RECENT LEGISLATIVE PROPOSALS AIMED AT THE PERCEIVED PROBLEM OF GENE PATENTS

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Although genes in their native state (e.g., as they exist in the human body) are considered products of nature and thus unpatentable, the term "gene patent" is widely used to describe a host of issued patents claiming products or processes that are the result of human invention and that involve a genetic polynucleotide or genetic sequence information.[1] Examples include patents claiming isolated polynucleotides corresponding in sequence to genomic DNA; cDNA molecules (synthetic, protein-encoding DNA sequences corresponding to expressed genes); expression vectors, cells and non-human organisms engineered to contain recombinant genes; probes useful for identifying genetic mutations; and certain genetic diagnostic testing methods.[2]

The U.S. Patent and Trademark Office (PTO) has issued thousands of gene patents since the early 1980s and the dawn of the biotechnology revolution, and these patents are widely recognized as having played a crucial role in enabling biotechnology companies to secure the funding required to finance the highly expensive and unpredictable development of biotechnology products.[3] Courts have upheld the validity and enforceability of these patents on numerous occasions.[4] Nevertheless, in spite of the clearly beneficial role these patents have played in the genesis and sustenance of biotechnology, and the importance of this industry to the economy and public health, a diverse coalition of critics has for years decried the very existence of gene patents.[5] Patents relating to human genetic sequences have come under particularly intense attack. Some equate patents claiming inventions relating to human genes with slavery, and suggest that patents could be used to restrict personal autonomy.[6] Others allege that gene patents impede basic biomedical research and restrict access to life saving technologies, especially genetic diagnostic testing services.[7] Regardless of the validity of these charges, and there appears to be little solid evidence to support them,[8] the critics have been heard in Congress. In recent years two bills have been introduced that would seek to address the perceived problem of gene patents, one by limiting their enforceability, the other by banning them outright.

The Genomic Research and Diagnostic Accessibility Act of 2002

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[1] Christopher M. Holman, *The Impact of Human Gene Patents on Innovation and Access: A Survey of Human Gene Patent Litigati*on, 76 UMKC L. REV. 295 (2007).
[2] *Id.*
[3] Christopher M. Holman, *Biotechnology's Prescription for Patent Reform*, 5 J. MARSHALL REV. INTELL. PROP. L. 318, 327-29 (2006).
[4] Holman, *supra* note 1, at 352.
[5] Holman, *supra* note 1, at 295-301.
[6] Holman, *supra* note 1, at 297.
[7] Holman, *supra* note 1 at 298.
[8] Holman, *supra* note 1, generally. See also Timothy Caulfield et al., *Evidence and Anecdotes: An Analysis of Human Gene Patenting Controversies*, 24 NATURE BIOTECHNOLOGY 1091, 1091-94 (2006).

In 2002 Representative Lynn Rivers (D-MI) introduced into Congress the Genomic Research and Diagnostic Accessibility Act ("GRDAA"),[9] a bill that would have provided limited exemptions from liability for certain uses of patented genetic sequences and genetic sequence information in the context of basic research and genetic diagnostic testing. Importantly, the GRDAA would not have affected the patentability of genetic inventions, the approach taken in a more recent legislative initiative discussed below.

One provision of the bill provided a limited exemption from infringement liability for the use of patented "genetic sequence information" in noncommercial research. Because of the ambiguous language of the legislation, it is not at all clear what sorts of infringement this provision would have covered, but it would seem to be quite limited in scope. The bill defines the term "genetic sequence information" as "any ordered ***listing*** of nucleotides comprising a portion of an organism's genetic code (emphasis added)," so the exemption would not encompass the use of patented polynucleotides or other patented products comprising actual genetic molecules. In fact, under current law it is already the case that "genetic sequence information" cannot be patented *per se*,[10] although patents have issued that claim "data structures" supporting computer access to data representing a specified genetic sequence, which comes close to claiming the underlying information.[11] A number of patents have issued that claim methods of using genetic sequence information in genetic diagnostic testing,[12] and patents of this type were probably a primary intended target of the exemption. However, because the exemption would have been limited to noncommercial research, its practical impact likely would have been minimal. As described in a recent law review article, my research indicates that noncommercial research has never been the subject of a patent infringement suit involving a human gene patent. More generally, lawsuits alleging patent infringement based on noncommercial research activities appear to be extremely rare if not nonexistent.[13] Recent surveys of researchers further suggest that third-party patents generally have had little impact on basic biomedical research.[14]

The GRDAA also would have provided an exemption from infringement remedies for any infringement by a medical practitioner in the "performance of a genetic diagnostic, prognostic, or predictive test." Note that this is not an exemption from infringement; the medical practitioner is still infringing the patent,

