

Testimony Before the House Judiciary Subcommittee on Courts, the Internet, and Intellectual Property

30 October 2007 Hearing on
*Stifling or Stimulating –
The Role of Gene Patents in Research and Genetic Testing*

Statement of
Lawrence M. Sung[†]
*Law School Professor & Intellectual Property Law Program Director,
University of Maryland School of Law;
Partner, Dewey & LeBoeuf LLP*

[†] Correspondence addresses: University of Maryland School of Law, 500 West Baltimore Street, Baltimore, MD 21201-1786, 410.706.1052, lsung@law.umaryland.edu; Dewey & LeBoeuf LLP, 975 F Street, NW, Washington, DC 20004-1405, 202.862.1025, lsung@dl.com. B.A. Biology, University of Pennsylvania; Ph.D., Microbiology, U.S. Department of Defense – Uniformed Services University of the Health Sciences; J.D. cum laude, American University, Washington College of Law; former judicial clerk to the Honorable Raymond C. Clevenger, III, U.S. Court of Appeals for the Federal Circuit.

Introduction

Chairman Berman, Ranking Member Coble, and Members of the Subcommittee, good afternoon. Thank you for this opportunity to appear before you to discuss the possible implications of patent protection for genomic inventions. I testify here on my own behalf, and my views are not necessarily those of any institution with which I am associated. While the other witnesses to this hearing are providing particular perspectives regarding the impact that gene patents might have on research and genetic testing, my testimony will focus on the nature of gene patents and the considerations surrounding the implementation of certain strategies, which have been proposed to balance, in varying degrees, the interests of commercial exclusivity with public access to genetic technology. To facilitate an understanding of the complexities involved, I would like to begin with an overview of gene patents.

What Is A Gene Patent?

The term “gene patent” is not part of a nomenclature with a customary or universally accepted meaning. I have heard the use of this term generically to refer to patents as well as patent applications where all or just some of the claims pertain to subject matter ranging from a full-length deoxyribonucleic acid (DNA) sequence that encodes a complete protein to a DNA sequence that has unknown biologic significance. Because the same term, “gene patent,” is often applied to very different things technically speaking, the legal governance of this technology is at sea without some measure of precision in the communication of what is being addressed. Indeed, a caution that reverberates throughout my testimony is the prudence to remain mindful that generalizations are problematic in this field.

Compounding the uncertainty that the science might carry is the vagary of our patent system that allows applicants to define their inventions in their own words, even where such definitions might otherwise contravene the customary meaning of such words to others skilled in the art. Accordingly, what one reads in a patent describing a “gene” may bear little resemblance to what a molecular geneticist would otherwise tell you a “gene” is as a matter of scientific truth. One can begin to appreciate the inherent difficulty in having confidence in a race where the starting line itself is debatable.

Without further technical elaboration, allow me for purposes of our brief time together to refer to a “gene” as a full-length DNA sequence that encodes a complete protein, and to any other DNA sequence with unknown or questionable biologic significance as a “genomic fragment,” and in some cases, as an expressed sequence tag (ESTs) or single nucleotide polymorphisms (SNP). Accordingly, when I refer to a “gene patent,” I will mean a patent that claims at least a DNA sequence that encodes a complete protein or a portion thereof. In this regard, traditional gene patents have been around for a relatively long time whereas patent applications claiming genomic

fragments of unknown or questionable biologic significance (such as ESTs and SNPs) have been the crux of more recent controversy.

