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Biotechnology's Prescription for Patent Reform

Christopher M. Holman
University of Missouri - Kansas City, School of Law

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ABSTRACT

On June 8, 2005, Congressman Lamar Smith introduced H.R. 2795, the "Patent Reform Act of 2005," aimed at improving the quality and certainty of issued patents, simplifying the patent procurement process, harmonizing U.S. law with international practice, and reining in abusive patent enforcement practices. Congress has set the legislation aside for the time being, but will likely revisit the issue again shortly. The biotechnology industry, one of the fastest growing sectors in the United States economy, strongly opposes many of the proposed reforms. This paper considers the Congressional testimonies of the Biotechnology Industry Organization ("BIO") and other representatives of biotechnology's interests, and finds that the industry's adamant opposition to many of the proposals is driven largely by a belief that biotechnology patents function primarily as tools for securing investment funding, and the fear that investment in biotechnology will be adversely impacted if investors perceive that patent reform has weakened the rights of patent owners and inventors. The paper also considers how the biotechnology sector might be impacted if the proposed reforms are enacted into law, and describes some recent biotechnology cases wherein the outcome might have been different if the reforms had already been in place.

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BIOTECHNOLOGY'S PRESCRIPTION FOR PATENT REFORM

CHRISTOPHER M. HOLMAN*

INTRODUCTION

On June 8, 2005, Texas Congressman Lamar Smith introduced H.R. 2795, with the short title of "Patent Reform Act of 2005," in the U.S. House of Representatives.[1] If enacted, H.R. 2795 would have constituted the most substantial and comprehensive package of patent law reforms since the Patent Act of 1952.[2] The proposed amendments not only would have changed the rules pursuant to the way that patents are procured, enforced, and challenged, they would have fundamentally altered the requirements for a patentable invention.[3]

Not surprisingly, the prospect of such sweeping reform engendered a strong backlash from a variety of interest groups whose constituencies might be adversely impacted by changes to the status quo,[4] and for the time being H.R. 2795 appears to have stalled.[5] Nevertheless, at some point Congress will return its attention to patent reform, and it seems likely that at least some of the provisions of the bill will eventually become law.[6]

One of the groups most critical of the reform package was the biotechnology industry.[7] Biotechnology is one of the fastest growing industrial sectors in the United States, and also one of the industries most dependent upon the availability of strong intellectual property rights.[8] This importance is reflected in the keen interest biotechnology takes in shaping patent law and policy both in the United States and abroad.[9] In this paper, I will consider the potential impact of various aspects of patent reform from the perspective of this important sector of the economy.

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* Christopher M. Holman is an associate professor of law at the University of Missouri-Kansas City School of Law. This article is based on the presentation "Innovation and it Discontents: Patent Reform and Innovation Policy in the 21st Century," given at The John Marshall Law School's Howard T. Markey Patent Law Symposium on Oct. 14, 2005.

[1] Patent Reform Act of 2005, H.R. 2795, 109th Cong. (2005).

[2] Patent Act of 1952, Pub. L. No. 593, 66 Stat. 792 (codified as amended in scattered sections of 35 U.S.C.).

[3] Patent Reform Act of 2005, H.R. 2795 § 3.

[4] *See infra* Parts I and II.

[5] Posting of Dennis Crouch to Patently-O: Patent Law Blog, http://patentlaw.typepad.com/patent/2005/12/patent_reform_2.html (Dec. 8, 2005).

[6] *Id.*

[7] Letter from A. Scott Whitaker, Chief Operating Officer, Biotechnology Industry Organization, to Lamar Smith & Howard Berman, Subcommittee on Courts, the Internet, and Intellectual Property, U.S. House of Representatives (May 12, 2005), *available at* http://www.bio.org/ip/action/20050513.pdf.

[8] Biotechnology Industry Organization, Intellectual Property, http://www.bio.org/ip/ (last visited Apr. 1, 2005).

[9] *Id.*

I. BACKGROUND ON H.R. 2795

The recent round of patent reform legislation was driven in large part by a widely held belief that deficiencies in the U.S. patent system are imposing substantial negative effects on U.S. research and development as well as the economy at large.[10] For example, in 2004 the economists Adam Jaffe and Josh Lerner published *Innovation and Its Discontents*,[11] a book which criticizes a number of aspects of the current system. The book stimulated much debate on the subject of patent reform, including the conference where this paper was first presented.

Many of the concerns expressed in the book were echoed in two comprehensive studies issued by the Federal Trade Commission ("FTC")[12] and the National Research Council of the National Academies ("NRC").[13] These studies identified a host of problems with the current patent system and proposed reforms aimed at addressing these problems.[14] Many of these proposals found their way into H.R. 2795.[15] In a nutshell, most of the reforms aim to improve the quality and certainty of issued patents, simplify the patent procurement process, harmonize U.S. law with international practice, and rein in abusive patent enforcement practices.[16]

With respect to patent quality, part of the problem arises from the legal presumption that an issued U.S. patent is valid and enforceable.[17] Reformers charge that the U.S. Patent and Trademark Office ("PTO") is issuing too many "junk" patents, i.e., patents that do not satisfy all of the requirements of patentability, such as novelty, nonobviousness, and enablement, but somehow slip through the filter of patent examination anyway.[18] Oftentimes, patent litigation is the only practical avenue available to challenge the validity of an issued patent, which typically occurs after an infringement suit has been filed, and even then the presumption of validity raises the specter that a junk patent will nevertheless be upheld by a court in deference to the PTO.

Many of the proposed reforms aimed at improving patent quality would do so by allowing interested third parties more opportunity to participate in the patent examination process and actively challenge questionable patents in the PTO, thereby preempting patent litigation. For example, the legislation would institute mechanisms by which interested third parties could submit to the PTO prior art

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[10] Fed. Trade Comm'n, To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy, Executive Summary, at 4–7 (2003), http://www.ftc.gov/os/2003/10/innovationrpt.pdf [hereinafter FTC Report].

[11] ADAM B. JAFFE & JOSH LERNER, INNOVATION AND ITS DISCONTENTS: HOW OUR BROKEN PATENT SYSTEM IS ENDANGERING INNOVATION AND PROGRESS, AND WHAT TO DO ABOUT IT (Princeton Univ. Press 2004).

[12] FTC Report, *supra* note 10, ch. 5, pt. 1, at 2–4 (2003), http://www.ftc.gov/os/2003/10/innovationrpt.pdf.

[13] Nat'l Research Council of the Nat'l Acads., A Patent System for the 21st Century, at 3–13 (Stephen A. Merrill, et al. eds. 2004), http://www.nap.edu/html/patentsystem/0309089107.pdf [hereinafter NAS Report].

[14] *See generally* FTC Report, *supra* note 10; NAS REPORT, *supra* note 13.

[15] *See* Patent Reform Act of 2005, H.R. 2795, 109th Cong. (2005).

[16] *See id.*

[17] 35 U.S.C. § 282 (2000).

[18] JAFFE & LERNER, *supra* note 11, at 34–35; FTC REPORT, *supra* note 10, ch. 4, pt. 2, at 4–26; NAS REPORT, *supra* note 13, at 69–77.

references relevant to the patentability of pending patent applications, thereby assisting the patent examiner in identifying references that the examiner might otherwise have missed.[19] The legislation would also expand *inter partes* reexamination, and provide for post-grant opposition proceedings in the PTO, similar to the practice in other jurisdictions such as Europe.[20] H.R. 2795 originally included two windows during which a granted patent could be opposed.[21] A challenger would have been able to file an opposition within the first nine months after the patent issued (the "first window") or within six months after suit has been actually been threatened (the "second window").[22]

There is also a proposal to require the publication of all pending patent applications eighteen months after filing.[23] Mandatory eighteen-month publication gives the public notice of pending patent applications, and thus provides an interested third party the opportunity to submit prior art references and take other preemptive measures to protect its freedom to operate.

These and some other of the proposed reforms would improve the predictability and certainty of the patent process with respect to the validity of issued patents. For example, the legislation would eliminate or restrict some of the subjective aspects of U.S. patent law such as the best mode requirement[24] and the inequitable conduct defense.[25] Other provisions that would improve predictability and certainty include changes that would enable the PTO to limit the excessive filing of continuation applications,[26] institute a first-inventor-to-file system,[27] and revise the definition of anticipatory prior art,[28] essentially adopting a "reasonable accessibility" standard.

Some of the reforms are aimed primarily at simplifying the patenting process, such as allowing a company or organization to file patent applications directly on behalf of its employees.[29] Under current law, employees must personally file patent applications and then assign the application to the organization. Other changes described above, such as changing to first-inventor-to-file and revising the definitions of prior art, will also likely serve to simplify the patent procurement process.[30]

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[19] Patent Reform Act of 2005, H.R. 2795, § 10.

[20] *Id.* § 9(a).

[21] *Id.* § 9(f).

[22] *Id.*

[23] *Id.* § 7. Currently publication is optional for patent applicants that file only in the United States. 35 U.S.C. § 122(b) (2000).

[24] Patent Reform Act of 2005, H.R. 2795, § 4.

[25] *Id.* § 5.

[26] *Id.* § 8.

[27] *Id.* § 3.

[28] *Id.* § 3.

[29] *Id.* § 4.

> A person to whom the inventor has assigned or is under an obligation to assign the invention may make an application for patent. A person who otherwise shows sufficient proprietary interest in the matter may make an application for patent on behalf of or as an agent for the inventor on proof of the pertinent facts and a showing that such action is appropriate to preserve the rights of the parties.

Id.

[30] Although some have pointed out that this simplification will only be realized after sufficient case law has been developed interpreting the new definition of prior art. *See, e.g.,* http://www.fr.com/news/Article-Hunsaker.pdf (last visited May 13, 2006).

Some of the reforms aim to limit what many view to be abusive patent enforcement practices. These provisions have proven particularly controversial since the curtailment of enforcement inherently tends to weaken the property rights of issued patents. Understandably, those that see strong patent rights as critical to their industries, such as the biotechnology and pharmaceutical industries, have voiced strong opposition to many of these proposals. One such proposal would change the manner in which damages are apportioned in cases where infringement has been found with respect to one component of a combination invention.[31] Another would expand the currently limited prior user's right defense, by removing restrictions such as the limitation of the defense to patents claiming methods of doing or conducting business.[32] It would also weaken the current strong presumption in favor of permanent injunction once a patent has been found to be infringed.[33] In addition, some of the previously mentioned reforms relating to continuation applications, willful infringement, and the various proposals for expanding the rights of third parties to challenge patents in the PTO would also fall within this category of limiting abusive patent enforcement practices.

Incidentally, many of the proposed changes would serve to harmonize the laws of the United States with those of Europe and the rest of the world.[34] In principle, harmonization should benefit most industries since it will simplify the procurement of corresponding patents in different jurisdictions.[35] The market for most U.S. companies is not limited to the confines of the United States, and in this regard, biotechnology is no exception.[36]

Some of the proposed reforms are relatively non-controversial, particularly those that would simplify the patent process without substantially weakening the rights of the patent holder. These reforms include establishing a first-inventor-to-file system, allowing assignee filing, allowing pre-grant submission of prior art, revising the definition of prior art, and mandatory publication of applications after eighteen months.[37] Other provisions however, particularly those that would tend to restrict the ability of inventive entities to procure and enforce patents, generated substantial resistance from a number of constituencies, including the biotechnology sector. In particular, the reforms relating to damage apportionment, injunctions, continuation practice, and the establishment of opposition proceedings, especially second-window oppositions, sparked the most resistance.[38]

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[31] *See* Patent Reform Act of 2005, H.R. 2795, § 6.

