

Washington University Journal of Law and Policy

Patent Law and Policy Symposium

Re-Engineering Patent Law: The Challenge of New Technologies

Introduction

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The constitutionally mandated purpose of the U.S. patent system is to promote the progress of “useful Arts”¹—or in more modern parlance, to promote technological innovation.² Congress is empowered to accomplish this purpose by securing for limited times to inventors the exclusive right to their discoveries. However, to ensure that the grant of exclusive patent rights does in fact promote—rather than retard—technological innovation, each of the institutional actors in the U.S. patent system—Congress, the courts, and the U.S. Patent and Trademark Office—must perennially balance the need to provide inventors with adequate incentives to innovate against the public interest in having access to and fostering a

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1. The U.S. Constitution, art. I, § 8, cl. 8, empowers Congress to “promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries”

2. See *In re Bergy*, 596 F.2d 952, 959 (1979) (citing *In re Musgrave*, 431 F.2d 882, 893 (1970) for the proposition that “the present day equivalent of the term ‘useful arts’ employed by the Founding Fathers is ‘technological arts’”).

competitive marketplace for innovations.

As the title of this symposium issue of the *Washington University Journal of Law and Policy* suggests, new technologies inevitably play as pivotal a role in shaping the development of patent policy as the patent system plays in the development of new technologies—though not always with salutary results or to universal applause. One need only consult the day's headlines to make the point. For example, in the short space of two weeks preceding the conference at which the papers included in this symposium were presented, not one but two separate news articles railed against what the headlines of both declared to be “patently absurd” claims contained in patents recently issued by the U.S. Patent and Trademark Office (PTO).³ Just one week before the conference, National Public Radio aired an hour-long segment of its popular “Talk of the Nation: Science Friday” program, which was devoted entirely to the two new technologies spawning all the headlines—namely digital technology and biotechnology—and featured among other guests one of the three scheduled keynote speakers for the conference, then Commissioner, now Director of the PTO, Q. Todd Dickinson.⁴

The challenge posed by these two new technologies implicates some of the fundamental premises of patent law. For

3. See James Gleik, *Patently Absurd*, N.Y. TIMES, Mar. 12, 2000, (magazine) at 44; Randall E. Stross, *Patently Absurd Claims: Clueless Courts and a Broken Patent System Help Amazon*, U.S. NEWS & WORLD REP., Mar. 20, 2000, at 56 (reporting on the issuance of U.S. Patent No. 5,960,411, “Method and system for placing a purchase order via a communications network”—better known as Amazon.com’s patented One Click® feature).

4. See *Science Friday, March 24, 2000: Hour One: Technology Patents*, (visited Apr. 13, 2000) (NPR radio broadcast, Mar. 24, 2000) <http://www.sciencefriday.com/pages/2000/mar/hour1_032400.html>. On March 29, 2000, just two days before the conference, Commissioner Dickinson’s title was changed to Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office, pursuant to the American Inventors Protection Act of 1999, which was enacted as Title IV-Inventor Protection of the Intellectual Property and Communications Omnibus Reform Act of 1999, P.L. 106-113. The title change was a part of a larger effort to transform the PTO into a “performance-based organization.” See generally Sabra Chartrand, *What’s in a Name? A Sign of Other Changes at the United States Patent and Trademark Office*, N.Y. TIMES, Apr. 3, 2000, at C6.

example, patent protection for inventions has been held to exclude any protection for abstract ideas, natural laws or principles, and phenomena of nature.⁵ For a time, courts also purported to exclude business methods from the subject matter of protection.⁶ Today, however, inventors of software-related inventions have come perilously close to obtaining patents on mathematical algorithms, or at least on the use of certain algorithms for particular purposes.⁷ Likewise, biotechnology patents have come very close to claiming phenomena of nature—namely, isolated genetic sequences.⁸ And, in a recent case, *State Street Bank & Trust Co. v. Signature Financial Group*,⁹ the Court of Appeals for the Federal Circuit (CAFC), the federal court specializing in patent appeals, held that there was no business methods exception to the patentability of processes and upheld a patent for a computerized data processing system for a “hub and spoke” financial services configuration for managing mutual funds.¹⁰

The result has been what one paper in this symposium calls “the patent gold gush,” in which “inventions long thought unpatentable—everything from gene sequences of unknown function to one-step purchasing over the Internet—are now being claimed as property.”¹¹ These developments are of particular concern because they tend to allow patents on subject matter that is both further “upstream” in the innovation process and further afield from traditional industrial products and processes than has ever before been the case. As the subject

5. See *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980) (noting that “laws of nature, physical phenomena, and abstract ideas have been held not patentable”).

