyfuss, *Protecting the Public Domain of Science: Has the Time for an Experimental Use Defense Arrived?*, 46 ARIZ. L. REV. 457, 463 (2004) (calling for a broad, statutory experimental use exception).

143. *See* TRIPS Agreement, *supra* note 11, art. 31(*l*); JEROME H. REICHMAN WITH 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 1–2 (June 2003), *available at* http://www.ictsd.org/pubs/ictsd_series/iprs/CS_reichman_hasenzahl.pdf.

144. *Compare, e.g.*, Richard A. Epstein, *Steady the Course: Property Rights in Genetic Material*, *in* PERSPECTIVES ON PROPERTIES OF THE HUMAN GENOME PROJECT, *supra* note 132, at 153, 168, 168 (suggesting the current system of genomic patent filings is preferable to alternatives), *with* Rochelle Cooper Dreyfuss, *Varying the Course in Patenting Genetic Material: A Counter-Proposal to Richard Epstein's Steady Course*, *in* PERSPECTIVES ON PROPERTIES OF THE HUMAN GENOME PROJECT, *supra* note 132, at 196, 195–96 (examining the assumptions underlying arguments for and against legislative stability); *see also* Reichman, *supra* note 136, at 289 (contesting Epstein's "all or nothing" premise and proposing greater reliance on liability rules).

in any attempt to alter the patent system to protect core scientific progress.

C. New Approaches

When faced with the problems of new technologies and new players, countries have adopted very different strategies. In particular, the U.S. approach differs significantly from developments in Europe. With regard to patents in biotechnology, for example, the EPO, following the European Directive on Biotechnology,[145] seems to be breaking away from the "chemical compound" analogy that typifies U.S. law. Instead, it has begun to treat DNA patents as information products, whose eligibility tests should turn on the quality and industrial applicability of the information revealed.[146]

The EC Biotechnology Directive also added a new compulsory license to facilitate interaction between infringing plant breeders and biotech patents.[147] When implementing the Biotechnology Directive, moreover, a number of European governments have embarked on new directions of their own at the expense of a uniform law. Although some nations were initially unwilling to fully implement the Biotechnology Directive,[148] others, such as Germany, have attempted to limit gene patents to the use or purpose recited in the application.[149]

The EPO also seems to have handled the information technology sector more cautiously than the United States by insisting on a demonstrable "technical contribution" palpably beyond the state of

145. Council Directive 98/44, Legal Protection of Biotechnological Inventions, 1998 O.J. (L 213) 13 (EC).

146. *See* Rob J. Aerts, *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, 351–52 (2004); Samantha A. Jameson, *A Comparison of the Patentability and Patent Scope of Biotechnological Inventions in the United States and the European Union*, 35 AIPLA Q.J. 193, 217–24 (2007).

147. *See* Council Directive 98/44, *supra* note 145, art. 12.

148. The recalcitrant EU Member States all implemented the Directive by the end of 2006. *See* STATE OF PLAY OF THE IMPLEMENTATION OF DIRECTIVE 98/44/EC (2007), http://www.europa.eu.int/comm/internal_market/indprop/docs/invent/state-of-play_en.pdf (last visited Oct. 4, 2007).

149. German Patent Statute, PatG § 1a(4). The provision is controversial. *See, e.g.*, Christoph Ann, *Patents on Human Gene Sequences in Germany: On Bad Lawmaking and Ways to Deal With It*, 7 GERMAN L. J. 279, 280, *available at* http://www.germanlawjournal.com/pdf/Vol07/pdf_Vol_07_No_03.pdf.

the art.[150] How the EPO proceeds in this area following the European Parliament's rejection of a proposed Community Directive on the Patenting of Software deserves careful scrutiny.[151] Furthermore, even if patents on software were eventually to produce the kind of blocking effects experienced in the United States, many European countries formally recognize the possibility of compulsory licenses for dependent patents on improvements.[152] Although these provisions are seldom invoked, they likely exert *in terrorem* effects that stimulate efficient licensing practices, and they provide patent authorities with a codified antiblocking measure when needed.

Moreover, the patent system is not the only mechanism for encouraging technological progress. A strong argument can be made for supplementing patents with new kinds of intermediate or second-tier protection systems that are more attuned to present-day technological realities. Although robust property-like regimes, such as patent law, presuppose clear boundaries between different rights holders, the actual boundaries between products of the new technologies are often ill-defined. The problem of cumulative innovation is thus aggravated by the ways in which new contributions are dependent on, and intermingled with, earlier innovations. Patents increasingly breed high litigation and transaction costs because they artificially divide that which is inherently indivisible, a practice that needlessly slows the rate of innovation by chilling the ability of second comers to build on earlier contributions for both scientific and commercial purposes.[153]

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150. Thomas Hoeren, *The European Union Commission and Recent Trends in European Information Law*, 29 RUTGERS COMPUTER & TECH. L.J. 1, 10 (2003); 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 & TELECOMM. L. REV. 126, 129 (2003); Wolfgang Tauchert, *Patent Protection for Computer Programs—Current Status and New Developments*, 31 IIC 812, 818 (2000).