Patenting DNA and Rising Concerns

Although DNA is naturally occurring as the biologic blueprint for living organisms, our patent system recognizes the subject matter as patentable where the claims set forth in a patent application properly distinguish the invention from the form of the genomic DNA found naturally. Because our patent system does not differentiate between the notions of invention and discovery, the elucidation of subject matter found in nature may nevertheless give rise to valid patent claims that relate to the natural product or process. Of course, beyond the qualification as statutory subject matter under 35 U.S.C. § 101, a genomic invention must satisfy the remaining conditions for patentability (utility, novelty and nonobviousness) under 35 U.S.C. §§ 101-103, and the patent application must satisfy the disclosure requirements under 35 U.S.C. § 112, to obtain a patent. These standards help ensure that the public receives a valuable benefit from the disclosure of an innovative technology in return for a grant of temporary exclusivity to the patentee. One inherent problem with making sense of the patent law vis-à-vis genomic inventions is the temporal distortion that occurs between the time patent claims are filed and the time the U.S. Patent & Trademark Office (PTO) and/or federal courts pass on the patentability or invalidity of those claims. Particularly with genomic inventions, a decade or more can separate these two events.

Although faced routinely with new technologies, our patent system has perhaps with no other class of inventions been so significantly challenged in dogma. In particular, a patent applicant must be able to teach the public about the invention by providing a reasonably clear answer to two fundamental questions: “What is it?” and “What does it do?” With regard to traditional gene patents, the response would include disclosure of the full-length DNA sequence that encodes a complete protein in conjunction with information about the protein and its potential beneficial uses. As a matter of scientific research, months, if not years, of characterization efforts might be entailed.

In more recent times, The Human Genome Project embodied breakthrough technology that made it possible for scientists to obtain vast numbers of genomic fragments by automated isolation and purification to facilitate chemical formula descriptions (high throughput polynucleotide sequencing) without learning anything about their origin, fit or function. The rub was that such an abstract process of invention hardly came with a complete answer to what the invention was, much less yielded any insight as to what the invention did. The dilemma of knowledge without wisdom came to the fore, and this change in the scientific paradigm relating to genomic discovery created significant problems for our patent system.

In the late 1990s, numerous patent applications were filed claiming thousands of genomic fragments with bare indications of what they were and even fainter disclosures of what they did. Moreover, these patent claims were of broad enough scope to capture as an infringer any user of a product derived from genomic material that included a patented DNA sequence. Such fears rekindled the public outcry over gene patenting generally and its potential chilling effect on research and development. But the Patent Gold Rush was on. Still, like most gold rushes, the dreams of riches from the ownership of genomic data alone began to fade almost as quickly as they arose. The PTO established an instant moratorium on the examination of EST and SNP claims.

The PTO struggled with attempts to reconcile the applicability of traditional, generic principles of patent law to this emerging technology. The PTO initially issued the 1999 Revised Interim Utility Examination Guidelines, only to withdraw them in the face of critical public comment. The reissue of the PTO prescriptions in this regard ultimately came in the form of the 2001 Utility Examination Guidelines. The operative framework for meeting the requirements of 35 U.S.C. § 101 now includes the mandate for a patent applicant to articulate a specific, substantial and credible utility.

Stemming the Patenting of Genomic Fragments

In 2005, the U.S. Court of Appeals for the Federal Circuit closed this chapter in a long-awaited ending to the suspenseful story of whether gene patenting would include claims to genomic fragments of unknown biologic significance. In *In re Fisher*,¹ the Federal Circuit explained that a claimed invention must have a specific and substantial utility to satisfy 35 U.S.C. § 101, that an application must show that an invention is useful to the public as disclosed in its current form, not that it may prove useful at some future date after further research, and that an asserted use must show that that claimed invention has a significant and presently available benefit to the public. The Federal Circuit specified that an asserted use must also show that a claimed invention can be used to provide a well-defined and particular benefit to the public.

The Federal Circuit noted that as of the filing date of its patent application, Fisher admitted that the underlying genes had no known functions and that the claimed ESTs acted as no more than research intermediates that may help scientists to isolate the particular underlying protein-encoding genes and conduct further experimentation on those genes. Fisher compared the claimed ESTs to certain other patentable research tools, such as a microscope. The Federal Circuit explained, however, that although both a microscope and one of the claimed ESTs can be used to generate scientific data about a sample having unknown properties, Fisher's analogy was flawed because a microscope has the specific benefit of optically magnifying an object to immediately reveal its

¹ 421 F.3d 1365 (Fed. Cir. 2005).

structure. One of the claimed ESTs, by contrast, could only be used to detect the presence of genetic material having the same structure as the EST itself.