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[9] Genomic Research and Diagnostic Accessibility Act of 2002, H.R. 3967, 107th Cong. (2002).
[10] Holman, *supra* note 1 at 311.
[11] *See e.g.*, U.S. Patent No. 6,421,613.
[12] *See e.g.*, U.S. Patent No. 6,432,644.
[13] Author's unpublished findings. See also testimony of E. Jonathan Soderstrom, *infra* note 36 and accompanying text, reporting a de factor research use exemption for noncommercial academic research.
[14] *Effects of Research Tool Patents and Licensing on Biomedical Innovation*, *in* PATENTS IN THE KNOWLEDGE-BASED ECONOMY 285-340 (Wesley M. Cohen & Stephen A. Merrill eds., 2003); John P. Walsh et al., *Working Through the Patent Problem*, 299 SCIENCE 1021, 1021 (2003); John P. Walsh et al., *View from the Bench: Patents and Material Transfers*, 309 SCIENCE 2002, 2002-03 (2005).

but the patent owner is provided with no remedy for the infringement. The practical effect would be that while an infringing medical practitioner would not be subject to liability, a third party that performed the test, or that supplied a kit for conducting the test, might be held liable under theories of direct or indirect infringement. Current law provides such an exemption from liability for medical practitioners who infringe a patent by performing a medical or surgical procedure.[15]

By focusing on basic, noncommercial research and genetic diagnostic testing, the GRDAA would have addressed the primary concerns of gene patents critics while permitting the continued patenting of genes and the enforcement of gene patents in other contexts, particularly with respect to therapeutic protein drugs (biologics) produced by means of recombinant genetic technology. The GRDAA proposed relatively modest reforms which would have allowed the continuing patenting of genetic sequence inventions, would not have exempted commercial research, or even basic research involving the use of actual polynucleotides or products including genetic molecules, and would only protect medical practitioners from patent remedies for infringement occurring in the course of performing a genetic test. However, Congress did not act on the GRDAA, and it was not pursued after Rep. Rivers left office the next year.

The Genomic Research and Accessibility Act of 2007

In 2007, Rep. Xavier Becerra (D-CA) introduced a much more aggressive piece of legislation, the Genomic Research and Accessibility Act (GRAA),[16] which would prospectively bar the patenting of any "nucleotide sequence, or its functions or correlations, or the naturally occurring products it specifies." Although the bill was clearly motivated by concerns over gene patents, its broad language would appear to encompass all inventions involving polynucleotides, even where the role of the polynucleotide has nothing to do with genetics, or even biology.[17] The scope of the proposed ban on a polynucleotide's "functions or correlations" is ambiguous, but might be interpreted as encompassing any process claim that involves the use of a polynucleotide, genetic information or perhaps any biological correlation. So far, the GRAA appears to have garnered little support, and has been actively opposed by representatives of the biotechnology industry and others.[18] As of early February, 2008, the bill has not made it out of committee, and has not been incorporated into the omnibus patent reform legislation recently passed by the House.[19] In contrast, a bill to ban the patenting of tax strategies,[20] introduced at about the same time as the GRAA

[15] 35 USC 287(c)(2).
[16] Genomic Research and Accessibility Act, H.R. 977, 110th Cong. (2007).
[17] Holman, *supra* note 1 at 296.
[18] *Stifling or Stimulating – The Role of Gene Patents in Research and Genetic Testing Before the Subcomm. on Courts, the Internet and Intellectual Property*, 110th Cong. (2007) (statement of Jeffrey Kushan on behalf of the Biotechnology Industry Organization (BIO)), *available at* http://judiciary.house.gov/media/pdfs/Kushan071030.pdf (last visited Feb. 7, 2008).
[19] Patent Reform Act of 2007, H.R. 1908, 110th Cong. (2007).
[20] Stop Tax haven Abuse Act, S. 681, 110th Cong. (2007).

and widely supported, was essentially incorporated into the patent reform bill. If a ban on gene or DNA patenting had substantial support, one might expect it also to be included in the larger patent reform bill.

Congressional Hearing on the Role of Gene Patents in Research and Genetic Testing

On October 30, 2007, the House Committee on the Judiciary, Subcommittee on the Courts, the Internet, and Intellectual Property held a hearing entitled "Stifling or Stimulating-The Role of Gene Patents in Research and Genetic Testing."[21] The hearing was called by Rep. Howard Berman (D-CA), chair of the subcommittee, and was presumably prompted by the GRAA and the increasingly strident rhetoric attacking gene patents. Four witnesses presented testimony, including Lawrence Sung, a law professor with expertise in biotechnology patent law; Mark Grodman, the founder and CEO of Bio-Reference Laboratories; E. Jonathan Soderstrom, the director of a university technology transfer office; and Jeffrey Kushan, an attorney appearing on behalf of the Biotechnology Industry Organization (BIO).

