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Bridging the Gap Between Invention and Innovation: The Bayh-Dole Act and Human Embryonic Stem Cell Research

By Kameron F. Bonner

Editor's Note: The following paper won Second Place in the 2012 Michigan Innovation and IP Legal Writing Competition, co-sponsored by the Intellectual Property Law Section and the Thomas M. Cooley Law School Graduate Program in Intellectual Property Law.

Volume 24 • Issue 2 • 2013

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I. Introduction

Developments in basic biotechnological research play an essential role in the growth of the economic and social well-being of a nation.[1] However, in the decades preceding the enactment of the Bayh-Dole Act in 1980, no simple mechanism existed to take advantage of the fruits of academic research and import those innovations into the marketplace.[2] The federal government could not agree on a uniform transfer process, and this resulted in twenty-six different agency policies regarding technology transfer.[3]

Concerned that this disarray of twenty-six different agency policies might be causing the United States to lag behind other industrialized nations, Congress took progressive steps to modernize federal policy towards commercializing government sponsored discoveries.[4] As a result, Congress enacted the Bayh-Dole Act to allow private ownership of inventions funded by the federal government.[5] The overall goal of the Act is to incentivize the utilization of inventions resulting from federally supported research or development by use of the patent system.[6]

Described as "[p]ossibly the most inspired piece of legislation to be enacted in America over the past half-century," the Bayh-Dole Act has catalyzed the biotechnology revolution and has reasserted America's global leadership in the field.[7] Yet, despite all the accolades, controversy remains prominent surrounding patenting medically significant biological inventions, such as those resulting from human Embryonic Stem Cell (hESC) research. In particular, there is a central worry that scientific research has shifted from the pursuit of a better understanding about hESCs—which is freely disseminated to the public—to a more focused search for

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View from the Chair

I hope to see you at the Section's annual business meeting, which will be held July 20 at 8 am at the Grand Hotel, Mackinac Island in conjunction with the 39th Annual Intellectual Property Law Summer Institute. We always get comments after the Summer Institute indicating that some of our members only come when it is in Traverse City, while others will only attend when it is on Mackinac Island. Relatively more of you will come to Mackinac Island than to Traverse City, and that is why we have had this two-years-at-Mackinac-then-one-at-Traverse-City schedule for so long. The Council strives to present a full slate of excellent speakers every year. At whichever location we hold the Summer Institute, we hope you will come and enjoy a top-quality seminar in a Pure Michigan setting. Last year's program received an overall rating of 6.54/7.0 from attendees, perhaps our highest ever, and I believe you will be as pleased with this year's slate of speakers. Come on up, the fudge has no calories if consumed on the island.

I have just prepared an annual report (June 1, 2012-May 31, 2013) on the Intellectual Property Law Section for SBM. Our membership stands at 1,106, and we continue to maintain a solid financial base. My thanks to the hard-working Council for all they have done through the year. I invite you to read the full report, which is posted on our website. If you are not familiar with our website, you can find it at www.michbar.org/ip/. The website has a calendar of events, Council information and meeting minutes, and past issues of IPLS Proceedings, among other things.

The Council continues to work toward establishing an intellectual property/patent pro bono program in Michigan. Section members have shown significant interest and support. We are not alone. The AIA charged the USTPO to work with intellectual property law associations to establish pro bono programs nationwide to assist individuals and small businesses. Contact any council member to get involved.

— *Anna Budde*
Chair, Intellectual Property Law Section

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results that have industrial applications and future commercial value.[8]

Whether the Bayh-Dole Act truly alters researchers' priorities is a matter of debate. However, this Note will show that the provisions of the Bayh-Dole Act stimulate hESC research and result in a net social economic benefit for United States citizens. Part II outlines the basics behind patent law and stem cell function, as well as the United States' policy behind federal technology transfer. Part III analyzes the government's ability to oversee the production of federal patent grantees and stimulate commercial development through march-in rights. The section further discusses the monetary return created by developing new biotechnology through hESC research. Finally, Part IV concludes that the Bayh-Dole Act achieves its general goal of placing inventions in the marketplace that would not have been commercialized otherwise.