The Federal Circuit further explained that the claimed ESTs were unable to provide any information about the overall structure let alone the function of the underlying gene. To further the comparison, the Federal Circuit explained that while a microscope can offer an immediate, real world benefit in a variety of applications, the same cannot be said for the claimed ESTs. Fisher's asserted uses, therefore, did not meet the standard for a "substantial" utility under 35 U.S.C. § 101. According to the Federal Circuit, Fisher's asserted uses represented merely hypothetical possibilities, objectives which the claimed ESTs, or any EST for that matter, could possibly achieve, but none for which they have been used in the real world. The Federal Circuit further explained that Fisher's asserted uses were not sufficiently "specific" — that is, nothing about Fisher's alleged uses set the five claimed ESTs apart from the more than 32,000 ESTs disclosed in the patent application or indeed from any EST derived from any organism."

In addressing the patentability of the EST claims in *Fisher*, the Federal Circuit reinforced the quid pro quo of a suitable primer on the claimed invention in exchange for the patent grant. In the words of the U.S. Supreme Court about the utility requirement, "[A] patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion."²

Stricter Patent Standards

Since the *Fisher* decision, the concerns over the implications for gene patents has largely returned to a focus on patents claiming DNA sequences that encode a complete protein or a portion thereof. In the meantime, the standards for patenting inventions generally arguably have become stricter in light of the evolving jurisprudence in the doctrines of inherent anticipation and obviousness.

To receive patent protection, the invention must be novel, i.e., not anticipated by the prior art under 35 U.S.C. § 102. An invention is anticipated if a single prior art reference expressly or inherently discloses each and every limitation of the claimed invention.³ Thus, a prior art reference without express reference to a claim limitation may nonetheless anticipate by inherency.⁴ Inherency is not necessarily coterminous

² *Brenner v. Manson*, 282 U.S. 519, 536 (1966).

³ See *Scripps Clinic & Research Found. v. Genentech, Inc.*, 927 F.2d 1565 (Fed. Cir. 1991).

⁴ See *Titanium Metals Corp. v. Banner*, 778 F.2d 775 (Fed. Cir. 1985); *In re Omeprazole Patent Litig.*, 483 F.3d 1364 (Fed. Cir. 2007); *Abbott Labs. v. Baxter Pharm. Prods., Inc.*, 471 F.3d 1363 (Fed. Cir. 2006); *In re Crish*, 393 F.3d 1253, 1258-59 (Fed. Cir.

with knowledge of those of ordinary skill in the art. Artisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art.⁵ The new realization alone does not render that necessary prior art patentable.⁶ This evolution of the doctrine of inherent anticipation may make it more difficult for applicants to obtain gene patents, particularly those claiming only certain fragments of a gene, which is otherwise disclosed in the prior art.

To receive patent protection, an invention must also be nonobvious at the time of the invention to one of ordinary skill in the relevant art under 35 U.S.C. § 103. In *KSR Int'l Co. v. Teleflex Inc.*,⁷ the Supreme Court rejected a rigid application of the Federal Circuit's approach known as the teaching, suggestion, or motivation (TSM) test, under which a patent claim is only proved obvious if some motivation or suggestion to combine the prior art teachings can be found in the prior art, the nature of the problem, or the knowledge of a person having ordinary skill in the art.

The Court opined that inventions in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known. According to the Court, the obviousness analysis cannot be confined by an overemphasis on the importance of published articles and the explicit content of issued patents. The Court noted that granting patent protection to advances that would occur in the ordinary course without real innovation retards progress and may, in the case of patents combining previously known elements, deprive prior inventions of their value or utility. The Court admonished that when there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and

2004) (holding asserted claims covering a gene's nucleotide sequence anticipated where the gene, though not its particular sequence, was already known to the art); *In re Cruciferous Sprout Litig.*, 301 F.3d 1343, 1349-50 (Fed. Cir. 2002) (ruling that an inventor's recognition of substances that render broccoli and cauliflower particularly healthy does not permit patent on identifying broccoli seeds or preparing broccoli as a food product).