6. See generally 1 DONALD S. CHISUM, CHISUM ON PATENTS § 1.03[5] (1999).

7. See, e.g., *In re Alappat*, 33 F.3d 1526, 1545 (Fed. Cir. 1994) (Archer dissenting).

8. See, e.g., *Amgen, Inc. v. Chugai Pharmaceutical Co., Ltd.*, 927 F.2d 1200, 1204 (Fed. Cir. 1991) (involving a patent claim to “a purified and isolated DNA sequence consisting essentially of a DNA sequence encoding human erythropoietin”).

9. 149 F.3d 1368 (Fed. Cir. 1998).

10. *Id.* at 1375.

11. See Arti Rai, *Addressing the Patent Gold Rush: The Role of Deference to PTO Patent Denials*, 2 WASH. U. J.L. & POL’Y 199 (2000).

matter of patent protection expands both upstream to basic research in new technology fields and outward from industrial to business methods, two fundamental questions arise: 1) whether the incentive of patent protection is really necessary to stimulate such innovation; and 2) whether the grant of such patent protection will, on balance, promote or discourage innovation.

In addition to these questions about the appropriate subject matter of patent protection, the new technologies are also challenging the traditional standards required for obtaining a patent for an invention. These standards require that an invention be new, useful, and nonobvious.¹² In other words, it is not enough that an invention be new; it must also be useful and not the sort of innovation that would have been obvious to one having ordinary skill in the particular “art” to which the invention pertains. In the biotech field, in particular, both the utility and the nonobviousness requirements seem to have been increasingly watered down. Questions concerning utility are particularly likely to arise with biotechnology inventions “where patent claims to DNA fragments that an applicant has shown to be functional genes or portions of genes but has not yet determined what the specific function is.”¹³ Likewise, CAFC case law seems to establish that a DNA sequence can be non-obvious even though the information necessary for isolating the sequence is publicly available.¹⁴ By statute, certain biotech processes are deemed nonobvious if the process uses or produces a new and nonobvious composition.¹⁵ These relaxed requirements certainly promote upstream innovation but at

12. See 35 U.S.C. §§ 101-103 (1994).

13. 1 CHISUM ON PATENTS, *supra* note 6, § 4.02[2][g]; Rebecca S. Eisenberg & Robert P. Merges, *Opinion Letter as to the Patentability of Certain Inventions Associated with the Identification of Partial cDNA Sequences*, 23 AIPLA Q. J. 1, 3-20 (1995).

14. See, e.g., *In re Deuel*, 51 F.3d 1552, 1557-58 (Fed. Cir. 1995), discussed in Rai, *supra* note 11, at 205-06.

15. See 35 U.S.C. § 103(b).

what cost to downstream innovation?

As contentious as these questions are within the U.S., they pale in comparison to the patent controversies that have arisen in the international arena. Chronic North-South (i.e. industrialized and developing world) divisions over the appropriate scope of protection for patented inventions and for intellectual property generally (i.e. patents, copyrights, trademarks, and trade secrets) eventually contributed to the establishment of the World Trade Organization (WTO), which is vested with authority to implement and enforce the provisions of the Agreement on Trade-Related Aspects of Intellectual Property Rights, commonly called the TRIPS Agreement. However, there are also growing “East-West” divisions—as illustrated by recent political demonstrations that began in Europe, protesting the importation of genetically modified foods, but now, as a result of the abortive 1999 WTO meeting held in Seattle, Washington,¹⁶ seem to be spreading to this side of the Atlantic Ocean as well. Likewise, far more concern has been expressed in Europe than has thus far surfaced in the United States over the “morality” of patenting living organisms.¹⁷

Meanwhile, on the other side of the Pacific, Japan’s patent system, in marked contrast to that of the U.S., has historically operated more for the benefit of users of the patent file (in doing research and development) than patent owners.¹⁸ Many

16. Nuno Pires de Carvalho makes passing reference to this WTO meeting in the introduction to his article. See Nuno Pires de Carvalho, *Requiring Disclosure of the Origin of Genetic Resources and Prior Informed Consent in Patent Applications Without Infringing the TRIPS Agreement: The Problem and The Solution*, 2 WASH. U. J.L. & POL’Y 371 (2000). For a general discussion of emerging “East-West” conflicts in cyberspace, see Charles R. McManis, *Taking TRIPS on the Information Superhighway: International Intellectual Property Protection and Emerging Computer Technology*, 41 VILLANOVA L. REV. 207 (1996).