II. Background

Patent Rights 101

In the knowledge-driven economy of the 21st Century, patents are essential for retaining rights in valuable intellectual property. In the United States, a patent is a negative personal property right in an invention.[9] This means that a U.S. patent owner has the right to exclude others from making, using, or selling any patented invention within the country.[10] Thus, a patent gives the patentee the right to prevent anyone else from using the invention, but not an affirmative right to use the patent.[11]

In exchange for a monopoly of rights for a limited duration, the patentee must disclose the metes and bounds of the invention to the public.[12] The purpose of this obligation is to promote the dissemination of scientific and technical information that would not occur but for the granting of a patent.[13] However, a constant struggle in the patent system involves balancing economic regulations and incentives to increase innovation on one end while promoting public access on the other.[14]

This balancing becomes even more difficult when patents are granted to private entities that use federal funds in their research and development of discoveries. Yet, the promise of developing stem cell research presses the government to take additional measures to facilitate commercialization of these inventions.[15]

The Importance of Stem Cells in the Human Body

Embryonic stem cells, as the name suggests, are derived from embryos that have developed from fertilized eggs.[16] Stem cells differ from other kinds of cells, such as muscle, blood, and nerve cells, because they are pluripotent, which means they have the potential to become nearly every one of the different types of cells in the human body.[17]

Stem cells are very important to the medical world because of two central characteristics. First, they are unspecialized cells capable of regenerating and renewing themselves through cell division.[18] Second, stem cells can be induced to become tissue- or organ-specific cells with specialized functions.[19]

Given their regenerative abilities, stem cells offer the potential to treat many diseases in the future. If scientists can reliably direct the differentiation of embryonic stem cells into specific cell types, some believe ailments such as Parkinson's, diabetes, traumatic spinal cord injury, Duchenne's muscular dystrophy, heart disease, and vision and hearing losses may all be treatable solely from stem cell therapy.[20]

Federal Policy on human Embryonic Stem Cell Research

The enactment of the Bayh-Dole Act coincided with a landmark Supreme Court decision that altered the landscape of patentable subject matter eligibility. In *Diamond v. Chakrabarty*, the court concluded that a genetically engineered micro-organism was in fact patentable subject matter so long as it is a product of human ingenuity.[21] Once thought as a "discovery [of] nature's handiwork," micro-organisms are now considered creations of human intervention,[22] thus laying down the footsteps to capitalize on the Holy Grail of biotechnology—stem cells.

Following the first successful isolation of hESCs in the laboratory in 1998, the National Institute of Health (NIH) formulated expansive guidelines for funding stem cell research.[23] Initially, federal policy only allowed funding for research that was linked to the use of sixty permitted stem cells lines created prior to August 9, 2001.[24] However, federal policy was substantially changed in 2009 with an executive order that effectively eliminated prior restrictions placed on hESC lines.[25] This order authorized the NIH to publish new, liberal guidelines which permitted funding for research using stem cells derived from embryos created for reproductive purposes and donated to further research progress.[26]

Nonetheless, funding embryonic stem cell research with taxpayers' dollars raised legal issues, which became the center of controversy in *Sherley v. Sebelius*.[27] In *Sherley*, two scientists brought an action challenging the 2009 federal funding policy as conflicting with a Congressional law known as the

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"Dickey-Wicker Amendment."[28] Originally enacted in 1996, the Amendment prohibits the NIH from funding research in which human embryos are destroyed, discarded, or knowingly subjected to damage.[29] On remand, the District Court determined the statute's language was ambiguous, and therefore held that it did not prohibit the NIH from funding human embryonic stem cell research based on the agency's reasonable interpretation of the Amendment.[30] Consequently, federal funding remains in full force for hESC research, but questions still surround the application of the Bayh-Dole Act to discoveries produced from that research and development.