151. *See, e.g.*, Andreas Grosche, *Software Patents—Boon or Bane for Europe?*, 14 INT'L J.L. & INFO. TECH. 257, 259–60 (2006) (providing analysis of a wide scope of patent laws and policies beyond the proposed provisions before the European Parliament).

152. *See, e.g.*, Patents Act, 1977, c. 37, § 48A(1)(b)(i) (Eng.); 2 J.W. Baxter, World Patent Law and Practice § 8.02 (2001); *see also* Robert Merges, *Intellectual Property Rights and Bargaining Breakdown: The Case of Blocking Patents*, 62 TENN. L. REV. 75, 104 (1994) ("[S]tatutes [that] provide, in varying ways, for a liability rule in the case of an improvement invention that infringes on a dominant patent . . . have no discernable effect on the incentives for European firms to invent."); REICHMAN WITH HASENZAHL, *supra* note 143, at 12 (discussing the presence of blocking patents on improvements to prior inventions in many countries).

153. *See* Reichman, *Of Green Tulips and Legal Kudzu*, *supra* note 92, at 23, 26–29.

In sectors where these conditions prevail, a different kind of regime may be superior. To give one example, compensatory liability regimes—liability rules—may be a good solution for cumulative technologies. They would protect first comers against wholesale duplication while enabling improvers to build on their work, subject to an obligation to return a healthy share of the potential gains to the earlier innovator.[154] These entitlements could be voluntarily adopted by industrial sectors or mandated by law or regulation to resolve blocking effects.[155] Other ideas—open source models, collaborative modes of production, clearinghouse models—have also attracted growing attention,[156] although their dependence on exclusive property rights is often overlooked.[157]

Of course, not all the advocates of deep harmonization claim to know all the answers; rather, some suggest codifying basic aspects of domestic patent law—so-called "best practices"—that would provide a solid foundation for transnational harmonization.[158] But this approach is premised on several fallacies. First, even for countries at similar levels of technological sophistication, "best practices" are not likely to be the same. Moreover, what any given country views as "best practices" in patent law may reflect other practices in other laws—including copyright, trade secret, utility model laws, and, above all, competition laws—that may vary widely from one country to another.[159] The advocates of a "best practices" approach to

154. *See, e.g.*, *id.*, at 48–52; Reichman & Lewis, *supra* note 74, at 337, 348–65.

155. *See generally* Reichman, *Legal Hybrids Between the Patent and Copyright Paradigms*, *supra* note 92 (showing breakdown of trade secret law under present-day conditions and advocating use of liability rules not premised on secrecy to deal with market failures affecting incremental innovation).

156. *See, e.g.*, YOCHAI BENKLER, THE WEALTH OF NETWORKS: HOW SOCIAL PRODUCTION TRANSFORMS MARKETS AND FREEDOM 463–66, 471–73 (2006); Ian Ayres & J.M. Balkin, *Legal Entitlements as Auctions: Property Rules, Liability Rules, and Beyond*, 106 YALE L.J. 703, 706–07 (1996); Janet Hope, Open Source Biotechnology (Dec. 23, 2004) (unpublished Ph.D. thesis, The Australian National University), *available at* http://rsss.anu.edu.au/~janeth/OpenSourceBiotechnology27July2005.pdf; Geertui Van Overwalle et al., *Models for Facilitating Access to Patents on Genetic Inventions*, 7 NATURE REVIEWS: GENETICS 143 (2006)Esther van Zimmeren et al., *A Clearing House for Diagnostic Testing: The Solution to Ensure Access to and Use of Patented Genetic Inventions?*, 84 BULL. WORLD HEALTH ORG. 352, 353–56 (2006).

157. *See* Boyle, *supra* note 28, at 67–69.

158. *See* Hauda, *supra* note 17, at 97.

159. *See* Mark D. Janis, *Second Tier Patent Protection*, 40 HARV. INT'L L.J. 151, 177–99 (1999) (critiquing the harmonization of second tier patent regimes); Jonathan Zuck, President, Ass'n for Competitive Tech., Comments to the Antitrust Modernization Comm'n (Feb. 7, 2006), *available at* http://www.amc.gov/public_studies_fr28902/international_pdf/060207_ACT_Intl.pdf (noting the importance of consistent treatment of small businesses in the information

harmonization do not explain how to identify which practices are genuinely the best, or explain how international lawmakers will keep the practices they choose responsive to changing needs.

