Impact of Global Patent and Regulatory Reform on Patent Strategies for Biotechnology

By

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Introduction

I come to you this morning not as an intellectual property lawyer but as a former general counsel of biotechnology and pharmaceutical related companies, as an attorney with significant exposure to intellectual property issues and as one who has seen first-hand the importance of intellectual property in shaping commercial strategies in biotechnology. With that as a backdrop, I would like to thank you for allowing me the opportunity to share with you today thoughts that I have regarding patents and the impact of patent reform on biotechnology. It has been said that the best way to predict the future is to invent it. However, I believe that the best way to control the future is to patent it.

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The existence of patents and patent law policy is, on one level, to protect patent holders and their discoveries while, on another level, it exists to foster innovation while facilitating and promoting the inventive process and commercialization.[1] In addition, patents and patent law reform policy assist firms, small and large, in attracting venture capital by signaling that a firm possesses valuable knowledge capital.[2] On a global basis, countries traditionally develop patent policies to complement industrialization and trade by encouraging invention and innovation. We have seen this with the promulgation of the Patent Cooperation Treaty, the Convention on the Grant of European Patents, the Agreement on Trade Related Aspects of Intellectual Property Rights (commonly referred to as the "TRIPS Agreement" or "TRIPS") and the further efforts by the World Intellectual Property Organization (WIPO) to examine the harmonization of domestic patent laws at the international level.[3]

While patents and the associated policies and reforms have impacted the direction of many technology driven industries, there is no one area greater than biotechnology where its influence is felt. Although a relatively

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[1] *See* John M. Golden, *Biotechnology, Technology, and Patentability: Natural Products and Invention in the American System*, 50 EMORY L.J. 101 (2001).

[2] Stuart Minor Benjamin and Arti K. Rai, *Who's Afraid of the APA? What the Patent System can Learn from Administrative Law*, 95 GEO. L.J. 269, 275 (2007).

[3] *See* Jerome H. Reichman and Rochelle Cooper Dreyfuss, *Harmonization Without Consensus: Critical Reflections on Drafting a Substantive Patent Law Treaty*, 57 DUKE L.J. 85 (2007).

young and emerging sector of the global economy,[4] biotechnology, along with its innovation and investment, depends on a reliable and strong intellectual property system generally and a robust global patent system specifically. Patents enable biotechnology firms to increase their expected profits from investments in research and development while fostering innovation that would not occur but for the existence of the patent.[5] Patents, moreover, promote the dissemination of scientific and technical information that would otherwise be unavailable but for the prospect of the patent.[6] In short, as indicated by World Intellectual Property Organization, patents are a mechanism that encourages creative activity, industrialization, investment, and honest trade thereby, contributing more to our global safety and comfort, less poverty and more beauty in our lives. The strength of a robust patent system and the protections accorded by such a system is rationalized by several goals. They include, 1) incentivizing creativity; 2) rewarding creativity; 3) providing rights to patent owners for the fruit of their creative labor; 4) satisfying principles of moral and natural rights; 5) promoting public disclosure of new information; 6) facilitating transfer of innovation;

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[4] *See* INNOVATION IN GLOBAL INDUSTRIES: U.S. FIRMS COMPETING IN A NEW WORLD (Collected Studies) 243 (2008).

[5] *See Antitrust Modernization Commission: Hearing on Patent Law Reform*, 109th Cong. 2 (2005) (statement of Susan. S. DeSanti, FTC Deputy General Counsel for Policy Studies.)

[6] *Id.*

7) facilitating investment in innovation; and 8) implementing industrial policy.

As a new entrant into the world economy, biotechnology and its associated patents and intellectual property are subject to pubic and political climate changes that may either adversely or positively impact biotechnology innovation. Theses changes, for example, range from legislative reform to judicial decisions to challenges to the United States Patent Office rule-making authority and to the United States Trade Commission patent enforcement activities to the TRIPS implementation. All of these policy and reform activities have, as a result, added a level of uncertainty to patent procurement, enforcement and business decision making. Clearly, the biotechnology industry, in its relative infancy, is confronted with challenges as it navigates through the myriad of patent related reforms and, in some cases, general public and political opposition to biotechnology patents. To understand these challenges, it is important to understand the development of patent law and patent policy in addition to the global demand for biotechnology and the impact of changes on biotechnology investment and innovation.

As we turn our attention to patent Law and Policy Development, we understand that the global demand for biotechnology and its resultant

products is significant. This demand is driven by the needs of a growing and aging world population and by the innovation that emerges from patent laws and policies.[7] To fully appreciate patent laws and policies, it is important to understand the historical context from which they have evolved. Patent laws, for example, were first promulgated in Venice during the 15th century as part of a policy to improve a fledgling Venetian economy that was suffering as a result of a substantial war between Venice and Turkey.[8] The impetus of Venetian patent law was the recognition that knowledge of a craft or a technology, such as the art of glassmaking, could have value apart from the products produced by such craft or technology.[9] The stated governmental policy regarding patents encouraged inventions by making it unprofitable for infringers to copy inventions and "take the inventor's honor away."[10] Granting inventors exclusive rights to their inventions, the Venetian patent law system influenced other countries to develop policies that would stimulate invention and innovation and the development of new industries through the issuance of patents.[11]

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[7] INNOVATION IN GLOBAL INDUSTRIES: U.S. FIRMS COMPETING IN A NEW WORLD (Collected Studies) 239 (2008).

[8] *See* Srividhya Ragavan, *Can't We All Get Along? The Case for a Workable Patent Model,* 35 ARIZ. ST. L.J. 117, 121 (2003).

[9] *See* Thomas M. Meshbesher, *The Role of History in Comparative Patent Law,* 78 J. PAT. & TRADEMARK OFF. SOC'Y 594, 605 (1996).