[32] *See* Patent Reform Act of 2005, H.R. 2795, § 9.

[33] *See* Patent Reform Act of 2005, H.R. 2795, § 7.

[34] For example, the move to first-inventor-to-file, opposition practice, and elimination of some of the subjective elements of patentability.

[35] Intellectual Property Organization, *Member States Begin Talks on Shaping a Future Global Patent System* (Nov. 13, 2000), http://www.wipo.int/edocs/prdocs/en/2000/wipo_upd_2000_114.html.

[36] Biotechnology Industry Organization, Intellectual Property, http://www.bio.org/ip/ (last visited Apr. 1, 2005).

[37] These proposals are, at least, non-controversial with respect to many of the various corporate interests. Small inventors and entrepreneurs tend to be opposed to many of the proposed changes that the various industrial sectors agree are desirable, such as the move to first-inventor-to-file and any expansion of *inter partes* reexamination or post-grant opposition procedures.

[38] *The Patent Act of 2005: Hearing on H.R. 2795 Before the Courts, the Internet, and Intellectual Property Subcomm. of the H. Judiciary Comm.*, 109th. Cong. (2005) (statement of Gary L. Griswold).

In response to this organized opposition, on July 26, 2005, Congressman Smith circulated a proposed Amendment in the Nature of a Substitute to H.R. 2795 ("Substitute").[39] The Substitute retreated from a number of the changes proposed in the original legislation by eliminating the provisions relating to injunctive relief, continuation practice, and second-window post-grant opposition procedures.[40] The Substitute also attenuated the damage apportionment provision relative to the originally filed legislation.[41] All of these provisions were supported by the information technology sector,[42] but strongly opposed by the biotechnology and pharmaceutical industries.[43]

The Substitute also included for the first time a provision relating to choice of venue in patent infringement suits.[44] Essentially, the provision would require that patents cases be brought only in the judicial district where the defendant has committed infringement, or resides, and has a regular and established place of business.[45] In contrast with the other changes in the Substitute, the venue provision favors the defendant in an infringement action by substantially limiting the ability of patentees to control the choice of forum in patent litigations. The addition of the venue provision has been seen as a concession to the information technology sector.[46]

Finally, a third version of the legislation, the so-called "Coalition Print," has been proposed.[47] Because it was apparent that the divergent interests of the various stakeholders might completely derail the move for patent reform, a coalition of thirty-five major companies constituting an assortment of the technology sector (the Coalition for Patent Reform) proposed an amended version of the legislation that reflected consensus or compromise positions on many of the issues.[48] The Coalition Print, released on September 1, 2005, tracks Congressman Smith's Substitute with a few differences.[49] For example, the Coalition Print attenuates the damage apportionment provisions even further than the Substitute,[50] but softens the choice of

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[39] Lamar Smith, Amendment in the Nature of a Substitute to H.R. 2795 (2005), http://www.promotetheprogress.com/ptpfiles/patentreform/patentact2005/Patentact2005_draftamendsubst.pdf. Although the Substitute was never formally introduced in Congress, the draft was widely distributed and was the subject of hearings before the Subcommittee on Courts, the Internet and Intellectual Property on Sept. 15, 2005, the last formal Congressional action on the bill.

[40] *See id.*

[41] *Id.* § 6.

[42] The term "information technology sector" refers to the computer, software, Internet, telecommunications, and other like industries.

[43] *See* Kate Ackley, Information Technology Industry Council, Roll Call: Patent Pending (2005), http://www.itic.org/archives/articles/20050525/roll_call_patent_pending.php (last visited Apr. 9, 2006).

[44] Smith, *supra* note 39, § 9.

[45] Smith, *supra* note 39, § 9.

[46] Promote the progress, Draft amendment to the Patent Act of 2005 - Pharma's bill, with a twist (2005), http://promotetheprogress.com/archives/2005/08/draft_amendment.html.

[47] A Coalition for 21st Century Patent Law Reform, Balanced Initiatives to Advance Quality and Provide Litigation Reforms (2005), http://www.promotetheprogress.com/ptpfiles/patentreform/patentact2005/Patentact2005_IPOcoalitionprint.pdf [hereinafter Coalition Print].

[48] *See generally id.*

[49] *Id.* (noting deletions and additions with strikethrough and underline formatting, respectively).

[50] *Id.* § 6.

venue provision.[51] Rather than necessarily letting the defendant dictate the forum, the Coalition Print merely requires, in certain instances, the transfer of venue to a more appropriate forum, and as such is less pro-defendant than the language in the Substitute.[52]

On September 15, 2005, hearings were held before the House Subcommittee on Courts, the Internet, and Intellectual Property, at which time various interest groups and commentators testified with respect to the three versions of H.R. 2795.[53] Subsequent to that hearing, Congress has failed to take any formal action on the legislation.[54] Nevertheless, it is widely anticipated that Congress will take up the issue again in the not too distant future, and many of the proposed reforms will continue to be the focus of debate among the various stakeholders.[55]

II. BIOTECHNOLOGY'S AGENDA FOR PATENT REFORM

In order to assess the position of biotechnology on various aspects of patent reform, I looked primarily to the Congressional testimony of Robert B. Chess, speaking on behalf of the Biotechnology Industry Organization ("BIO"), the main lobbying group representing interests of biotechnology.[56] BIO's membership includes more than 1,000 biotechnology companies, academic institutions, state biotechnology centers, and related organizations throughout the United States[57] "The mission of BIO is to be the champion of biotechnology and the advocate for its member organizations—both large and small."[58]

In pursuit of this mission, BIO actively advocates on behalf of its constituency with respect to a number of patent law issues, including gene patenting, the patenting of cloning technology and clones, Hatch-Waxman reform, PTO appropriations and fee diversion, and patent reform.[59] It has also filed amicus briefs in a number of intellectual property litigations of particular relevance to the biotechnology industry.[60] In fact, BIO has specifically identified intellectual property protection as "the key factor for economic growth and advancement in the

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[51] *Id.* § 9.

[52] *Id.*

[53] *The Patent Act of 2005: Hearing on a Proposed Substitute and Accompanying Redline to H.R. 2795 Before the H. Subcomm. on Courts, the Internet, and Intellectual Property of the H. Comm. on the Judiciary*, 109th Cong. (2005) (statement of Lamar Smith, Chairman), *available at* http://www.promotetheprogress.com/ptpfiles/patentreform/houseoversight/091505/smithopen.pdf.

[54] Library of Congress, Search Results–THOMAS, http://thomas.loc.gov/cgi-bin/bdquery/z?d109:h.r.02795: (last visited Apr. 9, 2006).

[55] Posting of Dennis Crouch to Patently-O: Patent Law Blog, http://patentlaw.typepad.com/patent/2005/12/patentlyo_tidbi.html (Dec. 19, 2005).

[56] *Patent Law Revision: Hearing on H.R. 2795 Before the Subcomm. on Courts, the Internet, and Intellectual Property of the H. Comm. on the Judiciary*, 109th Cong. (2005) [hereinafter *BIO Statement*] (statement of Robert B. Chess, speaking on behalf of BIO).

[57] *Id.*

[58] Biotechnology Industry Organization, BIO Mission Statement, http://www.bio.org/aboutbio/mission/ (last visited Apr. 9, 2006).

[59] *See* Biotechnology Industry Organization, BIO Domestic, http://www.bio.org/ip/domestic/ (last visited Apr. 9, 2006).

[60] Biotechnology Industry Organization, BIO Amicus Briefs, http://www.bio.org/ip/amicus/ (last visited Apr. 9, 2006) (providing links to ten amicus briefs).

biotechnology sector."[61] BIO views patents as critical in providing the necessary incentives for private sector investment into biotechnology development.[62] Because BIO represents such a wide spectrum of biotechnology companies, ranging from tiny start-ups to biotechnology giants such as Genentech and Amgen, and in view of the organization's longstanding interest in intellectual property issues as they relate to biotechnology, its congressional testimony with respect to patent reform should serve a good indicator of the consensus biotechnology position, to the extent such a consensus exists.[63]

I also reviewed the testimony of some other organizations in order to determine how they compare to that of BIO. For example, I considered the testimony given on behalf of Genentech, Inc.[64] As a leading biotechnology company, one would expect Genentech and its interests to be largely represented by BIO. But Genentech is a relatively mature company, selling products and generating substantial revenue from these sales, which distinguishes it from the typical biotechnology company. Many, if not most, of BIO's members are not selling products, and are often years from a viable commercial product.[65] These companies typically rely heavily on large infusions of investment capital,[66] and their interests in patent reform should be expected to diverge somewhat from a revenue-generating company such as Genentech. Indeed, while BIO and Genentech agree on most issues, there are a few issues upon which they disagree, and these divergences tend to reflect the different concerns of a mature biotechnology company as opposed to a start-up.

Biotechnology was born in university laboratories, and universities continue to conduct much of the basic research driving biotechnology. Particularly since the implementation of the Bayh-Dole Act[67] in the 1980s, universities have increasingly assumed the role of commercial players in the biotechnology sector, and many have profited handsomely.[68] In light of this phenomenon, I also considered the testimony of Carl E. Gulbrandsen, speaking on behalf of the Wisconsin Alumni Research Foundation ("WARF").[69] WARF manages technology transfer for the University of Wisconsin-Madison, and, as is the case with many universities, some of its most

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[61] Biotechnology Industry Organization, Intellectual Property, http://www.bio.org/ip/ (last visited Apr. 9, 2006).

[62] *Id.*

[63] *BIO Statement*, *supra* note 56 (testimony of Robert Chess). Of course, BIO's diverse membership is not a monolith, and on certain issues there is no consensus, as noted in BIO's congressional testimony. *Id.*

[64] *Patent Quality: Hearing on Committee Print Regarding Patent Quality Improvement Before the Subcomm. on Courts, the Internet, and Intellectual Property of the H. Comm. of the Judiciary*, 109th Cong. (2005) [hereinafter *Genentech Statement*] (statement of Jeffrey P. Kushan, speaking on behalf of Genentech)

[65] *See BIO Statement*, *supra* note 56 (testimony of Robert Chess).

[66] *BIO Statement*, *supra* note 56 (testimony of Robert Chess).

[67] Bayh-Dole Act, 35 U.S.C. §§ 200–212 (2000).

[68] *See* Arti K. Rai & Rebecca S. Eisenberg, *The Public Domain: Bayh-Dole Reform and the Progress of Biomedicine*, 66 LAW & CONTEMP. PROBS. 289, 290 (2003).