Another more subtle effect of premature legal harmonization is that it could unhelpfully homogenize creative development. The diverging approaches observed in national innovation laws may not solely depend on differing perceptions of how to cure the same set of problems. Some of these differences may emerge from differing problems, differences that arise because each society values its own specific kinds of creativity and prioritizes its technological requirements in its own way. The TRIPS Agreement still leaves countries some room to exclude developments from patentability on grounds such as public policy and lack of inventiveness, or because the work is not considered within a field of "technology" and therefore not within the subject matter of patent law.[160] As a result, a country that excels in certain kinds of work has some flexibility to put the tools for accomplishing that work into the public domain; other countries skilled in producing the tools may prefer to make them patentable.[161]

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technology sector). The debate outlined in the text accompanying this footnote suggests that, at a minimum, the level of intellectual property protection in any given country may depend on whether that country has enacted and implemented antitrust law to deal with competitive excesses. Yet, the SPLT (like TRIPS) does not mandate protection outside the intellectual property field, and antitrust law is only one of the many related issues that might influence the appropriate level of protection. *See* Josef Drexl, *The Critical Role of Competition Law in Preserving Public Goods in Conflict with Intellectual Property Rights*, *in* INTERNATIONAL PUBLIC GOODS AND TRANSFER OF TECHNOLOGY UNDER A GLOBALIZED INTELLECTUAL PROPERTY REGIME, *supra* note 23, at 709, 716–24; Eleanor M. Fox, *Can Antitrust Policy Protect the Global Commons from the Excesses of IPRs?*, *in* INTERNATIONAL PUBLIC GOODS AND TRANSFER OF TECHNOLOGY UNDER A GLOBALIZED INTELLECTUAL PROPERTY REGIME, *supra* note 23, at 758, 758–69; Maskus & Reichman, *supra* note 30, at 33–41; Hanns Ullrich, *Expansionist Intellectual Property Protection and Reductionist Competition Rules: A TRIPS Perspective*, *in* INTERNATIONAL PUBLIC GOODS AND TRANSFER OF TECHNOLOGY UNDER A GLOBALIZED INTELLECTUAL PROPERTY REGIME, *supra* note 23, at 726, 737, 752.

160. *See* TRIPS Agreement, *supra* note 11, art. 27.

161. For example, the United States and Canada have taken divergent positions on whether higher-order life forms can be patented, leading to different treatment of mice bred as research tools in the life sciences. *Compare* Harvard Coll. v. Canada (Comm'r of Patents), File 28155, 2002 S.C.C. 76 (Dec. 5, 2002), *available at* http://scc.lexum.umontreal.ca/en/2002/2002scc76/2002scc76.html (holding the oncomouse unpatentable), *with* Transgenic Non-Human Mammals, U.S. Patent No. 4,736,866 (filed June 22, 1984) (issued Apr. 12, 1988), *available at*, http://patft.uspto.gov/netahtml/PTO/search-bool.html (search for "4,736,866" in "Field1: Patent Number"), *and* Hibberd, 227 U.S.P.Q. 443, 445 (B.P.A.I. 1985) (holding certain living organisms patentable).

Because the information necessary to match particular approaches to specific types of innovation opportunities is lacking, allowing nations to experiment would be highly beneficial. Some will use legislative solutions; the Supreme Court's foray into patent law suggests that the U.S. approach may be judicially based;[162] and in some places, voluntary schemes will emerge. Over time, experts can compare and evaluate these experiments, and when one or another solution appears to yield positive results, nations can emulate that approach. Harmonization would, in that event, be achieved voluntarily and on the basis of actual empirical data and experience, not simply backroom wrangling and special-interest lobbying.[163]

Allowing nations to shape their laws also gives rise to comparative advantages by enabling each nation to foster what its technological community does best. So long as trade remains relatively free, the flexibility to experiment enhances social welfare worldwide. Accommodations between national and regional systems of innovation can then evolve over time on the basis of bottom-up preferences. Without an agreed-upon legitimate governance process (through administrative agencies, courts, and legislatures), it is difficult to see how these kinds of continual accommodations can occur. A politically skewed re-regulation of the world market,

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162. Between the summer of 2005 and the summer of 2007, the Supreme Court considered seven patent cases. *See* Microsoft Corp. v. AT&T Corp., 127 S. Ct. 1746 (2007); KSR Int'l Co. v. Teleflex Inc., 127 S. Ct. 1727 (2007); MedImmune, Inc. v. Genentech, Inc., 127 S. Ct. 764 (2007); Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc., 126 S. Ct. 2921 (2006) (per curiam) (dismissing writ of certiorari as improvidently granted); eBay, Inc. v. MercExchange, LLC, 126 S. Ct. 1837 (2006); Ill. Tool Works Inc. v. Indep. Ink, Inc., 126 S. Ct. 1281 (2006); Merck KGaA v. Integra Lifesciences I, Ltd., 125 S. Ct. 2372 (2005).