[10] *Id.*

[11] *Id.*

The Venetian law, which granted inventors exclusive rights for a limited time, influenced development of patent law and policy in other countries.[12] France and the Netherlands in the sixteenth, seventeenth and eighteenth centuries developed policies that resulted in the grant of patents to individuals; thus, creating private rights as an incentive for encouraging individuals to create new inventions.[13]

The British system of patent law, developed some 100 years after the Venetian system, developed in the form of the crown's prerogative to issue letters patent bestowing privileges upon individuals in furtherance of royal policies. This was the beginning of a deliberate and vigorous policy to expand British industry.[14] These letters patent were issued to foreigners coming to England for the purpose of training British subjects in various trades.[15] A tool of economic development,[16] they were also granted to attract foreign industries into England enabling Britain to become economically self-sufficient.[17] Clearly, the policy surrounding the development of patent laws in the United Kingdom was fueled by the need to stimulate domestic production and manufacturing. However, as part of a

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[12] Ragavan, *supra* note 8, at 121.

[13] Meshbesher, *supra* note 9, at 607.

[14] *Id.*

[15] Ragavan, *supra* note 8, at 122.

[16] Paul E. Schaafsma, *An Economic Overview of Patents*, 79 J. PAT. & TRADEMARK OFF. SOC'Y 241, 242 (1997).

[17] Ragavan, *supra* note 8, at 122.

reform that took place between the 1600s and 1800s there was a fundamental shift in British patent policy — a reform that went from viewing patents as a contract between the crown and the patentee to viewing patents as a social contract between the patentee and society. In short, the British patents evolved from being a royal prerogative to a system based on and adjudicated by common law courts to a system that is rooted in statute representing a legal right obtained by an inventor for the exclusive control over his invention.[18]

Unlike the British system of patent law which had its beginnings in royal prerogatives, the American patent law and policy is rooted in legislation and administrative procedure.[19] Viewed as the most dynamic patent system in the world, modern patent law and policy in the United States has its genesis in early drafts of the United States Constitution where the U.S. Congress was authorized to create a national patent law resulting in the subsequent introduction of the Patents Act in 1790.[20] This was a major reform in the history of patent law because it established important basic principles of patent law that serves as the bedrock of patent systems existing in other developed countries around the world. These principles include the

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[18] *Id.* at 123 (referring to the Patents Acts of 1997). *See also* Adam Mossoff, *Rethinking the Development of Patents: An Intellectual History, 1550-1800*, 52 HASTINGS L. J. 1255, 1255 (2001).

[19] Meshbesher, *supra* note 9, at 609.

[20] Ragavan, *supra* note 8, at 123.

ability of any person to 1) petition certain governmental officials to obtain a patent for an invention or discovery; 2) deliver to governmental officials a specification in writing "containing a description" of the invention to be patented; 3) petition for a patent for a term not exceeding a specified number of years; 4) petition for a patent on an invention that is sufficiently useful and important; 5) be accorded an evidentiary presumption favoring the patentee; and 6) be charged a fixed fee for filing a patent application.[21] Indeed, it was the Patents Act of 1790 coupled with the changing economic environment over the next century that lead to further reform.

Driven further by the economics of the time, the most significant of the patent law and policy reform that occurred subsequent to the Patents Act of 1790 was the promulgation of the Patent Act of 1952 (the "Patent Act"). This legislation, which represents the basic structure of the current U.S. patent law system, coupled with the subsequent passage of the Federal Courts Improvement Act[22] enabled the United States to emerge as the forerunner in encouraging patents in areas like chemicals, business methods, software and biotechnology. Development of patents in the emerging area of biotechnology became so vast in the U.S. that countries like Germany and

[21] *See* Patent Act of 1790, ch. 7, 1 Stat. 109 (1790). *See also* Meshbesher, *supra* note 9, at 610.

[22] The Federal Court Improvement Act established The Court of Appeals for the Federal Circuit and vested in it jurisdiction to hear patent appeals. 35 U.S.C. § 141 (2006).

the United Kingdom began to follow suit in the trend to support biotechnology patent development. Beginning with the Venetians, it has taken several centuries, influenced by the French, the British and the American patent systems, to develop a sustainable patent policy that has now made its way to influence the area of biotechnology.

Indeed, the United States and other developed countries have both strengthened the scope of patent laws while expanding the range of the subject matter covered. The intellectual property system and more specifically the global patent regime as we currently know it has grown and changed over the centuries through legal reforms as well as through business and technical innovation. Notwithstanding these gains in patent law development and reform, international protection of intellectual property, particularly patents, has been a global objective[23] bringing us to a time where creativity and innovation impacts everyone, rich and poor, in every nation — both developed and developing — affecting each of us in important and complex ways. More modern reform has begun to address these concerns through the enactment of the TRIPS Agreement.[24]

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[23] *See* Andrew Beckerman-Rodau, *Patent Law – Balancing Profit Maximization and Public Access to Technology*, 4 COLUM. SCI. & TECH. L. REV. 1, 2 (2002).

[24] Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, 33 I.L.M. 1197 (1994). *See also* Ragavan, *supra* note 8, at 117 and *Id.*

The TRIPS Agreement introduced intellectual property law into the international trading system for the first time, and remains the most comprehensive international agreement on intellectual property to date. TRIPS requires member countries to grant patents in all fields of technology, subject to the normal test of novelty, inventiveness and industrial applicability and without regard to the place of the invention.[25] TRIPS also allows member countries to, among other things, enforce intellectual property rights through trade sanctions.[26] The TRIPS Agreement specifies the subject matter to be protected, the minimum duration of protection as being twenty years, the rights to be conferred and permissible exceptions.[27] In as much as the TRIPS Agreement provides member states a comprehensive global patent regime, there are concerns, particularly those posited by developing countries, that economic conditions of their respective nations may preclude their embracing the Agreement.[28] Notwithstanding the intent and benefits of TRIPS, developing countries are struggling to adjust to the heightened standards of intellectual property protection required by TRIPS while also seeking to harmonize their domestic patent laws and

[25] Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, 33 I.L.M. 1197 (1994).