[69] *The Patent Act of 2005: Hearing on Patent Reform Before the Subcomm. on Courts, the Internet, and Intellectual Property of the H. Comm. of the Judiciary*, 109th Cong. (2005) [hereinafter *WARF Statement*] (statement of Carl E. Gulbrandsen, Managing Director, Wisconsin Alumni Research Foundation).

profitable technology is in the area of biotechnology.[70] For example, WARF owns the basic patents covering embryonic stem cell research.[71]

I also considered the testimony of Philip S. Johnson, chief patent counsel for Johnson & Johnson, representing the Pharmaceutical Researchers and Manufacturers of America ("PhRMA").[72] PhRMA represents the leading research-based pharmaceutical companies in the United States.[73] One would expect the interests of PhRMA to be aligned with those of BIO since many of its members are in fact biotechnology companies, or at least engage in some aspects of biotechnology. For example, Johnson & Johnson, a major pharmaceutical company and PhRMA member, recently acquired a number of smaller biotechnology companies, including Scios, Therakos, and Centocor.[74] Furthermore, pharmaceutical companies and biotechnology are both primarily interested in developing and marketing the same products, drugs, and diagnostics. Nevertheless, PhRMA generally represents more mature companies than BIO, companies that are generating substantial sales revenue and hence are less dependent upon investment funding. In other words, PhRMA represents companies more like Genentech than the more typical biotechnology start-up struggling to bring in investment capital in the hopes of one day developing a product for the market.

Finally, for a view from the other side of the patent reform debate, I consulted the testimony of Richard J. Lutton, Jr., Chief Patent Counsel for Apple, speaking on behalf of the Business Software Alliance ("BSA").[75] Not surprisingly, the BSA position on a number of patent reform issues is diametrically opposed to that of BIO. However, there are a number of reform proposals both agree on, an encouraging sign for those hoping that at least some of the patent reform measures are eventually enacted.

After reviewing the various congressional testimonies, it is apparent that the proponents of biotechnology tend to be the most adamant opponents of many aspects of patent reform. BIO opposes injunction reform, any limitations on continuation practice, second-window opposition proceedings, and any limitation on a patent owner's choice of venue in bringing suit.[76] In short, BIO is against virtually all of the major proposed reforms that would weaken patents or restrict the rights of patent holders. Still, BIO does support some reforms that could have a marginally negative impact on the interests of inventors, including first-inventor-to-file,

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[70] *Id.*

[71] U.S. Patents Nos. 5,843,780 and 6,200,806. *See also* DIANE T. DUFFY, ALMANAC OF POLICY ISSUES, BACKGROUND AND LEGAL ISSUES RELATED TO STEM CELL RESEARCH (2002), http://www.policyalmanac.org/health/archive/crs_stem_cell.shtml.

[72] *Patent Law Revision: Hearing on an Amendment in the Nature of a Substitute to H.R. 2795, the Patent Act of 2005 Before Subcomm. on Courts, the Internet, and Intellectual Property of the H. Comm. of the Judiciary*, 109th Cong. (2005) [hereinafter *PhRMA Statement*] (statement of Philip S. Johnson, speaking on behalf of PhRMA).

[73] PHRMA—About PhRMA, http://www.phrma.org/about_phrma/ (last visited Apr. 9, 2006).

[74] *See* Johnson & Johnson, Family of Companies, http://www.jnj.com/our_company/family_of_companies/ (last visited Apr. 9, 2006) (listing the "family of companies" Johnson & Johnson has acquired in the center drop-down menu).

[75] *Patent Quality: Hearing on Patent Quality and Improvement Before the Subcomm. on Courts, the Internet, and Intellectual Property of the H. Comm. of the Judiciary*, 109th Cong. (2005) (statement of Richard J. Lutton, Jr., Chief Patent Counsel, Apple).

[76] *See BIO Statement*, *supra* note 56 (testimony of Robert Chess).

mandatory eighteen-month publication, and pre-grant submissions of prior art by third parties.[77]

Conversely, BIO supports reforms that will strengthen patent rights by making it more difficult to challenge the validity and enforceability of issued patents during litigation.[78] In particular, BIO supports the move to eliminate the best mode requirement and to restrict the inequitable conduct defense.[79] Both of these issues have garnered considerable criticism as "subjective" requirements of patentability because they are based on the inventor's state of mind.[80] These issues can also be problematic because they are generally not amenable to examination by the PTO, and only arise during litigation. In the course of litigation, however, pre-trial discovery can be used to uncover evidence purporting to prove that the inventor (1) subjectively believed, but failed to disclose, that there was a best mode of practicing the invention or (2) knew of relevant prior art, and intentionally failed to disclose it to the PTO during examination.

Genentech's testimony is consistent with that of BIO, though Genentech is somewhat more open to limitations on the rights of patent owners.[81] In particular, Genentech actually supports first-window opposition proceedings, a subject with respect to which BIO expresses no opinion.[82] Conversely, Genentech expressed no opinion on second-window opposition, to which BIO was adamantly opposed.[83] The divergence makes sense. BIO appears to be biased in favor of early stage biotechnology companies, which generate most of their revenue from investment as opposed to product sales.[84] However, Genentech is a relatively mature biotechnology company that generates substantial sales revenue, and as such, is much more likely to find itself a defendant in a patent infringement action.[85] Hence, the ability to preemptively dispose of junk patents by means of post-grant opposition would be much more appealing to Genentech than to the average biotechnology company.

The position of WARF with respect to patent reform is even more reactionary than that of BIO. WARF agrees with BIO that there should be no second window for post-grant opposition, no weakening of the injunction standard, and no continuation practice reform.[86] However, WARF parts with BIO on a number of issues, for example, by opposing the change to the first-inventor-to-file system.[87] This stance likely reflects WARF's concern that universities are generally likely to delay filing an application, and hence WARF wants to retain the ability to prove priority of invention by invoking the interference procedure. Also, since universities have little

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[77] *BIO Statement*, *supra* note 56 (testimony of Robert Chess).

[78] *See BIO Statement*, *supra* note 56 (testimony of Robert Chess).

[79] *See BIO Statement*, *supra* note 56 (testimony of Robert Chess).

[80] See *infra* Part IV.D.

[81] *See Genentech Statement*, *supra* note 64 (testimony of Jeffery Kushan).

[82] *See Genentech Statement*, *supra* note 64 (testimony of Jeffery Kushan); *BIO Statement*, *supra* note 56 (testimony of Robert Chess).

[83] *See Genentech Statement*, *supra* note 64 (testimony of Jeffery Kushan); *BIO Statement*, *supra* note 56 (testimony of Robert Chess).

[84] *See BIO Statement*, *supra* note 56 (testimony of Robert Chess).

[85] *See Genentech Statement*, *supra* note 64 (testimony of Jeffery Kushan).

[86] *See WARF Statement*, *supra* note 69 (testimony of Carl Gulbrandson); *BIO Statement*, *supra* note 56 (testimony of Robert Chess).

[87] *See WARF Statement*, *supra* note 69 (testimony of Carl Gulbrandson).

need to worry about being sued for patent infringement, they are less affected by the uncertainty problems inherent in the patent interference system.[88]

For the most part, the position of PhRMA is aligned with BIO and Genentech. PhRMA does not express an opinion regarding some of the issues important to BIO and Genentech, such as the reform regarding the subjective elements of patent law and restrictions on continuation practice.[89] However, with respect to virtually all issues where PhRMA, Genentech, and/or BIO express an opinion, the groups are in agreement.[90] The one significant point on which they diverge is venue reform.[91] While BIO is against any reform that would limit the ability of the patentee to choose the venue for bringing suit, PhRMA is willing to accept the modified form of venue reform proposed in the Coalition version of the reform bill (although PhRMA does oppose the more extreme version of venue reform that appears in the substitute legislation).[92]

III. OBSERVATIONS REGARDING BIOTECHNOLOGY'S POSITION ON PATENT REFORM

Before discussing some of the implications of specific reforms on biotechnology, I digress briefly with a few general observations regarding biotechnology's patent reform agenda. First, to a large extent, it is apparent that biotechnology values patents primarily for their ability to attract investment, and thus, the perceptions of investors with respect to patent reform play a dominant role in shaping the biotechnology position. Second, despite the widely-expressed fear that a proliferation of patents would have a deleterious effect on biomedical research, one sees very little evidence of that concern coming from the industry itself. To the contrary, biotechnology is one of the staunchest defenders of a strong patent system, and generally evinces little enthusiasm for reforms that might address the problem of a "patent thicket."[93]

A. Focus on Investors

BIO's testimony can be paraphrased as follows: "Investors believe that in order for the biotechnology sector to succeed, it is critical that biotechnology firms be able to obtain and enforce strong patents. Biotechnology companies, particularly those that have yet to put a product on the market, must rely on substantial investment funding in order to survive. If there is any perception that patent reform will

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[88] *See infra* Part IV.B.

[89] *See PhRMA Statement*, *supra* note 72 (testimony of Philip Johnson); *BIO Statement*, *supra* note 56 (testimony of Robert Chess); *Genentech Statement*, *supra* note 64 (testimony of Jeffery Kushan).

[90] *PhRMA Statement*, *supra* note 72 (testimony of Philip Johnson); *BIO Statement*, *supra* note 56 (testimony of Robert Chess); *Genentech Statement*, *supra* note 64 (testimony of Jeffery Kushan).

[91] *See PhRMA Statement*, *supra* note 72 (testimony of Philip Johnson); *BIO Statement*, *supra* note 56 (testimony of Robert Chess).

[92] *See PhRMA Statement*, *supra* note 72 (testimony of Philip Johnson); *BIO Statement*, *supra* note 56 (testimony of Robert Chess).

[93] *BIO Statement*, *supra* note 56 (testimony of Robert Chess).

weaken patent protection for biotechnology inventions, investors will not be as willing to fund biotechnology, and this reluctance will adversely impact biotechnology. Therefore, BIO opposes any reform that would create such a perception."[94]

There is little discussion in BIO's testimony with regard to the importance of using strong patent protection to block competitors or generate licensing royalties, the conventional uses one normally associates with patents.[95] Rather, the only example Chess provides of a patent helping a biotechnology company was an anecdote regarding a particular patent that caused his company's stock to shoot up 20% on the day it issued.[96]

BIO testified that any aspect of patent reform that would "weaken[] the ability of innovators to obtain and enforce patent protection" should be eliminated because any such reform would deter investors.[97] For example, with respect to injunction reform, Chess testified that BIO was "concerned that lowering the present standard would create uncertainty and confusion in the law, hampering our ability to attract VC financing . . . ."[98] Similarly, BIO testified that second-window post-grant opposition would create too much uncertainty regarding the validity of issued patents.[99] "With no certainty, venture capital would leave our industry, again threatening our ability to bring new cutting-edge products to the market."[100]

In short, BIO's testimony focused almost entirely on the importance of patents as instruments for convincing investors to put their money into biotechnology companies. In contrast, PhRMA and BSA characterized patents a being important because patents provide the ability to exclude competitors from the market, which is the more conventional understanding of patent utility.

There is some basis for BIO's concern regarding perceptions of investors. For example, on March 14, 2000, former President Bill Clinton and British Prime Minister Tony Blair "issued a bland statement urging all lab[oratories] to provide 'unencumbered access' to raw DNA sequence information."[101] The statement reflected no actual change in patent law or policy, but was interpreted by skittish investors as suggesting that gene patents might be disfavored by the White House.[102] As described at the time in the journal *Science*, "[a]lmost immediately, biotech stocks, which were already headed downward, went into a nose dive; some companies lost as much as 20% of their value on paper in a few hours."[103] Many of the stocks never recovered. For example, a week later, the value of stock in genomic companies Celera and Incyte were "still 60% below their peak immediately before the statement."[104] "One biotech expert suggested a simple explanation: Stock buyers

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[94] *See generally BIO Statement*, *supra* note 56 (testimony of Robert Chess).