163. To be sure, special-interest politics will play out in domestic arenas as well. But in the international context, the problems are particularly severe: well-heeled groups may be better at attracting international attention, and differences in the ways in which international and domestic instruments are reviewed tend to systematically unravel carefully negotiated deals in a direction that favors right holders. *See* Graeme B. Dinwoodie & Rochelle C. Dreyfuss, *TRIPS and the Dynamics of International Property Lawmaking*, 36 CASE W. RES. J. INT'L L. 95, 119–21 (2004). *See generally* Laurence R. Helfer, *Regime Shifting: The TRIPS Agreement and New Dynamics of International Intellectual Property Lawmaking*, 29 YALE J. INT'L L. 1, 6 (2004) ("In the case of intellectual property rights, developing countries and their allies are shifting negotiations to international regimes whose institutions, actors, and subject matter mandates are more closely aligned with these countries' interests . . . challenging established legal prescriptions and generating new principles, norms, and rules of intellectual property protection . . . .").

coupled with excessive privatization of global public goods, could instead make both competition and innovation more difficult.[164]

To put this another way, patent law's *raison d'être* is to encourage the production of novelty and inventiveness. Its success means that there will always be new problems to solve. It makes little sense to preclude the U.S. Supreme Court, the European Court of Justice, and their equivalents elsewhere, along with national agencies and legislatures—all of which have shown themselves capable of creating law responsive to new circumstances—from offering their contributions to the evolution of the future patent system.

III. NURTURING AN INCIPIENT TRANSNATIONAL SYSTEM OF INNOVATION

Of course, if trade is relatively free and creativity flourishes, some international coordination of the patent system becomes a necessity. But instead of premature substantive harmonization, what an integrated world economy needs is a method for lowering the costs that discrepancies in national laws impose on international actors and a system 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.[165] The trick, then, is to decide which laws actually need some modest degree of harmonization and to find a mechanism for revising the law as new coordination problems crop up.

New measures are urgently needed at the prosecution stage. The priority rules of the Paris Convention, coupled with the Patent Cooperation Treaty and other procedural advances,[166] move the

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164. *See* Maskus & Reichman, *supra* note 30, at 19 (suggesting that a "knowledge cartel" 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 reasoning that "representatives of the global public interest are unlikely to be seated at the table where hard-law negotiations take place").

165. *See id.* at 33 ("All countries could benefit from a functionally efficient transnational system of innovation if low barriers to entry enabled entrepreneurs anywhere to invest in the production and distribution of knowledge goods."); *see also* KEITH E. MASKUS, COUNCIL ON FOREIGN RELATIONS, REFORMING U.S. PATENT POLICY: GETTING THE INCENTIVES RIGHT 8, 38 (2006) ("The needs of innovation will be better served by a more flexible—and better enforced—global regime than by the harmonization agenda being pushed by U.S. trade negotiators.").

166. Paris Convention for the Protection of Industrial Property, *supra* note 12, art. 4; *see supra* text accompanying notes 7–9.

system in a direction that makes serial applications easier to accomplish. Nonetheless, modest harmonization of the standards of patentability could dramatically lower private costs and make work sharing among national patent offices feasible.[167] It is not, however, necessary to rely on top-down negotiation at WIPO; beneficial moves toward a more unified approach could be made even in the face of a moratorium on new international lawmaking.[168] After all, when the advantages of a particular rule become evident, nations often tend to voluntarily conform their law to that rule. For example, with the exception of the United States, every country has acquiesced in awarding priority on a first-to-file basis;[169] the United States is considering the absolute novelty standard in use elsewhere;[170] and there is discussion (and some action) outside the United States to introduce a grace period similar to that found in American law.[171]

Cooperation at the level of government agencies and courts can achieve significant moves toward coordination.[172] These mechanisms are well known in international law generally and are taking hold in transnational patent law as well. For example, the European, Japanese, and U.S. patent offices regularly hold trilateral meetings to discuss sets of representative cases and to identify differences in examination practice. When law permits, the offices iron out their differences, so that they can examine applications using the same

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167. *See* John G. Mills III, *A Transnational Patent Convention for the Acquisition and Enforcement of International Patent Rights*, 88 J. PAT. & TRADEMARK OFF. SOC'Y 958, 963 (2006) ("This article revisits the long known problem of the doctrine of territoriality" and "proposes an alternative transnational model using as a basis the *de facto* regional approach of Europe.").

168. *See* Maskus & Reichman, *supra* note 30, at 36–39 (calling for such a moratorium).

169. Request for Comments on the International Effort to Harmonize the Substantive Requirements of Patent Law, 66 Fed. Reg. 15,409, 15,410 (Mar. 19, 2001).