⁵ See *Schering Corp. v. Geneva Pharms.*, 339 F.3d 1373, 1377 (Fed. Cir. 2003) (rejecting the contention that inherent anticipation requires recognition in the prior art).

⁶ See *Bristol-Myers Squibb Co. v. Ben Venue Labs., Inc.*, 246 F.3d 1368, 1376 (Fed. Cir. 2001) (explaining that newly discovered results of known processes are not patentable because those results are inherent in the known processes); *Verdegaal Bros., Inc. v. Union Oil & Co. of Cal.*, 814 F.2d 628, 633 (Fed. Cir. 1987) (holding that the recognition of a new aspect of a known process is not a patentable invention of a novel process).

⁷ 127 S. Ct. 1727 (2007).

common sense. This relaxation of the obviousness standard may also make it more difficult for applicants to obtain gene patents, particularly those claiming a novel combination or other use of known genes and/or gene fragments.

As a separate matter, a reinvigoration of the inventorship standards might serve to decrease the issuance of gene patents. The patent law jurisprudence uniformly recognizes the elements of conception and reduction to practice in defining invention. But the typical analysis is confined to questioning when these acts might have occurred for purposes of determining who is an inventor or who invented first. Little consideration is apparent on whether certain purported acts of invention actually meet these well accepted standards and otherwise constitute inventive acts.

One proposal might be to recast an inventive act as a governing threshold for patent protection, particularly as applied to genomic inventions. This standard does not incorporate the traditional considerations, such as novelty or nonobviousness, in assessing patent eligibility. Rather, like the requirement of originality in copyright law, this metric considers whether the claimed invention legitimately “owes its origin” to the named inventor, or for that matter, to anyone. This normative proposition contemplates a minimal showing of inventive activity embodied in the conception of an invention in order to qualify for patentability. But to the extent that the conception of the invention cannot fairly be ascribed to an individual, i.e., the named inventor or another, the claimed invention would be deemed to have resulted from a non-inventive act, and thus, be ineligible for patent protection.

Facilitating Enhanced Public Access to Patented Technology

Various mechanisms exist to facilitate public access to patented technology generally. As applied particularly to gene patents, such mechanisms balance, in varying degrees, the interests of commercial exclusivity with public access to patented genetic technology.

Injunctive Relief Restraint. While our patent system does not provide for compulsory licensing *per se*, the denial of injunctive relief on the balance of the equities and/or the public interest factors of the traditional four-factor tests for determining whether to grant a preliminary or permanent injunction essentially amounts to a *de facto* ability of the infringer to continue to use the patented invention, albeit subject to a reasonable royalty. The decision in *eBay Inc. v. MercExchange, L.L.C.*,⁸ where the Supreme Court vitiated the Federal Circuit presumptive grant of permanent injunctive relief to a prevailing patentee plaintiff in favor of the reliance on the traditional four-factor test, sustains the possibility of this approach to allow greater public access to patented genetic technology.

⁸ 126 S. Ct. 1837 (2006).

Patent Pools. For a biotechnology company, there is arguably no greater asset than a proprietary position on genetic data that might become the platform for the development of commercially significant biological products. Besides its straightforward function as a direct template for such biologics, genomic data also has enormous potential as a basic research tool with many possible applications. The technical leap from knowledge of mere DNA sequence to such downstream applications, however, while perhaps grounded in accepted scientific methods, is certainly not trivial. Accordingly, the dependency of the biotechnology industry on patent exclusivity remains robust. Matching this are the continuing concerns over patent thickets and other obstacles to access and development.