17. See, e.g. Cynthia M. Ho, *Splicing Morality and Patent Law: Issues Arising from Mixing Mice and Men*, 2 WASH. U. J.L. & POL’Y 247 (2000).

18. See Samson Helfgott, *Cultural Differences Between the U.S. and Japanese Patent Systems*, 72 J. PAT. [& TRADEMARK] OFF. SOC’Y 231 (1990); Toshiko Takenaka, *The Role of the Japanese Patent System in Japanese Industry*, 13 UCLA PAC. BASIN L. J. 25 (1994). See

Japanese applicants continue to file more for defensive purposes—that is, to prevent anyone else from getting a patent on a particular innovation—than to secure a patent for themselves.¹⁹ While U.S. companies often complain that Japanese patent protection is unduly weak, the reason is that the intended beneficiary of the Japanese patent system has historically been the user of the patent file, not the patent holder. This is slowly changing, because both the U.S. and Japanese patent systems are being amended to meet somewhere in the middle, but this is resulting in as many changes in U.S. as in Japanese patent law. For example, just last fall, U.S. patent law was amended to provide that any domestic patent application that is the subject of a foreign filing will henceforth be publicized, or “laid open,” before the patent is actually issued, thus possibly destroying any potential trade secret protection before there is any guarantee that a patent will be granted.²⁰ Prompt publication of patent applications is the norm in patent systems around the world, but the U.S. has historically been more interested in protecting the confidentiality of the application than in promoting prompt disclosure and public scrutiny of the claimed invention. The original proposal to publicize all U.S. patent applications prompted protest from U.S. small businesses and individual inventors and eventually necessitated retaining the confidentiality provision for applicants who file only in the U.S. and not in other countries.

Among developing countries, on the other hand, there is deep suspicion that strong intellectual property protection is simply colonialism by other means—requiring developing

generally Dan Rosen & Chikako Usui, *The Social Structure of Japanese Intellectual Property Law*, 13 UCLA PAC. BASIN L. J. 32 (1994). For recent developments in Japanese patent law, however, see Toshiko Takenaka, *Patent Infringement Damages in Japan and the United States: Will Increased Patent Infringement Damage Awards Revive the Japanese Economy?*, 2 WASH. U. J.L. & POL'Y 309 (2000).

19. See Helfgott, *supra* note 18.

20. See Domestic Publication of Foreign Filed Patent Applications Act of 1999, Pub. L. No. 106-113, 113 Stat. 1537-553, §§ 4501-4502 (1999).

countries to pay for imported technology that they can ill-afford. Developing countries also protest that the basic premises of intellectual property protection are skewed in favor of the industrialized world and against the essentially agrarian developing world. A particularly “hot-button” topic in the developing world is the issue of “biopiracy”—the practice of researchers from industrialized countries to rely on traditional knowledge of indigenous peoples to isolate promising biota that becomes the basis for patent protection in the industrialized world, without any compensation being given to the developing country that maintains the traditional knowledge and the relevant plant species for the benefit of the rest of the world.²¹

The patent policy issues at the heart of the foregoing conflicts present a particularly timely symposium topic for the recently re-engineered *Washington University Journal of Law and Policy*. Not only is Washington University playing a key role in the Human Genome Project and biomedical science generally, it has also entered into a partnership with the Missouri Botanical Garden, the Monsanto Company, and three other mid-western universities to establish in St. Louis a new \$146 million Donald Danforth Plant Sciences Center, whose first president is the noted plant scientist, Dr. Roger Beachy.²² Just within the last six months, St. Louis was the site of two world renown botanical events—the first annual World Agricultural Congress and the 16th International Botanical Congress—evidence of the growing recognition that St. Louis is becoming a leading center for biotechnology and plant science research.²³

21. See generally Charles R. McManis, *The Interface Between International Intellectual Property and Environmental Protection: Biodiversity and Biotechnology*, 76 WASH. U. L. Q. 255 (1998). For a proposed response to this concern, see Carvalho, *supra* note 16.