170. For an example of proposed legislation that would move the United States to first-to-file and an absolute novelty standard, see *supra* note 98.

171. *See* Kate H. Murashige, *Harmonization of Patent Laws*, 16 HOUS. J. INT'L L. 591, 610–11 (1994) (describing limited grace periods available in Japanese, Australian, and Canadian law); Toshiko Takenaka, *Rethinking the United States First-To-Invent Principle From a Comparative Law Perspective: A Proposal to Restructure § 102 Novelty and Priority Provisions*, 39 HOUS. L. REV. 621, 626–29, 663 (2002); *see also infra* note 187 and accompanying text.

172. *See* Robert O. Keohane & Joseph S. Nye, *Transgovernmental Relations and International Organizations*, 27 WORLD POL. 39, 42–43 (1974); Anne-Marie Slaughter, *Global Government Networks, Global Information Agencies, and Disaggregated Democracy*, 24 MICH. J. INT'L L. 1041, 1043 (2003); Anne-Marie Slaughter, *A Global Community of Courts*, 44 HARV. INT'L L.J. 191, 191 (2003). *See generally* GOVERNANCE WITHOUT GOVERNMENT: ORDER AND CHANGE IN WORLD POLITICS (James N. Rosenau & Ernst-Otto Czempiel eds., 1992) (compiling works discussing governance on a worldwide scale).

standards.[173] Further coordination is achieved through examiner exchange programs[174] and regular judicial forums at which patent-law judges can discuss common challenges that arise in their respective national jurisdictions.[175]

Many post-grant issues could benefit from comprehensive international attention. For example, because patentees operate on a global scale, costly infringement suits on parallel patents have become common.[176] Although different results remain technically possible (in that national patents are independent of one another[177]), inconsistent outcomes (in that different parties win in different locations) can complicate global marketing efforts. Some of these transnational cases have tempted courts to give extraterritorial effect to their own laws, a practice that can lead to multiple liabilities for the same harm and damage claims for acts that were legal in the territory where they were performed.[178]

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173. *See, e.g.*, Japan Patent Office, http://www.jpo.go.jp/index.htm (last visited Oct. 4, 2007) (showing examples of cooperative efforts by Japan and partner countries).

174. *See, e.g.*, The Website of the Trilateral Co-operation, Projects, Use of Work Results, Exchange of Examiners, and Comparative Studies, http://www.trilateral.net/projects/use_of_work_results (last visited Oct. 4, 2007).

175. *See, e.g.*, Invitation to the Fourth International Judges Conference on Intellectual Property Law, Intellectual Prop. Owners Educ. Found., *available at* http://www.ipo.org/AM/Template.cfm?Section=Past_Meetings_and_Events&Template=/CM/ContentDisplay.cfm&ContentFileID=6462 (announcing the schedule of conference events).

176. *See* John R. Thomas, *Litigation beyond the Technological Frontier: Comparative Approaches to Multinational Patent Enforcement*, 27 LAW & POL'Y INT'L BUS. 277, 291 (1996); *see also* Mills, *supra* note 167, at 989–96 (discussing a variety of disputes involving parallel patents). *See generally* European Max-Planck Group for Conflict of Laws in Intellectual Prop., *supra* note 5, at 196–97, 202 (proposing amendments to Regulation EC 44/2001 to ensure efficient enforcement of parallel intellectual property rights); sources cited *supra* note 6.

177. Paris Convention for the Protection of Industrial Property, *supra* note 12, art. 4*bis*(1).

178. The Federal Circuit was particularly drawn to this tactic. *See, e.g.*, AT&T Corp. v. Microsoft Corp., 414 F.3d 1366, 1367–72 (Fed. Cir. 2005), *rev'd*, 127 S. Ct. 1746 (2007) (applying U.S. patent law to the transfer of software onto foreign-assembled computers from "golden master" disks or electronic transmissions originating in the United States); Eolas Techs. Inc. v. Microsoft Corp., 399 F.3d 1325, 1938–41 (Fed. Cir. 2005) (same). The Supreme Court has presumably ended this practice by reversing the *AT&T* case. *AT&T Corp.*, 127 S. Ct. at 1759. *Cf.* Soc'y of Composers, Authors & Music Publishers of Can. v. Canadian Ass'n of Internet Providers, File 29286, 2004 S.C.C. 45 (June 30, 2004), *available at* http://scc.lexum.umontreal.ca/en/2004/2004scc45/2004scc45.html (noting that the decision to find jurisdiction over an Internet service provider "raises the spectre of imposition of copyright duties on a single telecommunication in both the State of transmission and the State of reception," and also noting that "as with other fields of overlapping liability . . . the answer lies in the making of international or bilateral agreements").