[26] *Id.*

[27] *Id.*

[28] Reichman and Dreyfuss, *supra* note 3, at PINPOINT.

policies at the international level.[29] Some would argue that while the TRIPS Agreement elevated patent standards globally, developing countries are struggling to absorb the social costs inherent in complying with this regime.[30] The British Government's Department of International Development through its Commission on Intellectual Property Rights concluded that an expansion of intellectual property rights under TRIPS is unlikely to result in significant benefits for most developing countries. Should developing countries be coerced into accepting developed world practices in patenting, the likelihood of higher priced medicines and other biotechnology related products would be the outcome.[31] Similarly, the African Group of countries in the World Trade Organization further expressed the concerns of developing countries on this point concluding that the expanded global patent regime outlined in the TRIPS Agreement has the propensity of yielding high priced patented drug treatments putting treatments for diseases like HIV/AIDS and other vitally-needed medicines out of the reach of those who need these treatments most.[32] Those who argue against the TRIPS level of international patent reform, however, fail to

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[29] *Id.*

[30] Ragavan, *supra* note 8, at 118. *See also* Reichman and Dreyfuss, *supra* note 3, and Beckerman-Rodau, *supra* note 23.

[31] *See* Commission on Intellectual Property Rights, Integrating Intellectual Property Rights and Development Policy: Report of the Commission on Intellectual Property Rights (2002).

[32] *See* Cecilia Oh & Ruth Mayne, *Please Join in the NGO Statement: 'Patents and Medicines: The WTO Must Act Now!* (2001), http:/www.twnside.org.sg/title/joint4.htm.

understand that TRIPS and harmonization provide needed incentive for inventors to invest in innovative sectors like biotechnology, to make high technology products available to local industries, to provide patent and licensing arrangements while providing a platform for direct foreign investment.[33]

From the early development of patent law and policy to the more modern day patent regimes to facilitate the growth of economies and the development of new technology sectors such as biotechnology, we as a world community, more than ever, possess the appropriate economic tools in patents to incentivize the inventive process and innovation. In doing so, through the efforts and knowledge base of biotechnology firms, we position ourselves to develop and identify treatments for some of the world's deadliest diseases — namely cancer, heart disease, Parkinson's, Alzheimer's, HIV/AIDS and others.

Global Demand for Biotechnology

With patent law and policy development as a framework, let us turn our attention to biotechnology and the global demand. Biotechnology is one of the most promising new high-tech phenomena advancing our global economy. It is responsible for a new wave of DNA based therapeutic drugs

[33] Reichman and Dreyfuss, *supra* note 3, at 94.

and diagnostics fueling the development of innovative products including genetically engineered forms of substances like insulin, human growth hormone and therapies like Enbrel for rheumatoid arthritis and Gleevec, a treatment for chronic myelogenous lukemia.[34] It is also a complex, fast moving, highly entrepreneurial, science-driven discipline that continually calls for new and evolving approaches to solving some of the global health issues that affect each and every one of us around the world. Relative to the size of other industries, the absolute size of the biotechnology industry is modest. However, the engine of innovation for the drug development industry, biotechnology firms achieved record revenue in 2007 crossing the $80 billion threshold for the first time.[35] Referring to the following chart, we see that year over year revenue has increased from $73 billion with an upward trend over the last three years. As biotechnology companies seek to achieve competitive advantage through the exploitation of their intellectual property generally and their patents more specifically, managing these assets and responding to the influence of patent policy makers in this area has become a key issue for these companies. The history of biotechnology patenting in the U.S. essentially arose out of the development of

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[34] *See* John A. Tessensolm, *Publish and Not Perish: Japan's Universities Designated to Enjoy Patent Novelty Grace Period Amidst Promethean Changes In Biotechnology & University Patenting*, 8 ASIAN PACIFIC L. & POL'Y J. 292, 293 (2007) (referring to note 6).

[35] *See* ERNST & YOUNG, BEYOND BORDERS: GLOBAL BIOTECHNOLOGY REPORT 23 (2008).

methodologies in the 1970s and early 1980s that allowed for the cloning of human genes. These genes produced large quantities of recombinant human protein therapeutics, which were the first important products of biotechnology.[36] The formal recognition of biotechnology patents occurred during this period with the U.S. Supreme Court decision in a case in which a General Electric Company genetic engineer applied for a patent on a genetically engineered bacterium that could break down crude oil.[37] The issuance of the patent was allowed on the basis that patent law, according to the Court, extends to living creatures as long as they are not naturally occurring but made by humans.[38] As a result of the Supreme Court's decision in this case and subsequent cases, legislative action and a resultant favorable patent climate for biotechnology innovation, the U.S. benefited from an environment that encouraged the commercialization of new biotechnology products.[39] Indeed, the United States is the dominant country of origin for biotechnology innovations, even those innovations that may be patented in Europe.[40] This view is further illustrated in the graphs in Figure

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[36] *See* Christopher M. Holman, *The Impact of the Human Gene Patents on Innovation and Access: A Survey of Human Gene Patent Litigation*, 76 UMKC L. REV. 295, 323 (2007).

[37] Diamond v. Chakrabarty, 447 U.S. 303, 305 (1980).

[38] MICHAEL R. TAYLOR AND JERRY CAYFORD, RESOURCES FOR THE FUTURE, AMERICAN PATENT POLICY, BIOTECHNOLOGY, AND AFRICAN AGRICULTURE: THE CASE FOR POLICY CHANGE 30 (2003).

[39] Raine Hermans et al., Biotechnology, in Innovation in Global Inudstries: U.S. Firms Competing in a New World 231, 259 (Jeffrey T. Macher & David C. Mowery eds., 2008).