Professor Sung began by explaining that the term "gene patent" lacks any standardized definition, but is widely applied to a host of divergent types of patents claiming, for example, DNA sequences that code complete proteins, as well as sequences of unknown biological significance.[22] He described the difficulty the courts and PTO have experienced in delineating a boundary between patentable and unpatentable genetic discoveries, but noted that *In re Fisher*[23] and the current PTO Utility Examination Guidelines[24] had clarified that the raw discovery of a novel genetic sequence is not a patentable invention, unless the patent applicant can articulate a specific, substantial and credible utility for the molecule.

Professor Sung went on to summarize several other recent patent decisions that could limit the patentability and enforceability of gene patents, in particular *KSR v. Teleflex*[25] (creating heightened obviousness standard), *eBay v. MercExchange*[26] (restraining the availability of injunctive relief), and *Merck v. Integra Life Sciences*[27] (holding that 35 USC 271(e)(1) provides an exemption to patent infringement liability for activities undertaken in connection with the generation of data that could be reasonably related to an FDA submission). He also briefly discussed the potential for patent pools and the exercise of march-in rights under the Bayh-Dole Act to expand access to government-funded inventions to attenuate any restrictive effects of gene patents on research and product development. Professor Sung concluded by warning that *Madey v. Duke*

[21] *See* http://judiciary.house.gov/oversight.aspx?ID=390 (last visited Feb. 7, 2008).
[22] *Available at* http://judiciary.house.gov/media/pdfs/Sung071030.pdf (last visited Feb. 7, 2008).
[23] 421 F.3d 1365 (Fed. Cir. 2005).
[24] 2001 Utility Examination Guidelines, *available at* http://www1.uspto.gov/go/notices/utilexmguide.pdf.
[25] 127 S. Ct. 1727 (2007).
[26] 547 U.S. 388 (2006).
[27] 545 U.S. 193 (2005).

University[28] had created "grave doubt" that the common-law exception provides any real safe harbor for modern academic research, and suggested legislation which would create a statutory research use exception limited to basic, noncommercial research. Dr. Grodman began by stating for the record that he was not there to attack the patenting of genes or gene sequences *per se*, but rather to challenge university technology transfer policies.[29] He testified that the ability of genetic testing laboratories to conduct genetic tests has been severely restricted by gene patent holders, in some cases resulting in the unavailability of commercial genetic testing services for a patented genetic condition, and that the owners of the most problematic patents are typically universities or their exclusive licensees.

According to Dr. Grodman , the problem of gene patents in the context of genetic diagnostic testing could be effectively addressed by the appropriate government exercise of the march-in rights provided by under the Bayh-Dole Act, echoing Professor Sung in this regard. Under Bayh-Dole, a federal agency such as NIH has the right to "march in" and compel a recipient of a federal grant to nonexclusively license patented technology when necessary to alleviate health or safety needs which are not being reasonably satisfied by the grant recipient.[30] Patient advocacy groups have on several occasions formally asked NIH to exercise its march-in rights, for example in cases where the requesters believe that the price of a drug created using federally funded discoveries is being offered at too high of a price, but to date NIH has declined all such requests. Dr. Grodman concluded his testimony by asking the committee to require NIH to enforce the march-in provisions of Bayh-Dole in appropriate cases involving diagnostic genetic testing, but suggested that in the event NIH is unwilling or unable to do so, Congress should review whether the power to enforce Bayh-Dole should be placed in the hands of another federal agency.

Mr. Soderman began his testimony by reviewing many of the concerns that have been expressed with respect to the patenting of genes, including the hypothesized gene patent thicket, and the fear that gene patents will impede the use of research tools by noncommercial academic researchers.[31] However, he noted that there appears to be little evidence suggesting that these potential concerns have materialized, and cited studies showing that patents have had little negative influence on the course of academic research. He testified that many universities have agreed to pursue a technology licensing policy that promotes access to patented technologies for universities and other nonprofit and governmental organizations, as well as nonexclusive licensing of research tools. This policy, embodied in a recently released white paper entitled "In the Public Interest: Nine Points to Consider in University Licensing,"[32] also provides

[28] 307 F.3d 1351 (Fed. Cir. 2002).
[29] *Available at* http://judiciary.house.gov/media/pdfs/Grodman071030.pdf (last visited Feb. 7, 2008).
[30] 35 U.S.C. 203(a)(2).
[31] *Available at* http://judiciary.house.gov/media/pdfs/Soderstrom071030.pdf (last visited Feb. 7, 2008).
[32] *Available at* http://www.autm.org/aboutTT/Points_to_Consider.pdf (last visited Feb. 7, 2008).