As the biotechnology industry has matured, the embrace of cooperative market-based technology transfer strategies similar to those relied upon in other technology sectors is perhaps within reach. In 1998, I suggested that the interplay between historical experiences and future prospects in biotechnology made patent pooling arrangements a ripe consideration for the industry, and that the patent landscape should not be allowed to preclude the realization of financial rewards associated with the complex research efforts of biotechnology companies to understand and to harness the biological processes involved.⁹

At its core, biotechnology is the exploitation of nature's design, standing on the shoulders of the biological templates of DNA and ribonucleic acid (RNA). For biotechnology, genetic information represents an "industry standard" analogous to those described above in the electronics and telecommunications areas. Accordingly, the landscape of increasing patent protection to this genetic material favors the voluntary entry of biotechnology industry members into patent pooling arrangements.

Indeed, the vast amount of genetic information, and its significance as a fundamental research tool even absent functional knowledge, can give rise to an almost overwhelming number of patents, the true value of which may be unascertainable

⁹ Lawrence M. Sung *et al.*, *Greater Predictability May Result in Patent Pools As the Federal Circuit Refines Scope of Biotech Claims, Use of Collective Rights Becomes Likely*, Nat'l L.J. (Jun. 22, 1998), cited in USPTO White Paper, *Patent Pools: A Solution to the Problem of Access in Biotechnology Patents?* (Dec. 5, 2000). In 2002, I testified, during part of the Joint U.S. Department of Justice and Federal Trade Commission hearings on Competition and Intellectual Property Law and Policy in the Knowledge-Based Economy, that given the dynamics of biotechnology research and development, the reliance by the industry on cooperative market-based technology transfer strategies through patent pools or other collective rights organizations may be inevitable. Lawrence M. Sung, *Patent Pools and Cross-Licensing: When Do They Promote or Harm Competition?* (Apr. 17, 2002).

without the cooperative efforts of other companies. In any event, the overall transactional costs associated with risk assessments based upon this relatively uninformed valuation of patent rights may alone outweigh any perceived benefit to the maintenance of an isolationist business strategy.

The establishment of a biotechnology patent pool will depend on the convergence of several factors. The first involves the determination of the patents necessary to undertake a particular research effort. Once the patent pool members set out research goals and define the technological aspects required to accomplish those goals, an independent licensing agent or patent pool administrator can assess which patents would be essential to achieve a freedom to operate in this regard. This assessment should involve the technical and legal expertise of qualified biotechnology patent attorneys.

A biotechnology patent pool can thus have a more horizontal scope relating broadly within a discipline, for example, encompassing genetic information likely associated with a particular biological function. Alternatively, a biotechnology patent pool can reflect a more vertical integration of scientific methods across various disciplines, for example, providing freedom to operate from genetic screening and lead identification to drug discovery. The determination of the appropriate scope of technology governed by the patent pool further allows the administrator to decide whether an invitation to patent pool membership should be extended to certain nonmembers owning essential patents.

During the patent pool's existence, a responsibility of the administrator will also be the strict regulation of the composition of the portfolio, which will likely change through the addition of newly issued, essential patents and the deletion of expired, nonessential, invalid or unenforceable patents. The administrator can further attend to the solicitation and engagement of nonmember licensees, the collection and distribution of royalty income, and the enforcement and termination of licenses.

The fundamental features of a patent pool include the integration of complementary technologies, the reduction of transaction costs, the clearance of blocking patent positions and the avoidance of costly infringement litigation. Its effectiveness springs principally from a consensus among the participants that individual patent rights will be made available to other members on fair, reasonable and nondiscriminatory terms. In any event, the ability to obtain a straightforward, reliable freedom to operate in an otherwise complex arena of intellectual property will be a dominant appeal of a biotechnology patent pool for prospective participants and nonmember licensees alike. The interest in the possibility of biotechnology patent pools

as mechanisms to balance the interests of commercial exclusivity with public access to patented genetic technology has resurged in recent years.¹⁰

March-In Rights. Under 35 U.S.C. § 203 (codifying a portion of the Bayh-Dole Act), the federal government retains “march-in rights” for government funded inventions owned by small businesses or nonprofit organizations. In situations of nonexploitation of the invention or public health threat, the funding agency may request the patentee or exclusive licensee to grant an appropriate license to another. If the request is refused, the funding agency may grant its own license, without restriction, including a license grant to a direct competitor. While the federal government historically has never exercised such rights, this entitlement has arguably greater implications for government funded genomic inventions, presumably because of the heightened relevance of the subject matter to potential public health and bioterrorism concerns.