22. See Liese Hutchison, *Planting the Seeds: The St. Louis region has the potential to become a world center for plant sciences, biotechnology and life sciences*, ST. LOUIS COM. MAG. (Oct. 1999); Vic Comello, *Roger Beachy: A Leader in Revitalizing Plant Science*, 41 CAHNERS R & D 18 (Oct. 1999).

23. See Richard C.D. Fleming, President and Chief Executive Officer, St. Louis Regional

To capitalize on these developments, the School of Law at Washington University has developed a strategic plan, entitled “Building on Strength: Washington University School of Law Strategic Plan (2000-2005),” which will concentrate on five program areas of particular strength at the law school, including interdisciplinary studies, international and comparative law studies, and intellectual property and technology law studies. By way of implementation, the School of Law recently established two new academic centers—the Center for Interdisciplinary Studies and the Institute for Global Legal Studies. More recently still, the Dean of the Law School has appointed an Intellectual Property Advisory Board to explore the possibility of establishing an LLM and/or joint-degree program in intellectual property and technology law. Co-hosting (with the Bar Association of Metropolitan St. Louis) the 2000 Heart of America Patent Law and Policy Conference, held at Washington University School of Law on March 31-April 1, 2000, and publishing the proceedings of that conference in the *Washington University Journal of Law & Policy*, represents the inaugural effort of the School of Law to contribute to the ongoing interdisciplinary, international, and comparative examination of the patent policy challenges posed by new technologies.

In keeping with this overall approach to the topic of this symposium, nine rising young patent law academics were asked to present papers on a topic of their choice, the only specified parameters being that they focus 1) on current patent policy issues; 2) particularly those with an international, comparative, or interdisciplinary dimension; and 3) more particularly still, those policy issues that might relate to biotechnology law or the life sciences. In response, these nine authors produced a wide range of complementary papers that seemed to fall rather

naturally into three overlapping clusters. Three of the papers address particular administrative issues of patent policy confronting the PTO; three papers address issues of judicial—i.e. CAFC—supervision of patent policy in the U.S.; and three papers focus on international and/or comparative issues of patent policy. Accordingly, the articles are grouped under these three general headings. To underscore the importance of international and comparative aspects of patent policy, the final section of the symposium includes two supplemental articles in addition to the three papers presented at the conference. The first is an article by Dr. Nuno Pires de Carvalho, who is on the staff of the World Intellectual Property Organization and served as one of the three keynote speakers at the conference. The second is an article by Professor Joseph Straus, Professor of Law at the Universities of Ljubljana and Munich, and Head of Department at the Max-Planck Institute for Foreign and International Patent, Copyright and Competition Law, Munich. Dr. Straus was to have been a paper presenter at the conference but because of a schedule conflict was not able to attend. However, he graciously allowed and secured permission for the *Washington University Journal of Law & Policy* to publish a slightly amended text of the Katz-Kiley Lecture which he gave at the University of Houston Law Center on November 3, 1999.

A. Administrative Issues of Patent Policy

The first three articles in this symposium focus on administrative patent policy issues confronting the PTO.

In the first article, “Patents as Incomplete Contracts: Reducing the Information Asymmetry Between the Patentee and the PTO,” Jay Kesan and Mark Banik propose viewing patents as *incomplete* contracts that create contingent, or probabilistic, property rights, where the probability of invalidation reduces the expected return of a particular research and development (R&D) investment, and thus diminishes the

incentive to innovate. They point out that, because efficient patent systems aim to induce investment in R&D, while limiting social costs in the form of reduced levels of competition or wasteful design-around efforts by competitors, patent policy makers must consider not only the potential distortions to perfect competition, but also a policy's distortions to incentives for investment in R&D. They then build on and apply to the patent system Grossman and Hart's economic model of incomplete contracts and conclude that in the case of high technology patents, where the PTO is poorly informed about the relevant prior art, it may be optimal for the PTO to provide incentives to the patentee to produce a complete prior art disclosure by according a high presumption of validity to the disclosed prior art, which would limit the use of the disclosed prior art for invalidation purposes in subsequent (i.e., post-issuance) litigation. Such a regime, they claim, would maximize social welfare because it renders both the patentee and the PTO (and hence, the public) better off. Such a policy would induce the patent applicant to make higher levels of ex ante investment in R&D, and with a fuller prior art disclosure the PTO may be able to grant patent rights commensurate with innovation and avoid the detrimental consequences of an overbroad patent grant.