[95] *See generally BIO Statement*, *supra* note 56 (testimony of Robert Chess).

[96] *BIO Statement*, *supra* note 56 (testimony of Robert Chess).

[97] *See BIO Statement*, *supra* note 56 (testimony of Robert Chess).

[98] *BIO Statement*, *supra* note 56 (testimony of Robert Chess).

[99] *See BIO Statement*, *supra* note 56 (testimony of Robert Chess).

[100] *BIO Statement*, *supra* note 56 (testimony of Robert Chess).

[101] Eliot Marshall, *Biotechnology: How a Bland Statement Sent Stocks Sprawling*, 287 SCI. 2127, 2127 (2000).

[102] *See id.*

[103] *See id.*

[104] *Id.*

'don't understand what they're investing in,' he said, and they can be easily spooked."[105] Clearly, biotechnology is justified in its concern with investor perceptions, regardless of whether or not there is any rational basis for the perceptions.

BIO's focus on investor perception reflects the concerns of an early-stage investor-funded biotechnology company, but as the industry matures to a point where more biotechnology companies are actually generating sales revenue, I predict that BIO's views on patents will also change, becoming more like those of Genentech. In particular, biotechnology will increasingly feel the negative effects of a strong patent regime, as is currently being experienced most acutely by the information technology sector. At that point, BIO's patent agenda might begin to resemble that of other, more established industries.

At some point, BIO's focus on the perceptions of investors could result in a positive feedback loop. Consider the possibility that the ideal patent regime for biotechnology is not so very different from that of other industries: what if junk patents and strong enforcement practices are as detrimental to biotechnology as they are to any other business sector? If biotechnology investors continue to believe that strong patent protection is critical to the industry, they will view any weakening of patents rights as injurious to the industry. Also, even if biotechnology companies conclude that patent reforms would benefit the industry, they might fear that investors would perceive the changes as detrimental. By focusing on the ability to attract investment capital, biotechnology would lobby to maintain the status quo, because any long term benefits to be derived from patent reform would be outweighed by a problem of investor perception. In a self-fulfilling prophecy, such lobbying would confirm the perception among investors that continuing strong patent protection is critical for biotechnology.

Perhaps at some point BIO should reconsider its focus on investor perception. The industry might ultimately be better off with some of the proposed reforms, even if they do weaken the rights of certain patent holders. Patent policy should not be primarily driven by the perceptions of investors, particularly if those perceptions are flawed or outdated.

B. Little Evidence of a Patent Thicket

Various commentators have proposed that a proliferation of patents poses a serious threat to biotechnology research by creating a patent thicket, sometimes referred to as a "patent anticommons."[106] The theory is especially associated with articles published by Heller and Eisenberg in 1998, and Eisenberg and Rai in 2002.[107] Proponents of the patent thicket hypothesis note that while patents traditionally were reserved for products, there has been an increasing tendency for biomedical researchers to patent upstream inventions, i.e., research tools and inputs

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[105] *Id.*

[106] Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation: The Anticommons in Biomedical Research*, 280 SCI. 698, 698 (1998).

[107] *See id.*; *see also* Rai & Eisenberg, *supra* note 68, at 297; Robert P. Merges & Richard R. Nelson, *On the Complex Economics of Patent Scope*, 90 COLUM. L. REV. 839 (1990).

used to conduct basic research and development, as opposed to the products of research and development.[108] This trend has been attributed to changes in the law, such as the enactment of the Bayh-Dole Act, and changes in the norms of science, such as the increasing commercialization and privatization of biomedical research.[109] These commentators predict that the patenting of upstream technology will result in a difficult-to-penetrate thicket of patent rights that will severely impede biomedical research and development.[110] The idea has found resonance with many, and its influence is evident in a variety of critiques of the current patent system.[111]

If in fact a patent thicket is significantly impeding biotechnology research and development, one might expect that organizations representing the interests of biotechnology, such as BIO, WARF, and Genentech, would be advocating for reforms that would address the problem. Indeed, the biotechnology industry has never been shy about advocating for legislative action to address its concerns.[112] But instead, these groups tend to be among the most adamant defenders of the status quo and strong patent rights. One might infer from this that a patent thicket is not in fact substantially impeding biotechnology.

The suggestion that patents are not significantly impacting the ability of researchers to conduct biotechnology research is consistent with the results of a recent study prepared for the National Academy of Sciences Committee on Intellectual Property Rights in Genomic and Protein-Related Inventions.[113] Through a survey of 1125 academic and 563 industry researchers, the authors of the study set out to assess the impact of patents on the ability of academic and industrial laboratories to conduct biomedical research.[114] Of a random sample of 398 academics surveyed, only 1% reported suffering a project delay of more than a month due to patents on knowledge inputs necessary for their research.[115] None of those surveyed had stopped a project due to the existence of third party patents on research inputs.[116] In contrast, access to tangible property in the form of material transfers was found to be much more likely to impede research.[117] The study also reported substantial commercial activity among academic respondents.[118]

With respect to industry researchers, the effect of patents was greater than for academic researchers, but was still relatively modest. Out of seventeen respondents, only two reported that they had to stop a project because of a patent, and one was a

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[108] *See* Rai & Eisenberg, *supra* note 68, at 289.

[109] *See* Rai & Eisenberg, *supra* note 68, at 289–91.

[110] *See* Rai & Eisenberg, *supra* note 68, at 295–303.

[111] *See, e.g.*, Stephen Hansen et al., The Effects of Patenting in the AAAS Scientific Community (2006), http://sippi.aaas.org/survey/AAAS_IP_Survey_Report.pdf; *see also* NAS report, *supra* note 13.

[112] For example, the industry successfully lobbied for the Biotechnological Process Patents Act of 1995, which added 35 U.S.C. § 103(b), which is an amendment to the patent code's nonobviousness standard, and provides an exception for biotechnology inventions. *See* 7 DONALD S. CHISUM, CHISUM ON PATENTS § 5.04(8)(b)(ii)(B) (2004).

[113] John P. Walsh et al., Patents, Material Transfers and Access to Research Inputs in Biomedical Research, at 3 (2005), http://tigger.uic.edu/~jwalsh/WalshChoCohenFinal050922.pdf.

[114] *Id.* at 2.

[115] *Id.*

[116] *Id.*

[117] *Id.*

[118] *Id.*

case involving a patent on a drug, i.e., the patented technology and the firm's technology objectives competed.[119] Thus, the study identified, at most, one case in which a research tool patent might have stopped a biomedical research project.

The study clearly suggests that patents are not substantially restricting biotechnology research, which is consistent with the strong pro-patent position of biotechnology that we see with respect to patent reform.

IV. A CRITIQUE OF THE BIOTECHNOLOGY POSITION ON SPECIFIC REFORM PROPOSALS

In the remainder of this paper, I will consider some of the proposed reforms and how the changes, if implemented, might impact biotechnology. I will also describe some specific recent biotechnology patent cases in which the outcome might have been affected if the reforms were already in place. With respect to some issues, I suggest that the biotechnology sector might reconsider its position, particularly as the industry evolves to produce increasingly complex products and derive its revenue more from product sales and less from investors.

A. Continuation Reform

United States patent law provides that a patent applicant may file one or more continuation applications.[120] If the continuation application meets the requirements of continuity of disclosure, copendency, cross-referencing, and identity of inventorship, it will gain the benefit of the filing date of the prior application for determining patentability and priority.[121] A patent applicant whose application has been "finally rejected" can file a continuation application, which results in effectively getting another chance to argue in favor of the patentability of his invention to the PTO. Since there is no limit to the number of continuations that can be filed, it is virtually impossible for the PTO to ever truly finally reject a patent application.[122]

Not only does continuation practice enable a patent applicant to keep an application alive in the PTO indefinitely, but it also allows the applicant to change and broaden the claims during prosecution, and to file divisional applications.[123] The divisional applications can result in multiple patents, with overlapping claims and different expiration dates, ultimately issuing out of the filing of a single initial patent application.[124] As a result, a patent applicant can strategically exploit continuation practice in a variety of ways.

Many argue that the strategic exploitation described above can oftentimes amount to abuse of the system. For example, Lemley and Moore have identified a number of pernicious effects of continuation practice as it currently exists, including

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[119] *Id.* at 36.

[120] CHISUM, *supra* note 112, § 13.01.

[121] CHISUM, *supra* note 112, § 13.01; *see* Mark A. Lemley & Kimberly A. Moore, *Ending Abuse of Patent Continuations*, 84 B.U. L. Rev. 63, 64 (2004) (describing and critiquing the continuation practice).

[122] *See* Lemley & Moore, *supra* note 121, at 68.

[123] *See* Lemley & Moore, *supra* note 121, at 68.

[124] *See* Lemley & Moore, *supra* note 121, at 81–83.

the delay and uncertainty it injects into the patent prosecution process, the tendency of patent practitioners to use the process to "wear down" the patent examiner, and the problem of "submarine patents."[125] Furthermore, by allowing applicants to amend and file new and broader claims during the course of patent prosecution, it has been possible for applicants to introduce claims that cover new developments in technology that were not envisioned by the patentee at the time the original patent application was filed.[126] Patent applicants also can abuse the process by filing divisional patent applications incorporating new or revised claims to obtain multiple patents that all cover essentially the same invention, a tactic referred to as "evergreening" that has become especially associated with pharmaceutical inventions.[127]

In response to these abuses, a number of commentators have proposed eliminating or strictly curtailing continuation practice.[128] The FTC report also discusses problems with the abuse of continuation practice and suggests that reforms be considered.[129]

As originally drafted, H.R. 2795 included a relatively modest proposal to reform continuation practice, essentially giving the Director of the PTO the authority to limit continuations in cases where the process was being abused.[130] The decision to act would be solely at the discretion of the Director.[131] BIO, joined by WARF, PhRMA, and Genentech, strongly opposed even this modest proposal for reform, which presumably contributed to its deletion from the Substitute and Coalition Print.[132]

Continuation practice is particularly important to biotechnology for a couple of reasons. First, the most important and potentially lucrative products being developed in biotechnology are drugs,[133] and pharmaceutical companies have traditionally employed continuation practice to evergreen their proprietary position, a process sometimes referred to as "life cycle management."[134] Through evergreening, many highly profitable drugs are kept "on patent" long past the

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[125] *See* Lemley & Moore, *supra* note 121, at 74–77, 79–80.

[126] *See* Lemley & Moore, *supra* note 121, at 76.

[127] *See* Lemley & Moore, *supra* note 121, at 81–82.

[128] *See, e.g.*, *The Patent Act of 2005: Hearing on H.R. 2795 Before the Subcomm. on Courts, the Internet, and Intellectual Property of the H. Comm. on the Judiciary*, 109th Cong. (2005) (statement of Daniel Ravicher, Executive Director, Public Patent Foundation); *Patent Law Revision: Hearing on H.R. 2795 Before the Subcomm. on Intellectual Property of the S. Comm. on the Judiciary*, 109th Cong. (2005) [hereinafter *Lemley Statement*] (statement of Mark Lemley, Professor, Stanford Law School).