[40] *Id.* at 256.

1, which highlight the number of biotechnology patents filed in the US Patent and Trademark Office and the European Patent Office by region of origin of the inventor. In both instances we see that the United States has at least doubled the innovative capacity of Japan and the European Union. This gap is, in large part, the result of the large scale private and public biotechnology research funding in the United States relative to Japan and the European Union.[41]

Notwithstanding the U.S. lead, attempts to close the gap between the United States and the European Union occurred through the European Union's implementation of the Directive on Legal Protections of Biotechnologies. The implementation of this Directive was a significant step by the European Union towards improving the patent climate for the biotechnology industry in Europe[42] for the attraction and retention biotechnology innovation. Such effort allows the EU to keep pace with U.S. biotechnology and the competition for research dollars while also creating a friendly environment for biotechnology research.[43] In addition, research and development investment expenditures in the U.S. are an order of magnitude higher than any other individual country. Similarly, venture capital

[41] The National Institute of Health, for example, through its increases in funding, complements venture capital and private investment which is typical in biotechnology.

[42] *See* Robin Beck Skarstad, *The European Union's Self-Defeating Policy: Patent Harmonization and the Ban on Human Cloning*, 20 U. PA. J. INT'L ECON. L. 353, 353-54 (1999).

[43] *Id.* at 355.

investment in the U.S. is greater than other countries signifying the United States' continued dominance in the creation and evolution of biotechnology enterprises.[44] Referring to Figure 2, if we view biotechnology as three classes — health-oriented biotechnology (Red), agriculture-focused biotechnology (Green) and industrial-related biotechnology (White) — we find that U.S. leadership in biotechnology is in patent classes that are more related to health-oriented biotech while the EU and Japan patenting activity is greater in the agriculture-focused and industrial related biotechnology areas. The patterns shown in Figure 2 reflect the historical strength of the EU in the chemical industry and related industrial applications of biotechnology. Similarly, the relative strength of Japanese inventors is apparent in areas such as waste disposal and the environment and chemicals. These patterns and figures suggest that the United States leadership in biotechnology is by no means monolithic.[45] According to the World Intellectual Property Organization, in the last year, we have seen a plethora of patents filed under the Patent Cooperation Treaty, which serves as the cornerstone of the international patent system.[46] Referring to Figures 3 and 4, with the U.S., Japan and Germany leading in filings, a total record of

[44] Hermans et al., *supra* note 39, at 253.

[45] *Id.* at 260.

[46] Press Release, World Intellectual Property Organization, Unprecedented Number of International Patent Filings in 2007 (Feb. 21, 2008), http://www.wipo.int/pressroom/en/articles/2008/article_0006.html.

156,000 applications was filed in 2007. This represents a 4.7% rate of growth in filings over the previous year with the U.S. representing 34% of the total global patent filings in 2007. The growth as reflected in the chart indicates shifting patterns of innovation around the world. It also reflects the relative strength of patents, including those which are biotechnology related, as visualized from a three dimensional perspective and as depicted in Figure 5. In this regard, consideration of patents is given in terms of 1) legal scope — considering the scope of exclusive rights in the covered subject matter; 2) geographical range — considering validity of rights in various countries; and 3) duration — considering the length or duration of the rights derived from the patent. Notwithstanding the growth rate in total patent filings, the gap in the global distribution of biotechnology patents and innovation between the United States and the rest of the world has remained relatively constant.[47] To close this gap, it requires a greater diffusion of ideas which leads to newer ideas through the expansion of public domain knowledge on which others can build. It is a cycle, as depicted in Figure 6 that results in the creation of new works from existing knowledge with sharing and establishing a new threshold for innovation.

[47] *Id.*

Key Patent Activities Affecting Biotechnology

As we turn to key patent activities affecting biotechnology, it is important to note that U.S. leadership in biotechnology has benefited historically from a strong intellectual property environment. Policies ensuring effective and efficient operation of the U.S. patent system, fostering early-stage venture capital investment, and enhancing the effectiveness of technology transfer are likely to enhance the strength of the U.S. and the global biotechnology sector.[48] However, some recent patent reform activities may have a negative impact on the ability of the U.S. to continue its leadership in biotechnology in a changing policy environment. Some of the key reform proposals under discussion by government and industry groups include: 1) first-to-file patent system; 2) limits on filing of continuation patent applications; and 3) limits on availability of injunctive relief.

First-to-File

With respect to a first-to-file system of patents, many hurdles and problems encountered by inventors in general could be minimized or eliminated. The United States is currently the only country in the world that gives priority to the application that claims the earliest invention date i.e.

[48] Hermans et al., *supra* note 39, at 266.

"first person to invent," regardless of which application arrives first. A first-to-file system as opposed to "first person to invent" system would provide certainty in the patent application process by a clear metric of a filing date. First-to-file would eliminate costly interference proceedings used to determine priority of invention dates, and it would harmonize US patent practice with the rest of the world, especially with the European Patent Office and the Japan Patent Office.[49]

However, a first-to-file patent system may not be the best for biotechnology or small inventors. Because of their complexity, biotechnology inventions may take a long time to develop, and a race to the patent office under a first-to-file system would likely lead to patent applications that do not satisfy the requirements for enablement and written description. Moreover, small inventors may lack the resources for expedited research and patent filings which would be necessary for success under a first-to-file system.

Continuation Applications

In the case of Continuation Applications, it is a well-settled practice in U.S. patent law that patent applicants can file an unlimited number of continuation applications that claim the benefit of the filing date of the

[49] Robert M. Seto, *A Federal Judge's View of the Most Important Changes in Patent Law in Half-A-Century*, 11 J. TECH. L. & POL'Y 141, 146 (2006).

original patent application. Continuation practice is extremely important to the biotechnology and pharmaceutical industries because it allows patent applicants time to continue research and development efforts to improve their discoveries and refine their technologies for commercialization. Because biotechnology companies typically file broad initial patent applications on a class of new drug products or therapeutics, which applications are subsequently refined and narrowed, continuation applications are the key to achieving the best patent coverage.