In the second article, "On Courts Herding Cats: Contending with the 'Written Description' Requirement (and Other Unruly Patent Disclosure Doctrine)," Mark Janis explores the problem of incoherence in and among the three modern disclosure requirements said to emanate from the first paragraph of section 112 of the U.S. patent statute—namely, the written description of the invention requirement, the enabling disclosure requirement (enabling any person skilled in the relevant art to make and use the invention), and the best mode requirement (setting forth the best mode contemplated by the inventor of carrying out his invention). Specifically, Janis argues that the distinction between the written description and enablement

requirements is artificial and that by perpetuating this distinction the CAFC has impaired the development of a coherent vision of the requirements for adequate disclosure, devising instead an essentially standardless disclosure doctrine that can be deployed arbitrarily, thus effectively arrogating to itself unbridled authority to strike down claims for inadequate disclosure. Janis goes on to examine the disclosure requirement in comparative perspective, analyzing the jurisprudence of the European Patent Office and the British patent system for evidence of the same phenomenon whereby decisionmakers reach beyond enablement for ill-defined ancillary disclosure doctrines. He concludes with a brief analysis of why the written description or analogous doctrines seem to proliferate spontaneously on the landscape of patent disclosure requirements and suggests that courts instead consider more carefully whether the enabling disclosure requirement is in fact being applied to require an enabling disclosure that correlates to the scope of the patent claims.

In the third article, "On Improving the Legal Process of Patent Claim Interpretation," John Duffy points out that, although many commentators have addressed the issue of claim interpretation, few have studied in depth the allocation of interpretative power among the legal actors in the patent system. The focus has been on the "how" of claim interpretation, not the "who." As Duffy points out, however, technological progress is inextricably intertwined with the advancement of the legal and social norms by which society organizes itself. Building on Williamson's observation that "the study of organizational innovation has never been more than a poor second cousin to the study of technological innovation," Duffy proposes to examine the process of patent claim interpretation by a method that parallels methods of technological innovation. Thus, in addition to reassessing a particular doctrinal area of patent law, his article is also a study, or experiment, in method: He employs the method of an

innovator to seek insight into a discrete but significant part of the legal process of innovation. In part I of his article, Duffy defines the particular legal problem to be addressed. By treating claim interpretation as a pure issue of law subject to *de novo* review on appeal, the case law has centralized claim interpretation in the Federal Circuit. While that makes for uniformity, it can also lead to dramatic procedural inefficiencies of precisely the sort that Kesan and Banik say reduces the value of patent rights and thus the incentive to innovate. The challenge, according to Duffy, is to reduce the inefficiency without sacrificing uniformity. In part II of his article, Duffy provides a “Winslow Tableau,” invoking *In re Winslow*’s image of the inventor “working in his shop with the prior art references . . . hang on the walls around him,” in order to offer a similar compendium of “the relevant prior art” for analyzing and resolving the technical legal problem introduced in part I. The tableau goes beyond American patent law to identify possible solutions both from other branches of domestic law and the patent law of other jurisdictions, focusing primarily on what Duffy calls “primary jurisdiction and administrative claim interpretation.” Finally, in part III, having noted that developing market-like mechanisms to test a legal technology may itself be an accomplishment of great ingenuity, Duffy discusses one such mechanism and its application to the procedural innovation introduced in part II of his article.

II. JUDICIAL ISSUES OF PATENT POLICY

The second three articles in the symposium focus on CAFC supervision of patent policy in the U.S.