Globalization has also created new opportunities for sharp practices. Examples include harassment of lawful users with successive suits[179] and so-called "torpedo actions" that prevent the patentee from obtaining timely relief.[180] In addition, because patents are territorial, infringers can spread their activities across several states and leave the patent holder with no single place where a court can find the patent to have been infringed.[181]

Once again, top-down solutions are not necessarily the right approach. Another less radical response would permit parties in transnational cases to consolidate all their claims before a single tribunal or to coordinate multiple lawsuits through cooperation among the courts in which actions are pending. This would reduce costs, conserve court resources, reduce opportunities for harassment, and hopefully mitigate the extraterritorial impulse. Furthermore, as Professor Graeme Dinwoodie has suggested, courts hearing multijurisdictional cases may be positioned to find middle ground among disparate rules—that is, to further harmonization efforts through common-law adjudication.[182] Although adjudicators have proved reluctant to forge new procedural approaches on their own,[183] several organizations are in the process of proposing guidelines and procedures that courts (or national governments) could adopt. Some apply to transnational litigation generally;[184] others to intellectual

179. *See, e.g.*, Computer Assocs. Int'l, Inc. v. Altai, Inc., 126 F.3d 365, 367, 371 (2d Cir. 1997) (successive suits for infringing trade secrets brought in the United States and France not barred by res judicata).

180. Paul A. Coletti, *No Relief in Sight: Difficulties in Obtaining Judgments in Europe Using EPO Issued Patents*, 81 J. PAT. & TRADEMARK OFF. SOC'Y 351, 367 & n.89 (1999); Robin Jacob, *International Intellectual Property Litigation in the Next Millennium*, 32 CASE W. RES. J. INT'L L. 507, 511 (1999).

181. Mark A. Lemley et al., *Divided Infringement Claims*, 6 SEDONA CONF. J. 117, 120–21 (2005); Melissa Feeney Wasserman, *Divided Infringement: Expanding the Extraterritorial Scope of Patent Law*, 82 N.Y.U. L. REV. 281, 281–82 (2007).

182. Graeme B. Dinwoodie, *A New Copyright Order: Why National Courts Should Create Global Norms*, 149 U. PA. L. REV. 469, 542–43 (2000).

183. *See, e.g.*, Voda v. Cordis Corp., 476 F.3d 887, 890 (Fed. Cir. 2007) (rejecting attempt to consolidate U.S. and foreign patent claims); Case C-4/03, Gesellschaft für Antriebstechnik mbH & Co KG v Lamellen und Kupplungsbau Beteiligungs KG, [2006] F.S.R. 45 (E.C.J. 2006) (refusing to permit a German court to determine the consequences of allegedly patent-infringing activity in France when the case required the determination of the validity of the French patent); *cf.* Case C-593/03, Roche Nederland BV v. Primus, Goldenberg, [2007] F.S.R. 5 (E.C.J. 2006) (refusing to permit a Dutch court to join foreign defendants to a patent infringement suit involving a resident defendant).

184. *See, e.g.*, F. K. Juenger, *The ILA Principles on Provisional and Protective Measures*, 45 AM. J. COMP. L. 941, 941 (1997); Int'l Law Ass'n [ILA], *International Civil and Commercial*

property cases specifically.[185] If one of these projects were to succeed, the experience generated would provide future advocates of harmonized patent law with data of extraordinary value.

Even when a more centralized approach becomes propitious, questions will remain about the level at which harmonization should take place. Thus, the European Community has long been debating the merits of instituting a Community Patent and other regions are considering similar projects.[186] The United States, Europe, Japan, and other industrialized countries have discussed the possibility of creating a "limited package" instrument.[187] These initiatives differ from the SPLT negotiations in a significant way. Because they involve nations that are similar economically and technologically, there is no need to compromise on rules that are, in fact, optimum for no one. If such arrangements were to move forward, broader harmonization might eventually trickle down, as nations reaching the technological frontier decided to voluntarily join an existing regime.

Finally, there are advantages to giving the system established under the TRIPS Agreement more time to evolve.[188] The

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Litigation, ILA Res. No. 1/2000 (July 25–29, 2000), *available at* http://www.ila-hq.org/pdf/Civil%20&%20Commercial%20Litigation/RESlitigation.pdf; Hague Conf. on Private Int'l Law, *Draft Convention on Jurisdiction and Foreign Judgments in Civil and Commercial Matters*, Oct. 30, 1999, *available at* http://www.hcch.net/upload/wop/jdgmpd11.pdf; Hague Conf. on Private Int'l Law, *Convention on Choice of Court Agreements*, June 30, 2005, *available at* http://pub.bna.com/eclr/hagueconvention063005.pdf.