The United States Patent and Trademark Office last year proposed new rules that would restrict the use of continuations in patent prosecution.[50] Last year, SmithKline Beecham Corporation filed a lawsuit against the United States Patent and Trademark Office to enjoin it from enacting the proposed rules.[51] This action by SmithKline was an historic challenge to rulemaking authority in an effort to protect the existing continuation practice. I represented Elan Pharmaceuticals in an amicus filing supporting SmithKline. As a result, we were successful in getting the United States District Court to permanently enjoined the United States Patent and Trademark Office from enacting the proposed changes to the continuation

[50] Changes to Practice for Continued Examination Filings, Patent Applications Containing Patentably Indistinct Claims, and Examination of Claims in Patent Applications, 72 Fed. Reg. 46716 (proposed Aug. 21, 2007) (to be codified at 37 C.F.R. pt. 1.114 – pt. 1.78).

[51] Tafas v. Dudas, 541 F.Supp.2d 805 (E.D. Va. 2008).

practice.[52] Preserving the practice of filing unlimited continuation applications will allow biotechnology and other science-based firms to develop and implement the best patent procurement strategies.

Injunctive Relief

Turning to injunctive relief, the issuance of permanent injunctions by trial courts in the U.S. has been a practice which is consistent with the fundamental right to exclude others from making, using, offering for sale or selling a patented invention. Injunctions were usually issued automatically once there had been a finding of infringement and validity. Last year, the U.S. Supreme Court in the case of *eBay v. MercExchange LLC*[53] decided that lower courts, in granting permanent injunctions to exclude others from making, using or selling a plaintiff's patented product, must consider the well established four-factor test in determining whether injunctive relief should be granted. Under the four-factor test, consideration should be given to: 1) whether the plaintiff suffered an irreparable injury; 2) whether the remedies available at law, such as monetary damages, are inadequate to compensate for that injury; 3) whether, in considering the balance of the hardships between the plaintiff and defendant, a remedy in equity is warranted; and 4) whether the public interest would be served by the

[52] *Id.* at 817.

[53] 126 S.Ct. 1837 (2006).

issuance of a permanent injunction.[54] While the Court's decision in *eBay* is consistent with the current patent statute which mandates courts to grant injunctions in accordance with the principles of equity, the Court's ruling was more than likely influenced, in significant part, by changes in technology, new trends in patent cases, and a past practice of not granting injunctions where the patent holder is primarily using his patents for obtaining licenses, where the patented invention is but a small component of the infringing product or where the patent is for a business method.[55] The Court's decision brings patent cases in line with other equitable actions and causes biotechnology companies and other related technology companies to raise concerns related to strategy and planning for leveraging their patent portfolios.

Other Key Patent Activities Affecting Biotechnology

Notwithstanding the U.S. leadership role in sustaining a viable patent system, the reforms that I have discussed may lead some inventors and innovators to believe that a greater level of uncertainty does in fact exist in the patent practice. Adding to this uncertainty is the totality of court decisions, congressional reform, United States Patent and Trademark Office rule changes, U.S. Federal Trade Commission (FTC) enforcement activities

[54] *Id*. at 1839.

[55] *Id.* at 1842 (Kennedy, J. concurring).

and media related scrutiny. Focusing specifically on court decisions, the U.S. Supreme Court has recently played more of an activist role in shaping the current state of patent law since the establishment of the Court of Appeal for the Federal Circuit in 1982. According to a study by Professor John Duffy of George Washington University School of Law, the U.S. Supreme Court has traditionally heard one patent case every two years. In the past three years the Court's involvement has been enhanced to include reviewing three patent cases every two years. The reason for this increased Supreme Court activity is not clear. Could it be because of increasing frustrations with the decisions of the Circuit Court of Appeals for the Federal Circuit? Is it over-aggressiveness of patent owners in obtaining and enforcing patent rights? Is there a need to harmonize patent law with other legal jurisprudence? Is it the huge impact that patents have on innovation, corporate valuation and overall global economy? Is it lastly, the increased media attention focused on bad patents and evils of intellectual property? Some would argue that the preponderance of the recent U.S. Supreme Court cases has weakened the rights of patent owners by making it more difficult to obtain injunctions on the one hand and easier to challenge or invalidate patents on the other.

A good example of the weakening of patent rights by the US Supreme Court is the case of *Merck KGaA v Integra Lifesciences I, LTD*.[56] Integra held patents directed to a class of compounds that Merck tested for use with angiogenesis inhibiters. Integra filed a patent infringement action against Merck, alleging that the use of its patented compounds in preclinical testing constituted patent infringement. The Court, in its decision, concluded that in certain circumstances drug companies can conduct preclinical research using patented compounds without risk of infringement.[57] Given the decision in *Merck v. Integra* and other recent Supreme Court decisions related to the validity of patents, pundits and Court watchers contend that the Court may be improperly legislating from the bench for outcomes that ultimately diminish the rights of patent owners.[58]

Issues to Watch – Final Thoughts

As I bring this discussion to a conclusion, I would like to share with you some final thoughts regarding issues to watch. As we discussed, at the broadest level biotechnology is an industry that includes innovation and commercialization that are supported by patents. The breadth of patent filings and the issuance of patents on more basic discoveries are on the rise.

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[56] 545 U.S. 193 (2005).

[57] *Id.* at 208.