[129] FTC report, *supra* note 10, at 16.

[130] Patent Act of 2005, H.R. 2795, 109th Cong. § 8 (as introduced in the House).

[131] *Id.*

[132] *BIO Statement*, *supra* note 56 (testimony of Robert Chess); *WARF Statement*, *supra* note 69 (testimony of Carl Gulbrandson); *see* Smith, *supra* note 39; Coalition Print *supra* note 47.

[133] *See, e.g.*, Dana Elfin, *Drug Patent Issues, Strategies to Delay Generics Hold Antitrust Lawyers' Attention*, PAT., TRADEMARK & COPYRIGHT L. DAILY (BNA), Mar. 30, 2001; Manisha Singh Nair, *Product Patent Regime & Pharmaceutical Industry in India—The Challenges Ahead*, MONDAQ, Jan. 10, 2005.

[134] Singh, *supra* note 133.

expiration of the initial patent covering the drug itself.[135] Surely biotechnology would like to maintain its ability to take advantage of this strategy.

Second, biotechnology companies are notorious for filing "genomics" patent applications disclosing hundreds or even thousands of individual gene sequences, each of which could potentially be a separate patentable invention warranting its own patent.[136] The difficulty for the typical biotechnology company is that at the time the genetic sequences are discovered, the "inventor" often has no idea which, if any, of the many sequences might some day turn out to be valuable and hence worthy of patent protection. Filing individual applications on each sequence would be prohibitively expensive, so the company files an omnibus "genomics" application disclosing all of the sequences, thereby establishing a priority date and staking a claim to all of the sequences.[137] Later, if it turns out that one or more of the sequences are indeed worthy of patent protection, the company can file one or more divisional applications directed to the particular sequences of interest. It is continuation practice that makes this approach possible. BIO's testimony alludes to this practice, highlighting its importance because the practice allows biotechnology companies to "obtain adequate protection for the full scope of their inventions [as] the inventor's understanding of his or her basic invention increases over time."[138]

Biotechnology companies have used (some would say abused) continuation practice to evergreen protection for some of the fundamental enabling technologies of biotechnology. For example, in a recent high profile case, Genentech took advantage of continuation practice to obtain what in effect amounts to a twenty-nine year patent term covering what the company characterizes as "the 'fundamental technology' required for the artificial synthesis of antibody molecules," commonly referred to as the "Cabilly patent."[139] The victims of this particular evergreening included another large biotechnology company, MedImmune, who decided to challenge Genentech in the courts and at the PTO.[140] MedImmune's appeal was rejected by the Federal Circuit for lack of jurisdiction, with the court essentially finding that as a licensee of the patent, MedImmune lacked standing to challenge the patent's validity.[141] The U.S. Supreme Court recently granted a *writ of certiorari* on the case to consider whether the Federal Circuit erred in denying standing to MedImmune.[142]

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[135] *See* Lemley & Moore, *supra* note 121, at 82 (stating pharmaceutical companies could obtain many sequential thirth-month stays through evergreening).

[136] *See, e.g.*, DOEGenomes.org, Human Genome Project Information: Genetics and Patenting, http://www.ornl.gov/sci/techresources/Human_Genome/elsi/patents.shtml (last visited Apr. 23, 2006).

[137] *See, e.g.*, U.S. Patent Application No. 2002/0045170 (filed Apr. 18, 2002) (example of a genomics patent application).

[138] *BIO Statement*, *supra* note 56 (testimony of Robert Chess).

[139] *See* Douglas Kline & Duncan Green Halgh, *When Patents Persist*, BIO-IT WORLD, Dec. 15, 2003.

[140] *See id.*; Medimmune, Inc. v. Genentech, Inc., 427 F.3d 958, 961 (Fed. Cir. 2005).

[141] *See id.* at 965 (holding Medimmune lacked standing to file a declaratory judgment action, because "under no threat or apprehension of suit").

[142] MedImmune, Inc. v. Genentech, Inc., 126 S. Ct. 1329 (2006).

In another widely publicized case, the availability of continuation practice and the ability to evergreen patent exlusivity worked to Genentech's disadvantage.[143] The technology at issue, known as co-transformation, is used in the production of many of biotechnology's most profitable protein-based drugs.[144] The original patent application covering the technology was filed in 1980, issued as U.S. Patent No. 4,399,216 in 1983, and expired in 2000.[145] Many biotechnology companies, including Genentech, licensed the technology from the patent owner, Columbia University, and paid millions of dollars in royalties annually to use the technology in their drug production processes.[146] One might have reasonably assumed that after the patent expired in 2000 the technology would have become part of the public domain, at which point it would be freely available without requiring royalty payments.

However, as is so often the case with valuable patents, Columbia pursued a variety of approaches in an attempt to evergreen its proprietary position.[147] In 2002, much to the chagrin of Genentech and the other companies using the co-transformation technology, Columbia succeeded in convincing the PTO to grant another patent, covering what many consider to be essentially the same technology, for another full seventeen year term.[148] These companies unexpectedly faced the prospect of seventeen more years of royalty payments, and this could not have occurred had Columbia not been able to exploit the laws of continuation practice.

Genentech and the other affected companies banded together and mounted a variety of legal challenges to the second patent, which ultimately resulted in Columbia agreeing not to assert the patent.[149] Still, the case illustrates the potential for mischief inherent in current continuation practice, and the kind of impact such mischief can have on biotechnology.

In the case of the Columbia and Cabilly patents, Genentech experienced both aspects of the two-edged sword that is continuation practice. These cases of evergreened protection on fundamental technologies could have been avoided by effective continuation reform, which probably would have been of overall benefit to biotechnology. Still, the ability to evergreen protection of drug products will be increasingly lucrative for biotechnology, so the industry will likely remain continue in the belief that, on the whole, continuation practice is good for business.

B. First-Inventor-to-File

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[143] *See generally* Recent Development, *Columbia, Co-transformation, Commercialization & Controversy: The Axel Patent Litigation*, 17 HARV. J. L. & TECH. 583 (2004).

[144] *Id.*

[145] *Id.* at 594. U.S. Patent No. 4,399,216 (filed Aug. 16, 1983).

[146] Recent Development, *supra* note 143, at 594.

[147] Recent Development, *supra* note 143, at 596–97.

[148] Recent Development, *supra* note 143, at 597. U.S. Patent No. 6,455,275 (filed Sept. 24, 2004).

[149] *See* Public Patent Foundation, *PUBPAT Scores Another Victory: Columbia University Abandons Assertion of Challenged Cotransformation Patent*, Dec. 1, 2004, http://www.pubpat.org/Axel_Patent_Abandoned.htm; *see also* Columbia University's Amended and Restated Covenant Not to Sue Plaintiffs for Infringement of the '275 Patent, *In re* Columbia Univ. Patent Litig., MDL No. 1592 (MLW) (Oct. 12, 2004), *available at* http://www.pubpat.org/Covenant%20Not%20to%20Sue.pdf.

One reform that BIO, PhRMA, and Genentech (but not WARF) support is the move to a first-inventor-to-file system.[150] One substantial benefit of the first-inventor-to-file system is that it eliminates the need for patent interference proceeding to determine priority of inventorship.[151]

By its nature, the biotechnology industry is particularly prone to multiple entities discovering an invention at about the same time. This arises in large part from the nature of biotechnology inventions, which often involve the identification of biological pathways, biomolecules and genetic sequences. Multiple laboratories and companies are often conducting research in the same area, so not surprisingly they often make the same discoveries at about the same time. This has resulted in an inordinately high percentage of patent interferences that involve biotechnology inventions.[152]

These patent interferences can have a number of adverse consequences for biotechnology as a whole. For one thing, they can be quite expensive for the companies involved. Perhaps more importantly, patent interferences introduce a great deal of uncertainty and delay into the patenting process, because the process can take many years to resolve, and until that time no one knows who will ultimately own the patent. Furthermore, during the course of an interference the claims can change substantially, and because the proceedings are often secret until a patent issues, entities that might be affected often have no way of knowing exactly when (or even if) the patent will ultimately issue, when it will expire, who will own the patent, and the scope of the claims that might ultimately be allowed.

These concerns with patent interference are analogous to those described above with respect to continuation practice. In fact, the *de facto* twenty-nine year patent term described above was the results of Genentech's exploitation of both continuation practice and the interference process.[153]

Another example where interference practice has imposed a great deal of uncertainty on biotechnology is the interference relating to Agrobacterium-mediated transformation, one of the fundamental enabling technologies of agricultural biotechnology that is used to introduce foreign genes into plants.[154] Both Monsanto and the Max Planck Institute initially filed patent applications on this technology in 1983.[155] Later, two other parties also alleged to have been the first to invent the

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[150] *WARF Statement*, *supra* note 69 (testimony of Carl Gulbrandson); *BIO Statement*, *supra* note 56 (testimony of Robert Chess); *Genentech Statement*, *supra* note 64 (testimony of Jeffery Kushan); *PhRMA Statement*, *supra* note 72 (testimony of Philip Johnson).

[151] Patent Act of 2005, H.R. 2795, 109th Cong. § 3; *see also* CHISUM, *supra* note 112, § 10.09 (describing current interference practices).

[152] Association of Patent Law Firms, *Current Patent Interference Statistics*, Feb. 3, 2003, http://www.aplf.org/mailer/interference-02.html (reporting the Board of Patent Appeals and Interferences' finding that the "greatest number of interferences continue to originate from Group 1600 (biotechnology)").

[153] MedImmune, Inc. v. Genentech, Inc., 427 F.3d 958, 958 (Fed. Cir. 2005). MedImmune has alleged that Genentech fraudulently abused the interference process in this case. *Id.*

[154] *See generally* Carl Pray & Anwar Naseem, Intellectual Property Rights on Research Tools-Incentives or Barriers to Innovation? Case Studies of Rice Genomics and Plant Transformation Technologies, (ICABR International Consortium on Agricultural Biotechnology: Ten Years Later, 2005), July 6–10, 2005, http://www.economia.uniroma2.it/conferenze/icabr2005/papers/Naseem.pdf.

[155] *Id.* at 7.

technology, resulting in a four-way patent interference.[156] In October of 2004, after a twelve-year interference procedure, Monsanto reported that it had finally prevailed.[157] As of the time this article was written no patent has issued, and because the proceedings are secret the status of the case is not public information. However, assuming a patent does issue at some point, it will do so with a full seventeen-year term, i.e., it will be in force more than 40 years after the initial invention. Because the technology is the primary method by which certain genetically modified crops are produced, the issuance of the patent could potentially be catastrophic for some agricultural biotechnology companies, depending upon the scope of the claims that ultimately issue, the willingness of Monsanto to broadly license the technology, and to what extent alternative technologies become available.