Clinical Trial Exemption. At present, the only statutory exemption to patent infringement liability exists with 35 U.S.C. § 271(e)(1), which is limited to activity reasonably related to the preparation and submission of an application for federal regulatory approval. Such activity may include experimentation and other data gathering. In this regard, § 271(e)(1) can be fairly characterized as an experimental or research use defense applicable only in the specific context of regulatory compliance.

While § 271(e)(1) exempts from infringement such activity by the generic drug manufacturer that would otherwise infringe § 271(a), so long as that activity is reasonably related to the FDA application, § 271(e)(2) provides a cause of action for infringement based upon the filing of an application to the Food and Drug Administration (FDA) for market approval of a generic drug. The statutory scheme thus balances the interests of a patented, brand-name drug manufacturer in enforcing its patent rights and the interests of the public in the availability of a competitively priced generic version of the drug as soon as possible. Given the infringement exemption under § 271(e)(1), § 271(e)(2) essentially authorizes a declaratory judgment suit by a patentee against a prospective infringer.

In *Merck KGaA v. Integra Lifesciences I, Ltd.*,¹¹ the Supreme Court held that 35 U.S.C. § 271(e)(1) extends to all uses of patented inventions that are reasonably related

¹⁰ See, e.g., Board on Science, Technology, and Economic Policy, REAPING THE BENEFITS OF GENOMIC AND PROTEOMIC RESEARCH: INTELLECTUAL PROPERTY RIGHTS, INNOVATION AND PUBLIC HEALTH (Nat’l Academies Press 2006) (“Recommendation 11: NIH should undertake a study of potential university, government, and industry arrangements for the pooling and cross-licensing of genomic and proteomic patents, as well as research tools.”).

¹¹ 545 U.S. 193 (2005).

to the development and submission of any information under the Federal Food, Drug, and Cosmetic Act (FDCA), including preclinical studies of patented compounds that are appropriate for submission to the FDA in the regulatory process. The Court clarified that the statute did not exclude certain information from the exemption on the basis of the phase of research in which it was developed or the particular submission in which it could be included. On remand,¹² the Federal Circuit further noted that the criterion of whether the experimental investigation of a patented compound is reasonably related to the development of information for submission to the FDA is established at the time of the experiment, and does not depend on the success or failure of the experimentation or actual submission of the experimental results. The Federal Circuit thus stated that studies of compounds that are not ultimately proposed for clinical trials are within the § 271(e)(1) FDA Exemption, when there was a reasonable basis for identifying the compounds as working through a particular biological process to produce a particular physiological effect. The Federal Circuit reasoned that the § 271(e)(1) safe harbor did not depend on a distinction between discovery and routine research, but on whether the threshold biological property and physiological effect had already been recognized as to the candidate drug.

Furthermore, the Supreme Court and Federal Circuit declined to address the potential implications for the rulings on the subject of research tools. Where a research tool has application only in the context of clinical trials, it becomes questionable how patent rights to such a research tool might be enforceable. But for other research tools, the *Merck* decision might have little bearing.

Research Use Exemption. Following the 2002 Federal Circuit decision in *Madey v. Duke University*,¹³ the research community has been on notice that the patent laws apply to basic research activities, whether or not performed at universities or non-profit institutions, as they relate to infringement. Of course, the Federal Circuit has yet to abolish the common law exemption to patent infringement liability.¹⁴ However, its decision in *Madey* leaves grave doubt that the common law exemption to patent infringement liability can act as a safe harbor for any academic research effort in this day and age. The relevant factors for such a determination arguably discount the nature

¹² 496 F.3d 1334 (Fed. Cir. 2007).