[58] *See, e.g., Impact of Patent Law Changes on Biomedical Investment and Innovation*, California Healthcare Institute (2008), http://www.chi.org/uploadedFiles/CHI%20Patent%20Law%20changes%20paper.pdf

This pattern, however, has created what some would characterize as a "Patent Thicket"[59] in biotechnology. That is, emerging from the overabundance of patent filings and associated activity is "a dense web of overlapping intellectual property rights"[60] that requires those seeking to commercialize new technology to obtain licenses from multiple patentees.[61] Pharmaceutical companies typically grow a patent thicket seeking a wide range of chemical variants and analogs, methods of synthesizing the drug, chemical intermediates in this synthesis, different crystal forms, different finished dosage forms and various methods of use.[62] Obtaining permission from various patent holders for use of patents can prove to be difficult particularly if the patent holder's objective in creating the thicket is to block innovation by outsiders. Because useful innovation in biotechnology requires multiple inventive steps and technologies, we could conceivably witness cumulative innovation with infringement on many patents which ultimately serves as a drag on innovation and commercialization.[63]

Another area which is emerging as a significant topic for consideration in patenting circles and is tangentially related to the "Patent

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[59] TAYLOR AND CAYFORD, *supra* note 38

[60] *See Navigating the Patent Thicket: Cross Licenses, Patent Pools and Standard Setting*, *in* 1 INNOVATION POLICY AND THE ECONOMY 119, 120 (Adam B. Jaffe, Josh Lerner & Scott Stern eds., 2001).

[61] *Id.*.

[62] *See* MICHAEL A. GOLLIN, DRIVING INNOVATION: INTELLECTUAL PROPERTY STRATEGIES FOR A DYNAMIC WORLD 168-69 (2008).

[63] Jaffe et al., *supra* note 60, at 121.

Thicket" phenomenon is compulsory licensing in both the U.S. and in Europe. While compulsory licensing in the U.S. is not a creature of patent law, an example of where there is an attempted statutory direction for compulsory licensing is through the implementation of the Bayh-Dole Act.[64] This act permits compulsory patent licensing when a recipient of federal grants and contracts has not taken, or is not expected to take within a reasonable time, effective steps to achieve practical applications of the subject invention. Attempts have also been made to carve out a compulsory licensing remedy judicially such as in the *eBay* case where the courts have utilized a public interest test in determining whether injunctive relief should be granted — the effect of which is compulsory licensing. In the European Union, the issue of compulsory licensing is murky, notwithstanding the existence of the Doha Declaration which allows for compulsory licensing in developed countries for the manufacture of patented drugs.[65]

Lastly, proposed legislation for bio-generics or bio-similars[66] should be carefully followed by the biotechnology industry. There is no current regulatory pathway for bio-generic products in the United States, although the European Union has enacted some regulations. Bio-generic and bio-

[64] Bayh-Dole Act, 35 U.S.C. §§ 200-212 (2008).

[65] World Trade Organization, Ministerial Declaration of 14 November 2001, WT/MIN(01)/DEC/1, 41 I.L.M. 746 (2002) [hereinafter Doha Declaration].

[66] Bio-similars refers to approved recombinant drugs (e.g. insulin, human growth hormone, interferons, erythropoietin) which are copied and marketed after the expiration of their patents.

similar regulations over the coming years will have a huge impact on the competitive landscape for biotechnology products.

Conclusion

In conclusion, the global intellectual property system, since the days of the Venetians, has evolved from a system of sectarian interest and parochial politics to one which is open to ensuring innovation throughout the world. More specifically, the international patent system "has entered a brave new scientific epoch"[67] in which scientists, inventors, researchers, jurists and business persons are beginning to understand how best to treat the daunting array of discoveries emerging from biotechnology.[68] With the U.S. patent system as the standard bearer and TRIPS as the global enforcer, innovation and the commercialization of biotechnology will not only be ensured, but it will also be guaranteed that life-saving medicines and other related products, which are a result of patented discoveries, will reach those in world who are most in need. The global patent system as we know it is not a perfect system but it is one that holds promise for success and one that

[67] Reichman and Dreyfuss, *supra* note 3, at 129.
[68] *Id.*

will allow us, as a world community, to heal, fuel and feed this planet we all share.[69]

Thank you for this opportunity to speak. I am happy to respond to any questions that you may have at this time.

[69] See A Vision For Innovation: Healing, Fueling and Feed the World, Address by the Honorable James C. Greenwood, President & CEO, Biotechnology Industry Organization, BIO International Convention, San Diego, California (June 19, 2008)