Regardless of the ultimate outcome of the Agrobacterium transformation interference, the ongoing uncertainty associated with the interference has in and of itself had a detrimental impact on agricultural biotechnology. The threat that a patent might at some point issue that would prevent the use of Agrobacterium technology has made it more difficult for some agricultural biotechnology companies to secure investment funding, and these companies have expended a considerable amount of energy attempting to design around the technology.[158]

C. Injunction Reform

Barring exceptional circumstances, such as an imminent risk to public health, permanent injunctive relief is virtually automatic once a court determines that a patent has been infringed.[159] The computer and software industries have been particularly adamant in arguing that injunctions should not be automatic.[160] Instead, they argue that in some cases equity requires that only money damages be assessed, particularly when the patentee is a "non-manufacturing entity" ("NME") that does not produce or market the patented technology but merely seeks to extract royalty payments from companies that do. NMEs are sometimes referred to pejoratively as "patent trolls."[161]

One of the reforms included in H.R. 2795 as originally filed would have weakened the presumption in favor of injunction by requiring a court to consider the fairness of an injunction in light of all the facts and the relevant interests of the parties.[162] It would have also permitted a court to stay an injunction pending appeal upon an affirmative showing that the stay would not result in irreparable harm to

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[156] *Id.* at 10.

[157] Monsanto News & Media, *Monsanto Wins Key Patent Dispute Regarding Dicot Plant Transformation*, Oct. 5, 2004, http://www.monsanto.com/monsanto/layout/media/04/10-05-04.asp.

[158] Personal communication, John Bedbrook, Ph.D., vice-president of Research & Development – DuPont Agriculture and Nutrition.

[159] MercExchange, L.L.C. v. eBay, Inc., 401 F.3d 1323, 1338 (Fed. Cir. 2005), *cert. granted,* 74 U.S.L.W. 3321 (U.S. Nov. 28, 2005) (No. 05-103) (asking parties to brief and argue on "when it is appropriate to grant an injunction against a patent infringer").

[160] FTC REPORT, *supra* note 10, ch. 3, pt. 4, at 38.

[161] *Lemley Statement*, *supra* note 128 (testimony of Mark Lemley) (explaining that "patent trolls" use the patent system to squeeze money out of those who develop products).

[162] Patent Reform Act, H.R. 2795 § 8.

the patent owner.[163] In their testimony, BIO, Genentech, WARF, and PhRMA adamantly opposed injunction reform. Consequently, injunction reform was not included in the Substitute or Coalition Print.

The opposing positions of BIO and PhRMA on one hand and the information sector on the other have often been attributed to the very different characteristics of the industries.[164] Software programs and semiconductor chips comprise thousands of individual components, each of which can be subject to an individual patent.[165] Furthermore, ownership of these component patents is typically distributed among multiple parties, many of whom are solely in the business of licensing the patent as opposed to actually making a product, i.e., NMEs.[166] This leads to a problem of hold-up, where the holder of a patent that covers only a small fraction of a commercial product leverages unjustifiably high royalty payments out of the manufacturer by enjoining sales of the entire product.[167] This scenario is particularly problematic because, in many cases, the manufacturer is locked into the product design. For example, once a software application or semiconductor chip has been designed, manufactured, and introduced into the market, it can be extremely expensive for the manufacturer to re-engineer the product to avoid an allegedly infringed patent, even though the patent might only cover a small fraction of the entire product.[168] It is the threat of permanent injunction that provides the patentee with leverage to demand an inordinately high royalty relative to the actual value the technology brings to the product. Essentially, the manufacturer is paying not for the technology *per se*, but to avoid the expense of having to switch technologies midstream.[169]

The biotechnology and pharmaceutical industries, on the other hand, have been characterized as having much simpler products that are typically only covered by a single or relatively few patents, e.g., drugs.[170] For this reason, the hold-up phenomenon tends to be much less of a problem, or so the conventional thinking goes. At the same time, injunctions are thought to be important for the biotechnology and pharmaceutical industries because they can be used to stop the sales of infringing generic products; the argument being that money damages would not be a sufficient remedy for such infringement.[171] In general, the availability of injunctive relief greatly increases the power of a patent, so any weakening of the strong presumption in favor of injunctions will necessarily tend to weaken the rights of patent owners, something that biotechnology generally opposes.

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[163] *Id.*

[164] *Lemley Statement*, *supra* note 128 (testimony of Mark Lemley).

[165] *Id.*

[166] *See id.*

[167] *Id.*

[168] *Id.*

[169] *Id.* For example, in his congressional testimony Prof. Mark Lemley referenced an example where a patent owner "charges a 0.75% royalty for patents that don't cover industry standards, and 3.75% for patents that do cover industry standards." *Id.* He asserts that the five-fold difference in royalty rates represents the difference in royalty rates for technology that is "locked in" versus the value of the technology itself. *Id.*

[170] *Id.*

[171] *Id.*

The generalization that biotechnology is characterized by simple, unitary inventions is probably an oversimplification. Biotechnology products are becoming increasingly complex, the result of the synthesis of multiple input technologies, each of which is potentially covered by one or more patents. This trend is certain to continue. As biotechnology products become more complex, they will increasingly become vulnerable to the threat of injunctive hold-up, and at some point biotechnology might need to reevaluate its support for virtually automatic permanent injunctions in all cases of patent infringement.

For example, consider agricultural biotechnology, which generally involves introducing one or more genetic changes into a crop plant, resulting in desirable new crop traits.[172] The process is quite involved, and relies upon the use of a variety of different enabling technologies, many of which are covered by patents.[173] In one highly publicized case study, scientists used biotechnology to create "golden rice," a form of rice genetically modified to produce elevated levels of vitamin A.[174] It was envisioned that golden rice could be grown in developing countries and serve as an inexpensive and accessible source of this vital nutrient for impoverished people suffering from vitamin A deficiency.[175] However, an initial freedom-to-operate analysis determined that the development of the product was covered by at least seventy different patents, and licensing the required intellectual property was viewed as a major obstacle to the project.[176] In the end, the developers of golden rice convinced patent owners to freely license the necessary technologies, who probably agreed because golden rice was being developed primarily for humanitarian purposes and was not thought to be viable as a commercial product.[177] However, one can well imagine that when a biotechnology company is attempting to develop a commercially viable recombinant crop product, this complex patent landscape could prove a formidable barrier to development. The potential for a single patent holder to obtain a permanent injunction barring the sale of the entire product surely compounds the problem. Once the product is on the market, the producer is at least as locked into the technology as the semiconductor chip manufacturer, and just as vulnerable to hold-up.

Golden rice is a fairly simple recombinant product, involving the introduction of a single gene conferring a single trait, and is typical of the first wave of agricultural biotechnology.[178] However, agricultural technology continues to move towards "trait stacking," i.e., the introduction of multiple genetically modified traits into a single

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[172] Cliff D. Weston, *Chilling the Corn: Agricultural Biotechnology in the Face of U.S. Patent Law and the Cartagena Protocol*, 4 J. SMALL & EMERGING BUS. L. 377, 384 (2000).

[173] *Id.*

[174] *See* Xudong Ye et al., *Engineering the Provitamin A (Beta-Carotene) Biosynthetic Pathway into (Carotenoid-Free) Rice Endosperm*, 287 SCI. 303 (2000) (discussing the case study on golden rice).

[175] *Id.* at 303.

[176] The ETC group, formerly RAFI–the Rural Advancement Foundation International, Golden Rice and Trojan Reps: A Case Study in the Public Sector's Mismanagement of Intellectual Property, Issue 66 (2000), http://www.etcgroup.org/documents/com_goldenrice.pdf.

[177] *Id.*

[178] Meeting Minutes of Product Characterization, Human Health Risk, Ecological Risk, And Insect Resistance Management For *Bacillus thuringiensis* (*Bt*) Cotton Products, FIFRA Scientific Advisory Panel, at 23 (June 8–10, 2004), *available at* http://www.epa.gov/scipoly/sap/2004/june/final1a.pdf.

product.[179] For example, a plant might contain recombinant genes conferring "input traits," such as tolerance to drought, tolerance to high soil salinity, resistance to one or more herbicides, and resistance to a variety of pests, as well as "output traits" aimed at improving the taste, nutrition, and durability of the final product.[180] The needs of individual growers will vary (for example, by geographical region), and ultimately the variety of different trait stacking combinations will be immense. Given that each of the individual traits will likely be covered by multiple patents protecting a variety of genetic starting materials and enabling technologies, the patent landscape will begin to look much like the one facing semiconductor chip manufacturers. As this occurs, the problems of hold-up and the threat of injunction characteristic of the computer industry will increasingly become a problem for biotechnology.

In fact, some would say that we are already facing this situation. It has been reported that obtaining freedom to operate has become a major obstacle in the development of genetically modified crops.[181] To address this situation, an organization called CAMBIA has embarked upon a mission to develop alternatives to patented technology that would be freely available to those developing agricultural biotechnology products, particularly those products aimed at developing countries.[182] This program would alleviate the bottleneck caused by the multitude of patents that encumber so much of the enabling technology.[183]

As another illustration of the increasing complexity of biotechnology products, consider the DNA microarray, often referred to as a hybridization array or DNA chip.[184] Microarrays consist of small DNA fragments, called probes, physically attached to a solid surface such as glass, plastic, or silicon chip to form an array.[185] The precise location of each distinct probe is called a feature, and thousands, or even millions of different features can be contained in a single microarray.[186] DNA microarrays have proven extremely useful in a variety of contexts, including gene discovery, basic biomedical research, disease diagnosis, drug discovery (pharmacogenomics), and toxicological research (toxicogenomics).[187] The leading

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[179] *Review of Agricultural Biotechnology: Before the Subcomm. on Conservation, Credit, Rural Development, and Research of the H. Comm. on Agriculture*, 108th Cong. (2004) (statement of Fred Yoder, Chairman, National Corn Growers Association), *available at* http://www.ncga.com/biotechnology/pdfs/YoderHouseAgSubcommitteeTestimony06_2004.pdf.

[180] *Id.*

[181] *See* Press Release, Rural Advancement Found. Int'l, Monsanto's "Submarine Patent" Torpedoes Ag Biotech: Monsanto & Syngenta Monopolize Key Gene Marker Technologies (Apr. 26, 2001), *available at* http://www.etcgroup.org/documents/news_monsantosub.pdf (expressing concern over the affect of the monopolization of antibiotic resistance gene markers in agricultural biotechnology companies' freedom to operate).

[182] Cambia, Cambia's Mission and Ethos, http://www.cambia.org/daisy/cambia/590.html (last visited Apr. 7, 2006).

[183] *See id.*

[184] *See generally* Leming Shi, DNA Microarray (Genome Chip), http://www.gene-chips.com (last visited Apr. 1, 2006) (describing the basic principles and uses of DNA microarray technology).

[185] William M Freeman et al., *Fundamentals of DNA Hybridization Arrays for Gene Expression Analysis*, 29 BIOTECHNIQUES 1042, 1046 (2000), *available at* http://photoscience.la.asu.edu/photosyn/courses/MCB_576/Freeman_et_al_arrays.pdf.

[186] Affymetrix, Technology: The Industry Standard in Quality and Excellence, http://www.affymetrix.com/technology/index.affx (last visited Apr. 1, 2006).