In the first article, “Strangers in a Strange Land: Biotechnology and the Federal Circuit,” Lawrence Sung, who holds a Ph.D. in microbiology as well as a law degree, surveys the recent CAFC biotechnology decisions from the combined perspective of science and the law. As he notes, while the

casual observer might attribute the seeming incongruity between the jurisprudence of the CAFC and the underlying scientific realities to the absence of judges on the court who may be said to exemplify the hypothetical person of ordinary skill in the art, the perceived incongruity might also be the result of the scientific community's ignorance of the procedural guidelines and substantive legal precedent to which the court must remain faithful in rendering its judgments. In particular, Sung notes the general failure to appreciate a significant temporal distortion in the court's biotechnology decisions. Much like an astronomer peering into the heavens, the CAFC in its biotechnology decisions not only confronts almost unfathomable complexity; it is also looking back in time. Given that backward temporal distortion, Sung wonders what meaningful guidance the court can provide for today's realities and tomorrow's possibilities. Still, as Sung goes on to demonstrate, the CAFC's recent biotechnology decisions provide a glimpse of the fundamental patent-law principles to which the court will likely continue to adhere. In part I of his article, Sung examines those cases in which the statutory conditions for patentability and the disclosure requirements are implicated. The requirements of utility, nonobviousness, written description, and enablement take center stage here. In part II, Sung examines issues of inventorship and priority of invention. In part III, he reviews biotechnology litigation at both the administrative and judicial levels, focusing on interference proceedings before the PTO and patent infringement actions before the federal courts.

In the second article, "Addressing the Patent Gold Rush: Deference to PTO Patent Denials," Arti Rai observes that, even for those who would rather do so, it is difficult to ignore the headlong rush to claim patent rights in the two dynamic, rapidly evolving industries that undergird the information economy—namely, biotechnology and computer technology. She goes on to make three basic points. First, she identifies the factors that

have led to the current spate of patent filings and argues that the evidence points squarely towards certain questionable CAFC decisions reversing PTO denials of patent protection to various biotechnology and computer program inventions as a major reason for the recent proliferation of high technology patents. Second, she stresses the importance of CAFC deference with respect to PTO determinations concerning nonobviousness, noting that although the PTO may well operate under a skewed set of incentives as well as limitations on its own resources and expertise, these incentives and limitations will tend systematically to produce errors in patent *grants*, not patent denials. Finally, she discusses the administrative law doctrines through which greater CAFC deference to the PTO should be implemented, arguing that the starting point must be the Supreme Court's seminal decision in *Chevron v. Natural Resources Defense Council*.

In the third article, "Patents and Cumulative Innovation," Clarisa Long addresses the widespread concern that granting proprietary rights to basic research results will hamper the progress of science, stifle the flow of new knowledge and the dissemination of research results, and chill the research efforts of scientists who fear infringement liability. She begins by noting that the discussion of the proper role of proprietary rights in general and patents in particular has long been dominated by models that apply a linear approach to the process of scientific discovery and innovation, which assume that a patented product is the final consumer end product. However, scientific research—and particularly biomedical research—is not linear and is in any event undergoing a paradigmatic shift as biomedical research is becoming increasingly information based; as basic research and product development increasingly depend on non-linear, continuous interactions with each other; and as scientific practices and industry business models evolve to blur traditional boundaries between public and private goods. Whereas traditional

pharmaceutical innovation tended to be a capital-intensive, high-risk process, which benefited from strong patent protection on the product that finally emerged at the end of the research pipeline, biomedical research, particularly that pertaining to genomics, departs from this model. Genomic information and information-based research tools have themselves become marketable. New entrants in the upstream market for genomic information are less capital intensive, exhibit much faster time to market, and offer different risk-reward models for investors than the traditional pharmaceutical companies. According to Long, the link between scientific breakthroughs and marketable innovations continues to shorten and tighten. In such an environment, she argues, it is unclear whether conclusions gleaned from industries characterized by tangible commercial products can be extrapolated to biomedical research generally, but she believes it to be certain that such conclusions cannot be extended to patents on biomedical research results that are so far upstream that no commercial product currently exists. She concludes that there is at present no clear analytical answer to the question of how to distribute the incentives between basic researchers and downstream innovators so as to optimize innovation at all stages of the research and development process. She believes that in all likelihood, the answer will differ from industry to industry and from scientific field to scientific field. What is clear is that we must revamp our models of proprietary rights to reflect the research environment accurately and to create the optimum incentive for scientific innovation.

III. INTERNATIONAL AND COMPARATIVE LAW ISSUES OF PATENT POLICY

The final three articles, supplemented by the articles of Dr. Carvalho and Professor Straus, concentrate on international and comparative issues of patent law and policy.