Figures

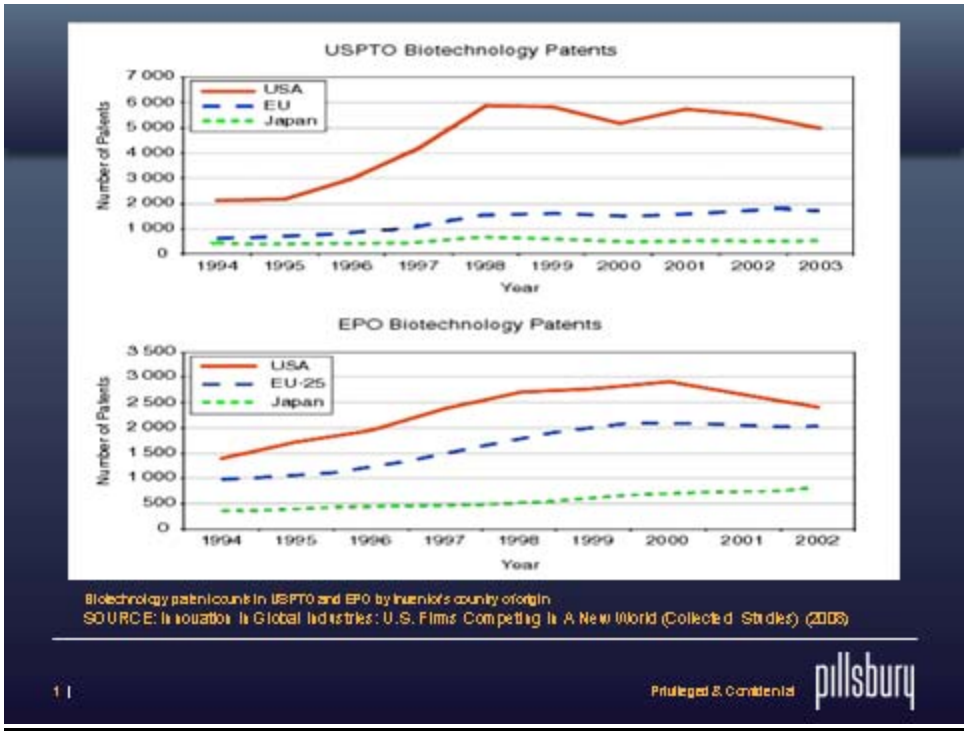
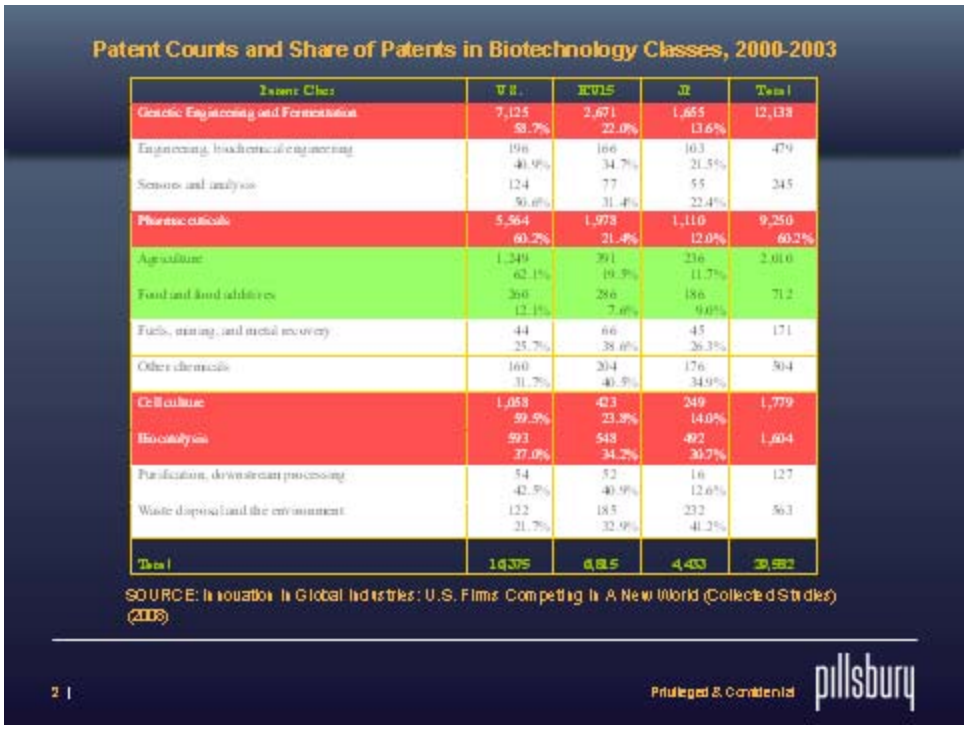


Figure 1



Patent Class	U.S.	EU15	JP	Total
Genetic Engineering and Fermentation	7,125 58.7%	2,671 22.0%	1,655 13.6%	12,138
Engineering, biochemical engineering	196 40.9%	166 34.7%	103 21.5%	479
Sensors and analysis	124 50.6%	77 31.4%	55 22.4%	245
Pharmaceuticals	5,564 60.2%	1,978 21.4%	1,110 12.0%	9,250 60.2%
Agriculture	1,249 62.1%	391 19.5%	236 11.7%	2,010
Food and food additives	266 12.1%	286 7.6%	186 9.0%	712
Fuels, mining, and metal recovery	44 25.7%	66 38.6%	45 26.3%	171
Other chemicals	160 31.7%	204 40.5%	176 34.9%	504
Cell culture	1,058 59.5%	423 23.8%	249 14.0%	1,779
Biocatalysis	593 37.0%	548 34.2%	492 30.7%	1,604
Purification, downstream processing	54 42.5%	52 40.9%	16 12.6%	127
Waste disposal and the environment	122 21.7%	185 32.9%	232 41.2%	563
Total	16,305	6,815	4,433	39,982