[187] *See* Shi, *supra* note 184.

company associated with the development and marketing of DNA microarrays is Affymetrix, Inc.[188]

DNA microarrays can contain a huge number of different genetic sequences in a single product, each of the sequences representing a different gene or genetic polymorphism.[189] Since genetic sequences and polymorphisms are often patented, a single DNA microarray might infringe on a host of individual patents.[190] In view of the non-centralized nature of gene discovery research, those patents will likely be owned by a large number of different entities.[191] In terms of complexity, the DNA microarray more closely resembles the semiconductor chip, with its thousands of patented components, than the unitary drug products that are traditionally associated with biotechnology and the pharmaceutical industry. One would predict that such a technology would create the same sort of hold-up concerns described above in connection with computer and software products.

As a hypothetical, consider a DNA microarray containing 1000 different DNA features corresponding to 1000 different human genes, some of which are covered by patents. The owner of a patent covering one of the features could sue the microarray manufacturer for infringement, but if the only available relief is money damages, the recovery would likely be minimal. Specifically, if the patent owner is not competing in the microarray market, the amount of damages would be based on a "reasonable royalty," and the reasonable royalty for a patent covering a component that constitutes only a small fraction of the total invention should be minimal. However, with the leverage of injunctive relief, the patentee would be able to demand an inordinately high settlement by threatening to enjoin sales of the entire array.[192] This is exactly the problem complained of by the information technology sector, but here we see an example where it applies equally to biotechnology.

Recognizing this problem, Affymetrix has separated itself from many biotechnology companies by actively lobbying for limitations on the patent system, particularly with respect to the patenting of genes and other genetic information.[193] For example, Affymetrix has filed amicus briefs arguing for restrictions on the patentability of genetic information in two recent high profile patent cases.[194] It has

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[188] *Signature Genomic Libraries, LLC and Affymetrix, Inc. Sign License Agreement*, FORBES.COM: BUSINESSWIRE, Feb. 14, 2006, http://www.forbes.com/businesswire/feeds/businesswire/2006/02/14businesswire20060214006128rl.html (asserting that Affymetrix has set the standard in microarray technology).

[189] *See* Luca Falciola, *Rewarding True Innovation: Experimental Use Exemption and the Trends in Gene Patenting*, 1 EUR. MOLECULAR BIOLOGY ORG. REP. 200, 201–202 (2000).

[190] *See* David E. Adelman, *A Fallacy of the Commons in Biotech Patent Policy*, 20 BERKELEY TECH. L.J. 985, 1023 (2005).

[191] Falciola, *supra* note 189.

[192] Lorelei Perez Westin, Note and Comment, *Genetic Patents: Gatekeeper to the Promised Cures*, 25 T. JEFFERSON L. REV. 271, 272 (2002) (suggesting that patentees can exclude others from using the invention and "control [the] licensing fee for use of the patented invention, such that the fee would be non-proportional to the value of the end product").

[193] Ronald Bailey, *BIO 2003: Reporter's Notebook*, REASON ONLINE, June 25, 2003, http://www.reason.com/rb/rb062503.shtml (reporting that "Affymetrix is advocating a controversial shift away from the current system, in which entities like individual genes and proteins can be patented").

[194] *See* Brief for Amicus Curiae Affymetrix, Inc. in Support of Appellee, *In re* Fisher, 421 F.3d 1365 (Fed. Cir. 2005) (No. 04-1465), *available at*

also been active in promoting the idea of pooling gene sequence patents to facilitate freedom-to-operate for companies commercializing genetic technology.[195]

Looking forward, the products of biotechnology will generally become more complex. One development that will be driving this trend is the movement toward "personalized medicine." Personalized medicine has been defined as "the use of new methods of molecular analysis to better manage a patient's disease or predisposition towards a disease."[196] It primarily involves the use of molecular diagnostic technologies, such as DNA microarrays, to tailor a personalized therapeutic regime based on the particular needs of an individual patient as determined by the particular genetic characteristics of that individual.[197]

Increasingly, the products of the biotechnology and pharmaceutical industries will not simply be drugs, but drugs packaged with complex molecular diagnostic and pharmacogenomic testing routines that will serve to tailor treatment to the needs of the individual patients, i.e., multiple component products.[198] Importantly, the diagnostic tools and reagents used to implement the promise of personalized medicine will tend to be subject to a host of widely dispersed patent rights. This movement toward more complex products, subject to multiple patent claims, will result in injunctive hold-up becoming much more of a concern for biotechnology, and could modify the industries current strong support for mandatory permanent injunctions.

D. Subjective Elements of Patent Law

One of the key reforms proposed by the National Academies was the elimination, or at least limitation, of what it referred to as "subjective elements of patent litigation," including the best mode requirement and the inequitable conduct defense.[199] The best mode requirement requires disclosure in the patent specification of the best mode contemplated by the inventor for carrying out the patented invention.[200] Inequitable conduct involves a breach of the duty of candor and good faith that all patent applicants owe to the PTO; the breach typically involves a material misrepresentation or a failure to disclose information known to be relevant to the patentability of a claimed invention.[201] A finding of inequitable conduct in

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http://patentlaw.typepad.com/patent/files/affymetrix_amicus_brief.pdf; Brief for Amici Curiae Affymetrix, Inc. & John H. Barton in Support of Petitioner, Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc., No. 04-607 (U.S. Dec. 23, 2005), *available at* http://patentlaw.typepad.com/patent/AffymetrixAmicus.pdf.

[195] Thomas Malone, Senior Intellectual Property Counsel, Affymetrix, Inc., Address at the Annual Meeting of the American Association for the Advancement of Science (Feb. 19, 2006).

[196] Personalized Medicine Coalition, Comments on SACGHS Draft Report "Coverage and Reimbursement of Genetic Test and Services" (May 11, 2005), http://www.personalizedmedicinecoalition.org/sciencepolicy/public-policy_sacghs-position.php.

[197] *See id.*

[198] *See* Biotechnology Industry Organization, Biotechnology Tools in Research and Development, http://www.bio.org/speeches/pubs/er/biotechtools.asp (last visited Apr. 7, 2006) (describing a new generation of targeted products and genetically tailored therapeutics).

[199] NAS Report, *supra* note 13, at 182

[200] CHISUM, *supra* note 112, § 7.05.

[201] CHISUM, *supra* note 112, § 19.03.

connection with procurement of a patent will render the entire patent unenforceable.[202]

These doctrines are referred to as subjective because they require an inquiry into a person's state of mind.[203] For example, an inventor is not required to disclose what might objectively be the best mode of practicing an invention, but what the inventor *believes* to be the best mode. Failure to disclose material information to the PTO is only inequitable conduct if the inventor (or patent attorney) is aware of the information and believes it to be material.[204] Because the state of mind of inventors and patent attorneys is typically not ascertainable from the patent or any other publicly accessible source, violation is usually only identified during litigation, when pre-trial discovery allows the defendant access to the files and records of the patentee.[205] For this reason, Professor Lemley has referred to the subjective elements of patent law as "gotchas": deficiencies in the patent that become apparent only during litigation, and can be devastating to a patent owner when a presumptively valid patent is found to be invalid or unenforceable based upon a culpable state of mind.[206]

There are a number of costs associated with these subjective elements of U.S. patent law.[207] First, these elements can substantially add to the expense and burden of pre-trial discovery as the parties go to great lengths to uncover the smoking gun tending to show proof of a culpable state of mind.[208] Perhaps more importantly, these elements create substantial uncertainty with respect to the validity and enforceability of any issued patent. Unlike more objective patentability requirements, such as novelty, nonobviousness and enablement, this uncertainty normally cannot be ameliorated by an interested third party's "due diligence" inquiry. With respect to the objective patentability requirements, an interested third party can review the patent specification, the file history, and the state of the art at the time of the invention, all of which are public information, to make a reasonable assessment as to the validity and scope of an issued patent. In contrast, it will generally be impossible for a third party to effectively assess the state of mind of inventors and the patent attorneys that were involved with procuring a patent, and thus extremely difficult to assess the likelihood that a culpable state of mind might be uncovered during pre-trial discovery that would render the patent invalid or unenforceable.[209]

To the extent patents are particularly critical to the biotechnology industry and the decision to invest in biotechnology, this uncertainty will disproportionately

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[202] CHISUM, *supra* note 112, § 19.03.

[203] NAS Report, *supra* note 13, at 117.

[204] NAS Report, *supra* note 13, at 121.

[205] NAS Report, *supra* note 13, at 121.

[206] *Patent Law Reform: Injunctions and Damages, Hearing Before the Subcomm. on Intellectual Property of the S. Comm. on the Judiciary,* 109th Cong. 3 (2005) (statement of Mark A. Lemley, Professor, Stanford Law School), *available at* http://www.promotetheprogress.com/ptpfiles/patentreform/senateoversight/061405/prepared/lemley.pdf.

[207] These subjective elements are unique to U.S. patent law.

[208] NAS Report, *supra* note 13, at 7.

[209] NAS Report, *supra* note 13, at 121.

impact biotechnology.[210] Early-stage biotechnology companies are often based on a single core technology that has the potential to lead to products, and investment financing is imperative.[211] A proprietary position with respect to the core technology, secured by one or more patents, is generally a prerequisite for venture funding.[212] Given the possibility that the key patent might be found invalid or unenforceable for violation of one of the subjective requirements of patentability, a rational investor will discount the value of the patent, which will negatively impact the ability of the company to secure the required funding.[213] Because the state of mind of inventors and patent attorneys is difficult, if not impossible, to effectively ascertain, investors will not be able to adequately address this fear even by conducting a thorough due diligence inquiry.

Oftentimes, a patented technology is not commercially developed by the inventor, but rather is licensed to another company for development and marketing.[214] This situation is characteristic of technology invented in university laboratories, but also occurs when biotechnology companies invent technology and license it to larger biotechnology or pharmaceutical companies.[215] A competent licensee of new technology will conduct a due diligence inquiry in order to assess the strength of the patent, but will normally not be able to rule out the possibility of best mode or inequitable conduct "skeletons in the closet." Once again, this uncertainty should cause a rational licensee to discount the value of the patent, to the ultimate detriment of the licensor. Patent law reforms eliminating or restricting the subjective elements of patent would reduce this uncertainty, to the benefit of biotechnology investors, licensors, and licensees alike.

Tressa James, a commentator on the subject, has argued that biotechnology inventions are uniquely vulnerable to invalidation under the best mode requirement because the subjective nature of the inquiry affords judges substantial discretion to

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[210] *See* Dan L. Burk & Mark A. Lemley, *Policy Levers in Patent Law*, 89 VA. L. REV. 1575, 1676–1677 (2003) (explaining that biotechnology is a particularly risky and time consuming field, such that any additional uncertainty would discourage the incentive to engage in further innovation).

[211] *Patent Reform Act of 2005: Hearing on an Amendment in the Nature of a Substitute to H.R. 2795 Before the Subcomm. on Courts, the Internet, and Intellectual Property of the H. Comm. on the Judiciary*, 109th Cong. 4 (2005) (statement of Robert B. Chess, Executive Chairman, Nektar Therapeutics, on Behalf of the Biotechnology Industry Organization), *available at* http://www.promotetheprogress.com/ptpfiles/patentreform/houseoversight/091505/prepared/chess.pdf.

[212] *Id.*

[213] *See* Mark A. Chavez, *Gene Patenting: Do the Ends Justify the Means?*, 7 COMP. L. REV. & TECH. J. 255, 261 (2003) (suggesting that if the secure rights of patent protection were not available to biotechnology companies, investors would be less attracted to such companies because the prospect of earning large profits is less certain).