that exclusive licenses should only be granted in a manner that encourages the development and use of the patented technology, and minimizes the licensing of "future improvements." The Nine Points Guidelines specifically recommend that universities refrain from patenting genomic inventions that will serve primarily as research tools. Dr. Soderstrom stated that there is evidence that a *de facto* research exemption exists, because companies rarely prosecute academic investigators for research uses that may be infringing. In short, he is of the view that any problematic aspects of gene patents are being addressed by universities and by the market, and any legislative action would be unwarranted at this time.

Finally, Mr. Kushan summarized the importance of biotechnology to the U.S. economy and public health, and stressed the importance of patents in securing funding for this highly research intensive technology sector.[33] He then explained that nucleic acid patents (a term he employed for what others have referred to as gene patents) are used in a variety of different and important ways by the biotechnology industry, and that legislation that would eliminate the possibility of patenting nucleic acids (such as the GRAA) would not only substantially harm the biotechnology industry, but would be inconsistent with U.S. compliance with the World Trade Organization (WTO) Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS).[34]

Mr. Kushan argued strongly that none of the concerns that have been raised with regard to gene patents would merit legislative action, particularly legislation that would substantially harm the biotechnology industry. In particular, he rejected the argument that gene patents interfere with academic research, pointing out the close relationship between the biotechnology industry and the academic scientific community, and the lack of any evidence of infringement actions against university researchers engaged in noncommercial research. He also sought to debunk the patent thicket theory, pointing to the lack of evidence that patents are inhibiting research and development activities in either the public or private sectors. With regard to the fear that patents impede access to genetic diagnostic testing, he pointed out that in fact very few disputes of this type have materialized, in his view confirming that the vast majority of gene patents do not significantly impede clinical diagnostic testing.

To summarize, none of the witnesses testified in support of the GRAA, or advocated any sort of legislation limiting the patentability of genes or DNA. A research use exemption for noncommercial research was suggested by Professor Sung, but similar proposals have been made on multiple occasions[35]

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[33] *Available at* http://judiciary.house.gov/media/pdfs/Kushan071030.pdf (last visited Feb. 7, 2008).

[34] Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, Legal Instruments - Results of the Uruguay Round vol. 31, 33 I.L.M. 81 (1994) [hereinafter TRIPS], *available at* http://www.wto.org/english/docs_e/legal_e/27-trips.pdf (last visited Feb. 7, 2008).

[35] *See, e.g.,* Patent Competitiveness and Technological Innovation Act, H.R. 5598, 101st Cong. § 402 (1990) (proposed 35 U.S.C. § 271(j): "It shall not be an act of infringement to make or use a patented invention solely for research or experimentation purposes unless the patented invention has a primary

and have been effectively defeated by interest groups opposing such legislation, including universities and biotechnology companies.[36] A research use exemption is not included in the patent reform legislation currently being considered by Congress.[37]

Conclusion

As noted above, it appears highly unlikely that legislation banning the patenting of genetic inventions will be enacted anytime soon. If Congress does take any action in the near term, it will most likely be directed towards encouraging NIH and other funding agencies to exercise march-in rights in cases where a patent resulting from government funded research stands as a substantial impediment to biomedical research or access to important technologies such as diagnostic testing. In view of the high percentage of gene patents that arise out of federally funded research, particularly patents covering the use of genes in research and diagnostic testing, invocation of the march-in right could effectively address many of the concerns that have been raised by critics of gene patents without the negative unintended consequences that would arise from a legislative ban on the patenting of genes or DNA.

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purpose of research or experimentation. If the patented invention has a primary purpose of research or experimentation, it shall not be an act of infringement to manufacture or use such invention to study, evaluate, or characterize such invention, or to create a product outside the scope of the patent covering such invention. This subsection does not apply to patented invention to which subsection (e)(1) applies."); *see also* the GRAA, discussed *supra*.

[36] *See, e.g.*, Letter from W. Mark Crowell, President, Association of University Technology Managers to Michael Kirk, Executive Director, American Intellectual Property Law Association 1-2 (Mar. 8, 2005) (expressing opposition to AIPLA's proposal for legislation to codify the experimental use exception based on its application to research tool patents); Harold C. Wegner, *Post*-Merck *Experimental Use and the "Safe Harbor,"* 15 FED. CIR. BAR J. 1, 36 (2005).

[37] Patent Reform Act of 2007, H.R. 1908, 110th Cong. (2007).