In her article, “Splicing Morality and Patent Law: Issues Arising from Mixing Mice and Men,” Cynthia Ho begins by describing how the long-dormant issue of “moral utility” was recently (and dramatically) resurrected by the filing of a patent application claiming “chimeric embryos” containing both human and non-human cells—a filing designed to engender discussion and debate on precisely that obscure patent issue. The strategy of the applicants was evidently successful, because it prompted the PTO to issue a “media advisory” on the subject and led then PTO Commissioner Bruce Lehman to state publicly that “there will be no patents on monsters, at least not while I’m commissioner.” Ho’s article seeks to advance this discussion by examining existing models for incorporating ethics into the determination of patentability, particularly those developed in Europe for excluding patents on the basis of ethics and morality. In part II of her article, Ho discusses the prohibition contained in article 53(a) of the European Patent Convention (EPC) and its application in four specific cases. In part III, she discusses how article 6(2) of the EU Directive on Biotechnology might be applied in the case of the U.S. “chimeric embryos” application. Ho concludes that, despite substantial consideration of the issue, the EU was unable to arrive at a formulation that is any more effective than the original system under the EPC—and in some ways its formulation may in fact be less preferable. In the end, she doubts whether the game is worth the candle. Instead of using the patent system to address controversial issues concerning the morality of certain lines of research, Ho believes that these issues should be addressed through a more direct approach regulating the research itself.

As indicated by the title of his article, “Contributory Infringement of Patents in Korea,” Sang-Jo Jong discusses the Korean doctrine of contributory infringement, as it was applied (or in Professor Jong’s judgment, misapplied) by the Korean Supreme Court in the 1996 case of *Samsung Electronics, Inc. v.*

Sung-kyo Cho. Jong's analysis of the case graphically illustrates how difficult it can be for the legislature and judicial system of a newly industrialized country, having only limited experience with patent legislation and enforcement, to grasp or articulate all of the nuances of a doctrine that required almost a century of judicial development in the U.S. before being codified. The experience of the Republic of Korea—which is viewed by many as a model to be followed by the developing world—serves as a cautionary tale for anyone who naively expects that implementation of the 1994 Agreement on Trade Related Aspects of Intellectual Property Rights (better known as the TRIPS Agreement) will necessarily result in a rapid, or salutary, transplanted of patent law in the developing world, or even in the newly industrialized world, where the endeavor stands the best chance of success.

By way of instructive comparison, Toshiko Takenaka, in her article, "Patent Infringement Damages in Japan and the United States: Will Increased Patent Infringement Damage Awards Help Revive the Japanese Economy?," points out that the Japanese government, in looking for ways to revive the Japanese economy, has become convinced that U.S. patent policy and other legislation designed to encourage technology transfer are among the primary reasons that the U.S. recovered from its most recent recession so much more quickly than Japan. In April, 1997 a government sponsored commission, the Commission on Intellectual Property Rights in the Twenty-First Century, published a report emphasizing the need to strengthen intellectual property rights in Japan in order to promote development of breakthrough technologies. The report has prompted major changes in Japanese patent policy at all levels—administrative, judicial and legislative—culminating with a revision of the patent law provisions relating to patent enforcement procedures and the calculation of damages for infringement. In her paper, Takenaka examines the impact of the new legislation governing patent damages and discusses

whether the increase in damage awards contributes to the creation of breakthrough technology. Part I of her article discusses the pre-1998 law governing patent damages and highlights the differences between U.S. and Japanese practice by comparing specific case examples. Part II of her article focuses on a particular case, *SmithKline & Beecham French Laboratories Ltd. v. Fujimoto Seiyaku*, decided under the 1998 amendments, in which the Tokyo District Court awarded the plaintiff \$23.5 million in lost profits in a case in which a Japanese generic drug manufacturer had imported the product of the allegedly infringed process from Slovenia and sold it in Japan. In part III of her article, Takenaka addresses the question of whether these changes in Japanese patent law will achieve their policy objectives and concludes that the increased damage awards create a risk of overcompensation, but that, despite this risk, they may well encourage investment in technology and assist in the establishment of start-ups and spin-offs based on new technologies.

In his article “Patent Litigation in Europe—A Glimmer of Hope? Present Status and Future Perspectives,” Joseph Straus provides a comprehensive overview of the present status of patent litigation in Europe, particularly as it compares with other efforts to achieve economic and legal integration in Europe. While not yet a reality, there is, he says, a glimmer of hope that Europe will adopt an integrated system for litigating European patents within the foreseeable future.