185. AM. LAW INST., INTELLECTUAL PROPERTY: PRINCIPLES GOVERNING JURISDICTION, CHOICE OF LAW, AND JUDGMENTS IN TRANSNATIONAL DISPUTES, approved May 14, 2007 (forthcoming 2008); Dreyfuss & Ginsburg, *supra* note 6, at 1065–66. The Max Planck Institute is also working on an International Convention on Jurisdiction and Enforcement of Judgments. Annette Kur, *Applicable Law: An Alternative Proposal for International Regulation—The Max-Planck Project on International Jurisdiction and Choice of Law*, 30 BROOK. J. INT'L L. 951 (2005); *see also* Int'l Ass'n for the Prot. of Intellectual Prop. [AIPPI], *supra* note 5, at 827 (resolving that "courts of a given country should be allowed to make a ruling over infringing acts regarding certain intellectual property rights, which have taken place in any other country"); Yoav Oestreicher, Recognition and Enforcement of Foreign Intellectual Property Judgments: Analysis and Guidelines for a New International Convention 10 (2004) (unpublished S.J.D. dissertation, Duke University School of Law), *available at* http://ssrn.com/abstract=939093 (proposing a minimalist international intellectual property convention to solve the world community's continuing inability to regulate the field). The European Union has also had a European Patent Litigation Agreement under consideration. Draft Agreement on the Establishment of a European Patent Litigation System, *supra* note 10.

186. *See supra* note 9.

187. *Industrialized Countries to Seek Deal on Global Patent Treaty Outside WIPO*, 72 Pat. Trademark & Copyright J. (BNA) No. 1788, at 606 (Oct. 6, 2006).

188. The Council for TRIPS bears responsibility for monitoring TRIPS implementation issues. *See* TRIPS Agreement, *supra* note 11, art. 68. There are also nongovernmental

international intellectual property community would learn a great deal from examining how well emerging economies adapt to the minimum standards TRIPS sets out, from scrutinizing the decisions of the WTO's dispute-settlement apparatus,[189] and from observing how WTO Members cope with TRIPS mistakes, such as the one solved in the Doha round.[190]

As drafted, TRIPS has some of the features that a responsive harmonized law needs. It has a dispute resolution system that could be used to keep the law current and, as the Doha Ministerial Declaration on TRIPS and Public Health demonstrated, a quasi-legislative body able to make larger corrections.[191] It is worth waiting to see how well these existing mechanisms deal with the problems challenging the international patent community.

As it stands, however, the TRIPS Agreement is not a final answer to the problem of harmonizing global patent law. The regime lacks a solid legislative basis for adjusting intellectual property law to changing needs. Despite precatory statements about the need for balance,[192] the Agreement focuses solely on the producer end of the equation and does not establish user rights. Thus, it includes no way for the parties to strike, at the international level, the balance between proprietary and access interests that good patent law

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organizations that follow international intellectual property policy making. *See, e.g.*, Intellectual Property Watch, http://ip-watch.org/index.php?res=1024&print=0 (last visited Oct. 4, 2007); Médecins Sans Frontiéres (MSF), Campaign for Access to Essential Medicines, http://www.accessmed-msf.org/index.asp (last visited Oct. 4, 2007); Knowledge Ecology International (KEI), http://www.keionline.org/index.php?option=com_frontpage&Itemid=1 (last visited Oct. 4, 2007).

189. Understanding on Rules and Procedures Governing the Settlement of Disputes, art. 22, Apr. 15 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 2, Legal Instruments—Results of the Uruguay Round, 33 I.L.M. 1126 (1994).

190. *See supra* notes 48–49 and accompanying text; *see also* MASKUS, *supra* note 165, at 7 (recommending "a formal complaint at the WTO that specific countries have failed to meet their enforcement obligations under TRIPS."); Marianne Levin & Annette Kur, Special Session at the Annual Meeting of the International Association for the Advancement of Teaching and Research in Intellectual Property: Towards More Balanced, User-Friendly Paradigms in IP Law: A Project Reform of TRIPS (Sept. 5, 2006) (spearheading a proposal to amend the TRIPS Agreement).

191. *See, e.g.*, Doha Declaration, *supra* note 37 (mandating further negotiations). *See generally* GAIL E. EVANS, LAWMAKING UNDER THE TRADE CONSTITUTION: A STUDY IN LEGISLATING BY THE WORLD TRADE ORGANIZATION (2000); Abbott, *supra* note 48 (commenting on the implementation of the Doha Declaration).

192. TRIPS Agreement, *supra* note 11, art. 7; *see id.*, pmbl. & art. 8(1).

requires.[193] Although dispute resolution panels have hinted that their charge includes making normative assessments of the legitimate expectations of patentees—a procedure that could, in theory, develop a series of user rights—these panels have looked no further than a narrow reading of *existing* rules protecting user interests.[194] They articulate nothing like the normative vision required of a dynamic system, capable of responding to new situations.