¹³ 307 F.3d 1351 (Fed. Cir. 2002).

¹⁴ See *Whittemore v. Cutter*, 29 F. Cas. 1120, 1121 (C.C.D. Mass. 1813) (No. 17,600) (“[I]t could never have been the intention of the legislature to punish a man, who constructed such a machine merely for philosophical experiments, or for the purpose of ascertaining the sufficiency of the machine to produce its described effects.”); *Poppenhusen v. Falke* 19 F. Cas. 1048, 1049 (C.C.S.D.N.Y. 1861) (No. 11,279) (“[A]n experiment with a patented article for the sole purpose of gratifying a philosophical taste, or curiosity, or for mere amusement, is not an infringement of the rights of the patentee.”).

of the defendant (whether academic, non-profit or not-for-profit in status) as well as the intent behind the conduct (non-pecuniary or non-commercial) as long as the act somehow can be related to a legitimate business purpose. Moreover, even where the experimental work can be shown to occur outside the umbrella of a research institution or other enterprise, the protection of the common law exemption to patent infringement liability likely will not extend to activity other than hobbyist tinkering or testing of a patented invention for verification and reproducibility.

The theoretical constructs behind § 271(e)(1) and other legislation, extant or proposed, to exempt certain activities from patent infringement liability all flow from specific policy considerations beyond the diverse objectives that are offset in a delicate interplay to promote the progress of the useful arts. The divergence, therefore, that rests with a proposal to establish a universal statutory research use exemption, without regard to technology, industry or regulatory concerns, is the need to reassess the very nature of the patent system.

The literature is rich with excellent considerations of this topic. Indeed, commentators, like Professors Janice Mueller, Katherine Strandburg, and Rochelle Dreyfuss, have set forth sound rationales for a research use exemption, whereas others like Professor Richard Epstein have advocated that compulsory licensing, experimental use defenses, condemnation proceedings, and such, which assertedly reflect *ad hoc* interventions, defy the reality that the extant system works acceptably.

Prior, more broad-based, approaches included aspects of compulsory licensing. In this vein, for example, Professor Mueller's proposed a standard reach-through royalty of 25% of pre-tax profits. Professor Strandburg further proposed a two-tiered compulsory licensing scheme for research tool patents. In this regard, research tool patents would be entitled to three to five years of default exclusivity, after which compulsory licensing could apply. This approach, according to Professor Strandburg, would encourage early commercialization and voluntary licensing. Such an outcome seems likely, particularly if voluntary licensing during the exclusivity period prescribes some benchmark for the royalty rate applied during the compulsory licensing period. Professor Dreyfuss raised detailed insights into a balancing of the benefits and harms between patentee and basic researchers in her proposal for special liability rules attached to research uses of patented technology. One suggestion was a statutory amendment to exempt basic research from patent infringement remedies, similar to 35 U.S.C. § 287(c)(2) for certain uses of patented surgical and medical methods. Professor Dreyfuss alternatively (and more favorably) advocated a waiver registry that enabled basic researchers to gain access to a patented technology by executing a written waiver that publicly dedicated any subject matter discovered or invented through the use of the patented technology. The dedication to the public under the Dreyfuss proposal would take the form of novelty-defeating publication, statutory invention registration

under 35 U.S.C. § 157, or the like. In this model, the research use of the patented technology subject to waiver could occur without authorization or compensation.

While such elegant solutions have been proposed, it appears that little support for any one proposal has manifested. Despite a clear mandate for change, advocates such as the National Academies have yet to articulate a position beyond recognizing a need for further study. While once regarded by many as a significant adjunct to sweeping reform of the U.S. patent system, no present legislative proposal embodies a research use exemption provision.