[214] *See* Charles Allen Black, *The Cure for Deadly Patent Practices: Preventing Technology Supression and Patent Shelving in the Life Sciences*, 14 ALB. L.J. SCI. & TECH. 397, 402 (2004). "[P]atents motivate inventors to sell or license the invention to generate the monopolistic profits." *Id.*

[215] *See, e.g.,* Hoffman-LaRoche, Inc. v. Promega Corp., 323 F.3d 1354, 1357–58 (Fed. Cir. 2003) (describing the exclusive licensing of patents relating to PCR technology from a small biotechnology company to a major pharmaceutical company).

invalidate patents that they might actually find offensive for policy reasons.[216] For example, a judge who believes that genes should not be patentable might use the best mode requirement as a pretense to invalidate a genomic patent.[217] James cites a number of cases where the validity of biotechnology patents has been challenged under the best mode requirement.[218] However, the courts never actually invalidated the patent in any of the decisions. Recently, Allison and Lemley surveyed every written, final validity decision by both the district courts and the Federal Circuit reported in the United States Patent Quarterly during the period extending from early 1989 through 1996.[219] The study encompassed 299 patents litigated in 230 different cases.[220] They reported that only one pharmaceutical patent, and not a single biotechnology patent, had been invalidated for failure to comply with the best mode requirement.[221]

James did cite one case, *Regents of the University of California v. Oncor, Inc.*, where a court found that a defendant had at least raised a justiciable issue of fact as to whether the inventor of a biotechnology invention had complied with the best mode requirement.[222] In *Oncor*, the claimed invention was a molecular biology procedure that involved the use of blocking DNA probes.[223] The defendant alleged that the inventor knew that the best mode of practicing the invention involved including an RNase in the procedure, but that the specification failed to mention the use of RNase.[224] As evidence, the defendant pointed to grant applications and notebooks of the inventor (obtained during pre-trial discovery) that recommended the use of RNase in the procedure; this recommendation apparently did not end up in the patent specification.[225]

Oncor exemplifies the uncertain position third parties face when considering whether to license or invest in a patent. In order to discover the best mode problems with the patent, an analyst would have had to review all of the laboratory notebooks and grant applications for all of the inventors listed on the patent. For the most part, these documents are not publicly available, and reside in the files of the individual inventors. A third party lacking the benefit of discovery would essentially never be able to gain access to them. This problem is compounded in biotechnology, where many of the patents do not have a single inventor, but a large number of inventors.[226] Even though best mode violations have not yet resulted in many biotechnology patents being found invalid, the potential for such findings exist, and the subjective

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[216] Tressa Jennifer James, Comment, *Implications of the Best Mode Requirement on Patents Involving Biotechnology*, 2 HOUS. BUS. & TAX L.J. 96, 101 (2002).

[217] *See id.* at 136–37 (asserting that variations in the standard for resolving best mode cases seem to indicate that the decisions are based on a high degree of subjectivity).

[218] *See id.* at 117–33.

[219] John R. Allison & Mark A. Lemley, *Empirical Evidence on the Validity of Litigated Patents*, 26 AIPLA Q.J. 185, 187 (1998).

[220] *Id.*

[221] *Id.* at 221.

[222] Regents of the Univ. of Cal. v. Oncor, Inc., No. C-95-3084, 1997 U.S. Dist. LEXIS 15068, at *32 (N.D. Cal. Aug. 19, 1997).

[223] *Id.* at *4.

[224] *Id.* at *33.

[225] *Id.*

[226] *See, e.g.*, U.S. Patent Application No. 2002/0045170 (filed Apr. 18, 2002) (genomics patent application listing eight individual inventors).

nature of the inquiry will generally render it difficult, if not impossible, for a potential investor or licensee to identify the problem by reasonable due diligence.

The inequitable conduct defense, on the other hand, actually has had a major impact in biotechnology patent litigation. In some high profile cases, valuable patents have been held to be unenforceable,[227] and even in cases where the enforceability of the patent is ultimately upheld, [228] these challenges add to the expense of litigation. Perhaps more importantly, these challenges lead to significant uncertainty with respect to patent valuation.

A good example of the problems this poses for biotechnology can be seen in *Hoffman LaRoche v. Promega*.[229] The case involved the patent covering Taq polymerase, a thermostable DNA polymerase used in performing Polymerase Chain Reaction ("PCR"), a groundbreaking invention that earned the inventor a Nobel prize and has fundamentally transformed medicine and science.[230] PCR technology, including the Taq polymerase, was developed in the early days of biotechnology by Cetus, a small biotechnology start-up company.[231] Cetus, which eventually merged with Chiron, exclusively licensed the PCR technology to Hoffman-LaRoche ("Roche"), a large, multinational pharmaceutical company.[232] Unfortunately for Roche, Cetus apparently engaged in some misconduct during the prosecution of the Taq polymerase patent that ultimately resulted in the patent being found unenforceable for inequitable conduct.[233] In particular, the Federal Circuit found that some Cetus inventors or attorneys had intentionally made material misrepresentations to the PTO during the prosecution of the patent.[234] Specifically, one of the examples in the patent specification described a procedure for purifying Taq polymerase in the past tense, and according to well-established convention, past tense is only used in patent specifications to describe experiments that have actually been performed.[235] However, at trial it was shown that the procedure had actually not been performed as described in the example.[236] Instead, it was a prophetic example based on a combination of two separate experiments that had been performed.[237] On remand, the trial court entered final judgment finding the patent to be unenforceable for inequitable conduct, effectively killing the patent.[238] The result was devastating for Roche, who not only had to accept the death of its exclusive license, but also suit

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[227] *See, e.g.*, Novo Nordisk Pharm., Inc. v. Bio-Tech. Gen. Corp., 424 F.3d 1347 (Fed. Cir. 2005); Hoffmann-La Roche, Inc. v. Promega Corp., 323 F.3d 1354 (Fed. Cir. 2003).

[228] *See, e.g.*, Bayer AG v. Housey Pharms., Inc., 128 Fed. Appx. 767 (Fed. Cir. 2005); Alza Corp. v. Mylan Labs., Inc., 391 F.3d 1365 (Fed. Cir. 2004); Monsanto Co. v. Bayer Bioscience N.V., 363 F.3d 1235 (Fed. Cir. 2004).

[229] Hoffman-LaRoche, Inc. v. Promega Corp., 323 F.3d 1354, 1357–58 (Fed. Cir. 2003).

[230] Smithsonian Institution Archives, The History of PCR, http://www.si.edu/archives/ihd/videocatalog/9577.htm (last visited Apr. 8, 2006).

[231] Roche Molecular Diagnostics, Chronology of PCR Technology, http://www.roche-diagnostics.com/ba_rmd/pcr_evolution.html (last visited Apr. 8, 2006).

[232] *Id.*

[233] *See Promega*, 323 F.3d at 1354.

[234] *See id.*

[235] *Id.* at 1363.

[236] *Id.* at 1364–65.

[237] *Id.* The court also held that Cetus had intentionally misstated experimental results from the prior art to distinguish their invention. *Id.*

[238] Hoffman-LaRoche, Inc. v. Promega Corp., 319 F. Supp. 2d 1011, 1029 (N.D. Cal. 2004).

under the antitrust laws for licensing a patent obtained by fraud.[239] The subjective nature of the inquiry makes it difficult, if not impossible, for a company like Roche to identify these "gotchas" prior to licensing the technology, and this uncertainty must surely affect the confidence potential investors and licensees have in the patents covering biotechnology.

E. Post-Grant Oppositions

The BIO and PhRMA testimonies both express strong opposition to second-window post grant-opposition proceedings. BIO primarily argued that such proceedings would create too much uncertainty with respect to issued patents since the opportunity to challenge would extend beyond the initial nine-month first-window opposition, and investors would see this extension as casting a cloud of uncertainty around any issued patents.[240] Of course, a party charged with infringement can always challenge patent validity during litigation, but the availability of second-window oppositions make patent validity challenges easier and less expensive. Therefore the opportunity for second-window oppositions likely would embolden alleged infringers to more often challenge patent validity rather than merely settling in order to avoid the huge costs associated with full-blown patent litigation. Thus, the general effect would be to weaken the practical ability of patentees to enforce their patents.

As pointed out by Mark Lemley in his Senate testimony, one of the primary beneficiaries of second-window opposition would likely be generic drug manufacturers, who could use the process to easily challenge the validity of drug patents.[241] Thus, it is not surprising that developers of innovative new drugs hoping to delay generic competition would object to this provision.

Although BIO and PhRMA were both silent on the issue, Genentech did voice support of first-window opposition proceeding. Many of the fundamental enabling technologies that companies, like Genentech, use in conducting research and development have been the subject of broad patents, and Genentech has on a number of occasions been forced to defend itself against charges of patent infringement.[242]

Currently, *inter partes* and *ex partes* patent reexamination is available to challenge a patent's validity. However, reexamination cannot be used to challenge a patent for non-compliance with sections 101 and 112 of the patent statute, which are the basis for the utility, enablement, and written description requirements.[243] As pointed out by Genentech in its congressional testimony, violations of these requirements are the most commonly encountered deficiencies in biotechnology patents.[244] The proposed first-window post-grant opposition procedure would allow a patent to be challenged on most grounds relating to patentability, including failure to

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[239] Molecular Diagnostics Labs. v. Hoffman-LaRoche, Inc., No. 04-01649, slip op. at 4 (U.S. Dec. 1, 2005), *available at* http://www.dcd.uscourts.gov/opinions/2005/Kennedy/2004-CV-1649~10:25:48~12-1-2005-a.pdf.

[240] *BIO Statement*, *supra* note 56 (testimony of Robert Chess).

[241] *Lemley Statement*, *supra* note 128 (testimony of Mark Lemley).

[242] *See, e.g.*, *supra* Part IV.A; Chiron Corp. v. Genentech, Inc., 363 F.3d 1247 (Fed. Cir. 2004).

[243] 35 U.S.C. § 302 (2000); 35 U.S.C. § 311 (2000).

[244] *Genentech Statement*, *supra* note 64 (testimony of Jeffery Kushan).

satisfy sections 101 and 112, and thus could be a particularly useful tool for biotechnology companies seeking to nip an overly broad or otherwise defective biotechnology patent in the bud.[245]

V. CONCLUSION

Although H.R. 2795 has been side-tracked for the time being, patent reform will no doubt be the subject of legislative attention in the not too distant future. The proposed changes could significantly impact the biotechnology industry both positively and negatively. Currently, biotechnology's agenda for patent reform appears to be shaped primarily by a perception that strong patent rights are critical to secure the investment funding required to support early-stage biotechnology companies engaged in expensive research and development. However, as the industry evolves to comprise more companies generating substantial revenues from product sales and as those products become more complex, appropriate restraints on patent procurement and enforcement will likely become increasingly important to biotechnology. When the concerns of biotechnology become more aligned with those of other industries, particularly those in the information technology sector, biotechnology firms might take a more moderate view of patent reform and choose to support some restrictions that would serve to limit the rights of patent applicants and patent owners.

[245] Patent Reform Act of 2005, H.R. 2795, 109th Cong. § 9 (2005).