Figure 2

Figure 3

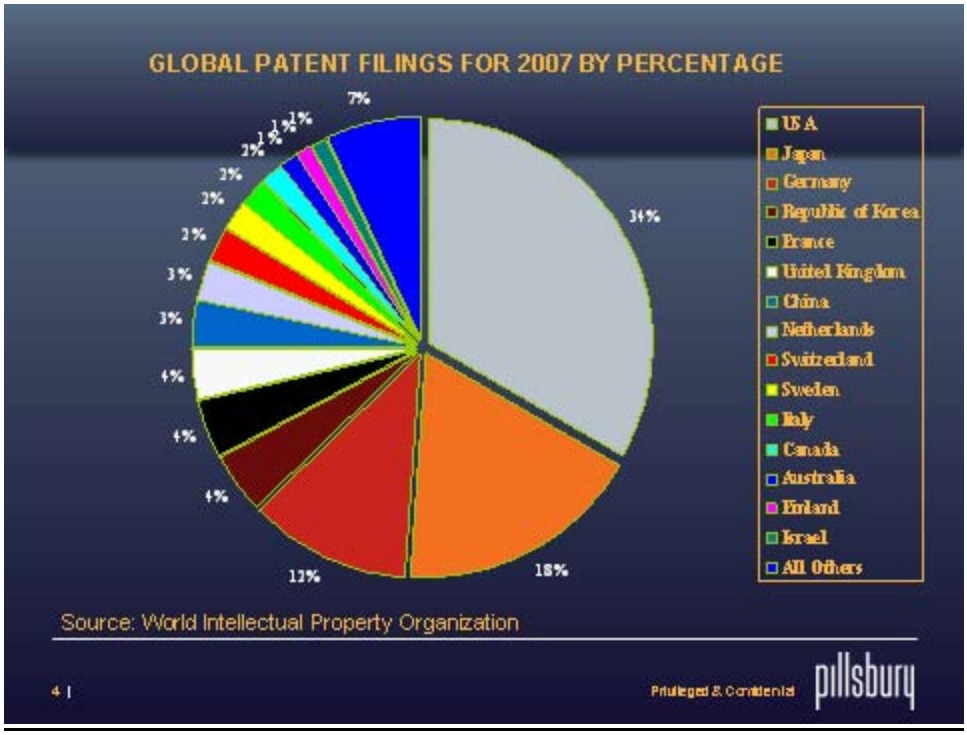


Figure 4

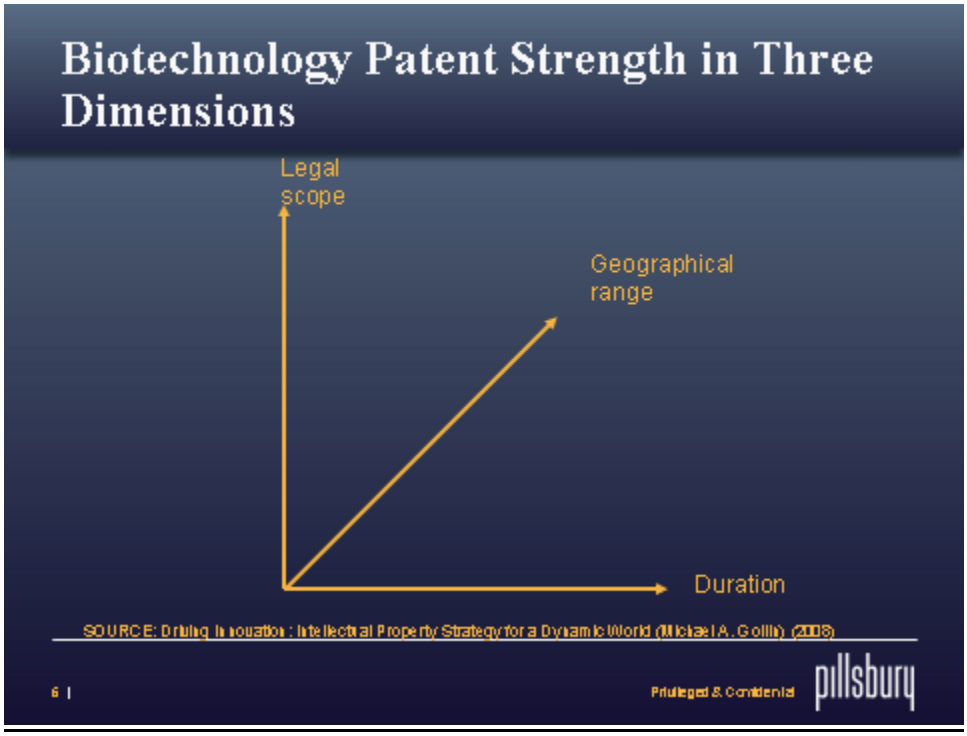


Figure 5

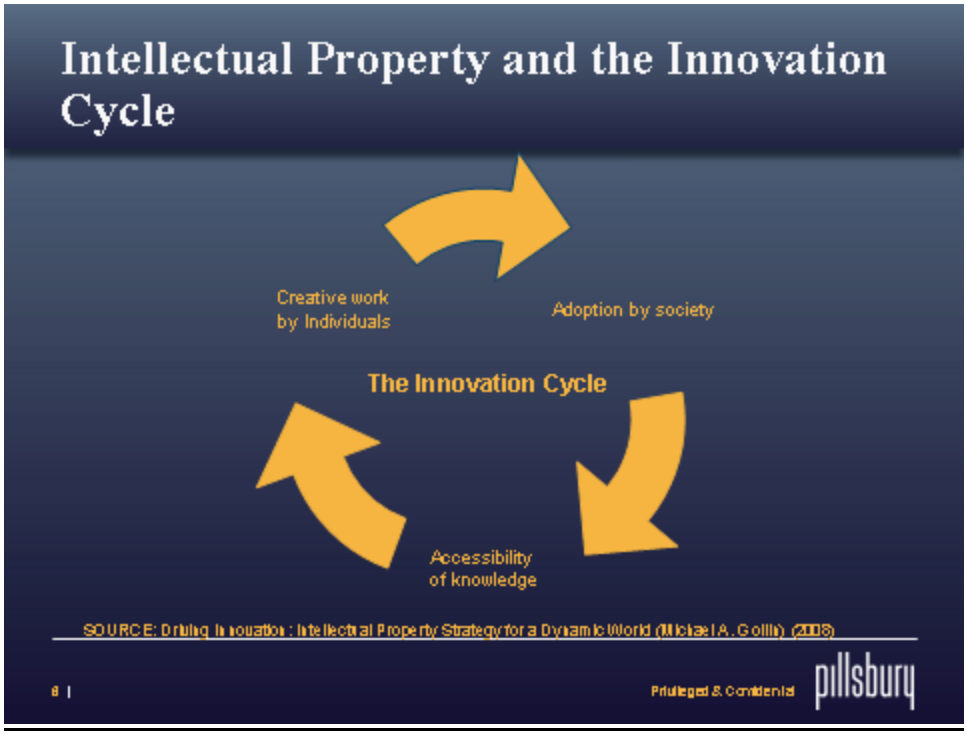


Figure 6