In a modest proposal to refocus the dialogue, I have suggested a legislative proposal to amend the U.S. patent laws to establish a basic research right to use patented technologies. The proposal draws from the present and proposed statutory framework governing prior user rights against patent infringement that may be found with 35 U.S.C. § 273, and the proposed amendments to that statute. The draft legislation would balance the interests of academic research freedom with patent exclusivity. While the proposal would hold the academic research community more accountable for their conduct, it would immunize academic researchers and their institutions from patent infringement liability and damages, and more importantly, would establish a right to use patented technology for basic research unfettered by threat of injunction. The draft legislation would accomplish this by precluding claims against academic researchers and their institutions for patent infringement, where such individuals and entities provide actual notice to the patent owner of the open and notorious use of the patented technology for basic research uses that become dedicated to the public, but by allowing claims against commercial entities that knowingly provide funding or materials, which facilitate the otherwise infringing activity. In so doing, the proposed statute would foster the increased awareness and respect of patent rights by the academic research community while alleviating the apprehension of patent infringement suit, by penalizing only commercial activity done under the guise of academic research.

35 U.S.C. § 274 Defense to infringement based on election of basic research right to use.

(a) DEFINITIONS. – For purposes of this section –

(1) the term “basic research use” means use of a device or method in the United States performed by a nonprofit research laboratory, or nonprofit entity such as a university, research center, or hospital, a use for which the public is the intended beneficiary, except that the use –

(A) may be asserted as a defense under this section only for continued use by and in the laboratory or nonprofit entity; and

(B) may not be asserted as a defense with respect to any subsequent commercialization or use outside such laboratory or nonprofit entity.

(b) DEFENSE TO INFRINGEMENT. –

(1) IN GENERAL. – It shall be a defense to an action for infringement under section 271 of this title with respect to any subject matter that would otherwise infringe one or more claims in the patent being asserted against a person, if such person had, acting in good faith, provided actual notice to the patent owner of the use of the patented device or method no later than six months after such use has commenced.

(2) LIMITATIONS AND QUALIFICATIONS OF DEFENSE. – The defense to infringement under this section is subject to the following:

(A) NOTICE CONTENT. – The actual notice must include a research plan that sets forth the use of the patented device or method; information regarding the identity of all persons engaged in the research plan and their affiliations, the nature and amount of funds used to support the activities performed under the research plan, and the identity of the funding sources.

(B) NOT A GENERAL LICENSE. – The defense asserted by a person under this section is not a general license under all claims of the patent at issue, but extends only to the specific subject matter claimed in the patent with respect to which the person can assert a defense under this chapter, except that the defense shall also extend to variations in the quantity or volume of use of the claimed subject matter, and to improvements in the claimed subject matter that do not infringe additional specifically claimed subject matter of the patent.

(3) BURDEN OF PROOF. – A person asserting the defense under this section shall have the burden of establishing the defense by clear and convincing evidence.

(4) PERSONAL DEFENSE. – The defense under this section may be asserted only by the person who performed the acts necessary to establish the defense and, except for any transfer to the patent owner, the right to assert the defense shall not be licensed or assigned or transferred to another person except as an ancillary and subordinate part of a good faith assignment or transfer for other reasons of the entire research program to which the defense relates.

(5) UNSUCCESSFUL ASSERTION OF DEFENSE. – If the defense under this section is pleaded by a person who is found to infringe the patent and who subsequently fails to demonstrate a reasonable basis for asserting the defense, the court shall find the case exceptional for the purpose of awarding attorney fees under section 285 of this title.

Conclusion

To the extent the balance between the interests of commercial exclusivity with public access to genetic technology is deemed suboptimal, and the legislature seeks to remedy the situation by statutory change, several mechanisms exist that may be adapted in an attempt to achieve such a purpose. However, the potential for unintended consequences in any change to the patent laws, which might have disparate impact upon various technologies and industries, strongly suggests that such action should be approached with careful deliberation. Thank you.