Finally, Dr. Nuno Carvalho, in his paper “Requiring Disclosure of the Origin of Genetic Resources and Prior Informed Consent in Patent Applications without Infringing the TRIPS Agreement: the Problem and the Solution,” discusses a patent policy issue that was initially stimulated by the Convention on Biological Diversity, which was opened for signature on June 5, 1992, at the United Nations Conference on the Environment and Development (the Rio “Earth Summit”). What is at stake, he says, is the possibility of detecting

commercial gains from the use of genetic resources so that countries supplying those resources can demand their share of the benefits. Dr. Carvalho first describes how the requirement that the origin of genetic resources and prior informed consent be disclosed in patent applications has been raised by different countries in at least two different international *fora*—namely the World Trade Organization (WTO)(before the Council for TRIPS and the General Council) and the World Intellectual Property Organization (WIPO)(before the Standing Committee on Patents). Then he discusses how such a requirement might conflict with the WTO TRIPS Agreement. Finally, he suggests a practical solution to the problem, indicating how such a requirement might be incorporated into nation, regional, or international law without conflicting with TRIPS.

II. ACKNOWLEDGEMENTS

No introduction to this symposium issue would be complete without mention of those most responsible for making it a reality. Certainly, no one deserves greater thanks than Heather Leawoods, Editor in Chief of the *Washington University Journal of Law & Policy*, Phillip S. Lupton, Managing Editor, Ms. Teri Dent, Administrative Coordinator for Publications, and the entire editorial board, who intrepidly took on the task of publishing an entire volume on patent law and policy, even though few members of the board had any previous exposure to patent law and policy matters. Equally deserving of thanks are the authors of the articles appearing in this symposium issue, who readily agreed to participate in the symposium and then produced extremely thoughtful articles within a very tight time frame.

I would also like to thank the three keynote speakers, who agreed to grace the conference proceedings with their wisdom and insights, not only as keynote speakers but as panelists responding to the papers presented at the conference: Q. Todd

Dickinson, Under Secretary of Commerce for Intellectual Property and Director of the U.S. Patent and Trademark Office; the Honorable Randall R. Rader, Circuit Judge of the Court of Appeals for the Federal Circuit; and Dr. Nuno Pires de Carvalho, of the Global issues Division of the World Intellectual Property Organization. I am likewise grateful to those who agreed to serve with our keynote speakers as panelists: Dr. Robert H. Waterston, James S. McDonnell Professor of Genetics and Head of the Department of Genetics at Washington University; Dr. Frank C-P. Yin, Stephen & Camilla Braur Professor of Biomedical Engineering and Chair of the Department of Biomedical Engineering at Washington University; Gregory Upchurch, Partner, Thompson Coburn, and Adjunct Professor of Law, Washington University; Michael Warner, Patent Counsel, Monsanto Company; and Thomas Borecki, Associate General -Counsel and Chief Patent Counsel, Baxter Healthcare.

I would also like to thank the following law firms and organizations, who generously agreed to underwrite the two conference receptions: Armstrong Teasdale; Blackwell Sanders Peper Martin; Bryan Cave; Howell & Haferkamp; Interim Legal Services; Senniger Powers, Leavitt & Roedel; Suelthaus & Walsh; and Thompson Coburn.

Finally, I would like to thank my co-chair for the conference, G. Harley Blosser, Partner, Senniger, Powers, Leavitt & Roedel, and several other very special people who assisted behind the scenes to make the conference a reality: Ms. Gwendolyn Byrd, of the Bar Association of St. Louis, who made the transportation arrangements for the conference; Dr. Michele Shoresman, Director of Graduate and Joint Degree Programs at Washington University School of Law, who coordinated conference arrangements at the law school; Ms. Aris Woodham, Electronic Resources Librarian, who took charge of web page organization for the conference; Ms. Erin Burress, Administrative Assistant to the Director of Graduate

and Joint Degree Programs; Daryl Barker and Robyn Achelpohl, who provided audiovisual support for the conference; Ms.

Ann Nicholson, News Writer for Washington University, who coordinated media coverage for the conference; my Administrative Assistant, Ms. Jane Bettlach, Ms. Sharon Strathman, Executive Assistant to the Dean, and the entire staff of the Dean's Office, who assembled the materials for the conference. To each of these persons I owe a very special debt.