Arguably, a properly functioning patent law also requires competition law safeguards. The TRIPS Agreement permits Members to control anticompetitive abuse, but it does not mandate such control.[195] If WIPO intends to proceed with the SPLT, it would do well to consider what sorts of user safeguards are needed, to determine whether it is viable to separate the regime that creates exclusive rights from the regime that controls monopolies, and to develop experience and consensus regarding the delicate intersection

193. *See* Graeme B. Dinwoodie, *The International Intellectual Property Law System: New Actors, New Institutions, New Sources*, 10 MARQ. INTELL. PROP. L. REV. 205, 214 (2006) (advocating the inclusion of "substantive maxima" in the TRIPS Agreement to provide balance to the international intellectual property system). *See generally* Rochelle Cooper Dreyfuss, *TRIPS—Round II: Should Users Strike Back?*, 71 U. CHI. L. REV. 21 (2004) ("The TRIPS Agreement . . . is structured to directly protect the rights of intellectual property holders . . . [but] does little . . . to explicitly safeguard the interests of those who seek to use protected works.").

194. *See, e.g.*, Panel Report, *Canada-Patent Protection of Pharmaceutical Products*, *supra* note 125, ¶ 7.56 (finding an exemption permitting the testing of patented pharmaceuticals for regulatory review purposes to be normatively appropriate (without stockpiling) but only because many members already had experimental use exceptions in their patent laws); Dinwoodie & Dreyfuss, *supra* note 29, at 435 ("WTO panels tend to hew closely to text when resolving disputes."); Jane C. Ginsburg, *Toward Supranational Copyright Law? The WTO Panel Decision and the "Three Step Test" for Copyright Exemptions*, 187 REVUE INTERNATIONALE DU DROIT D'AUTEUR 3, 49 (2001) (arguing that the United States–Section 110(5) of the US Copyright Act, WTR/DS/160/R (WTO Dispute Settlement Panel 2000) case sought only to "anticipate what the empirical situation [would] be, [rather] than [provide] an explanation of what the right holder's markets *should* cover").

195. TRIPS Agreement, *supra* note 11, art. 31(k); *see id.* art. 8(2); Mark D. Janis, *"Minimal" Standards for Patent-Related Antitrust Law Under TRIPS*, *in* INTERNATIONAL PUBLIC GOODS AND TRANSFER OF TECHNOLOGY UNDER A GLOBALIZED INTELLECTUAL PROPERTY REGIME, *supra* note 23, at 774, 776–78; Ullrich, *supra* note 159, at 731–35.

between these two bodies of law,[196] with due regard to the needs of countries at different levels of development.[197]

CONCLUSION

This Article demonstrates that any efforts to achieve deep harmonization of world patent law at the present time, such as those contemplated by the SPLT, are both premature and counterproductive. The evidence shows, instead, that the worldwide intellectual property system has entered a brave new scientific epoch, in which experts have only tentative, divergent ideas about how best to treat a daunting array of emerging new technologies. The existing system has become increasingly dysfunctional because it operates with a set of rudimentary working hypotheses that have not kept pace with technical change. As different countries put these hypotheses to the test, the focus of international lawmakers—whether at WIPO, the WTO, or in a trilateral coalition—should be on gaining experience and data from living within the parameters set out by the TRIPS Agreement during a prolonged period of open-minded experimentation.

If international policymakers rise above sectarian interests and power politics to concentrate on nurturing the incipient transnational system of innovation that the TRIPS Agreement brought into being, they can stimulate research and innovation on a grander scale than ever before. But they must take the time and invest the effort to get it right. Locking in the fleeting, competitive advantages of one group of stakeholders or another at the expense of real innovators and dynamic entrepreneurs everywhere is a bad strategy that will compromise the world's aggregate innovative capacity in the long run. Instead of moving forward with harmonization for its own sake, the

196. GUSTAVO GHIDINI, INTELLECTUAL PROPERTY AND COMPETITION LAW: THE INNOVATION NEXUS 99–115 (2007); *see* Emanuella Arezzo, *Intellectual Property Rights at the Crossroad between Monopolization and Abuse of a Dominant Position: American and European Approaches Compared*, 24 J. MARSHALL J. COMPUTER & INFO. L. 455, 477–94 (2006).

197. *See* Drexl, *supra* note 159, at 709, 720 ("[R]elevant product markets usually have a limited geographical scope. Whereas intangible goods protected by IPRs may be exploited worldwide, the geographical market for products based on such IPRs is not necessarily a global one. . . . For instance, in poorer countries that are net importers of agricultural goods, small farmers will not compete with farmers on foreign markets."); Ullrich, *supra* note 159, at 40 ("Community and national protection must be seen as complimentary parts of an overall system of protection, where unification and harmonization allow to balance uniformity with specificity and stability with flexibility of protection.").

international intellectual property community must first identify and test trustworthy, empirically supportable solutions likely to benefit humanity at large.