III. Analysis

Many believe that the Bayh-Dole Act has been very successful in stimulating innovation and transferring government-funded inventions into the possession of entities with the ability to utilize the discoveries.[31] To date, the NIH has invested more than $500 million in human embryonic stem cell research alone.[32] As a result of increased funding, academic institutes have contributed to over seventy percent of the top 100 innovations in the past year.[33]

Even so, as the United States federal debt increases, the Act has become the subject of substantial criticism. Two such criticisms regarding the Act are: (1) that the granting of patents on discoveries hinders subsequent research by permitting owners to charge a premium for the use of discoveries that would otherwise be available more cheaply in the public domain; and (2) if granting patents is preferable, then the government should receive some tangible return of profits generated from the commercialization of those inventions.[34]

This section discusses why these worries are misplaced and often unfounded. It argues that the safeguards contained in the provisions of the Act provide sufficient protection for the public from exploitation by patent owners.

The Government's Involvement with hESC Research

The classic example of the first criticism involves a Wisconsin Alumni Research Foundation (WARF) patent on a purified preparation of hESCs discovered by Dr. James Thompson of the University of Wisconsin.[35] This patent was the first successful attempt at isolating hESCs and was a breakthrough for biomedical innovation.[36] In 1999, the Geron Corporation obtained an exclusive license from WARF to this patent.[37] Notably, in this case, Geron financed Dr. Thompson's research alone, without any federal financing, at a price of one million dollars. As a result, Geron acquired the exclusive commercial rights to selective human embryonic stem cells.[38]

Many commentators argue that the license of the WARF patent provides profits to the Geron Corporation at the expense of the public and also prevents many scientists from conducting life-saving medical research.[39] Critics say that the breadth of the patent, which encompasses virtually all hESCs of significant research value, halts stem cell advancement because it creates a financial burden by charging fees for any inventions developed using its technology.[40] Consequently, potential developers, both public and private, were deterred from pursuing biomedical research involving hESCs.[41]

The Government's Unlimited Access

Fortunately, the provisions of the Bayh-Dole Act all but eliminate this research problem. When the government finances any portion of the research and development that leads to a new discovery, the agency retains a non-exclusive, royalty-free right to use the patented technology by or on behalf of the government.[42] This allows the government to use the invention for further research in any of the government laboratories and by any government contractors. At the same time, the government does not have any direct title or control over the patenting and licensing activities related to the federally funded discovery.[43] Thus, individual owners are able to license their discovery out to major pharmaceutical companies for compensation.[44] On the other hand, when research is funded entirely by the private sector, as in the case with the WARF patent, the government has no statutorily authorized license and society must abide by whatever terms and conditions the private organization places on the new technology.[45]

Accordingly, the limited government control created by the Bayh-Dole Act offers a happy medium in which private developmental companies can retain exclusive control over the commercialization of the product and where governmental researchers have unlimited access to the technology.[46]

The Government's Ability to Compel Transfer: "March-In"

Furthermore, the Bayh-Dole Act also provides a solution to circumstances in which a market breakdown leads to the licensee's failure to commercialize the technology. Section 203 of the Act permits a third party to petition the government to "march-in" and compel the organization to grant the petitioner a reasonable license when the organization is unable or unwilling to meet the needs of the public.[47] Providing this second opportunity at commercialization further ensures that the government's funding of research and development contributes to the ultimate goals of the Act—utilization, commercialization, and public availability.[48]

Since the parties affected by a patent are the patentee and the public in general, the primary purpose of the government's march-in ability is to strike a balance between the private interest of the patentee and the public's right to inventions developed by federally funded research.[49] This march-in ability diminishes the exclusive monopoly normally associated with patents and forces organizations to be proactive with their technology. For this reason, the worry that patent owners will stymie research by sitting on their inventions—as in the case with the WARF patent—is no longer a bona fide concern, because the patent owner risks having an involuntary license granted to a competitor.[50]

The Bayh-Dole Act acknowledges that inventors should retain proprietary rights in their discoveries, but is also directed at benefiting the public at large. By petitioning the government to receive a federal grant, the research organization is tacitly agreeing to fulfill all the goals of the Act in a reasonable manner.[51] If the organization is unable to succeed in this task, the government is allowed, in fact *obligated*, to step in to secure the public's access to products that society essentially financed.

Recovering Taxpayers' Money

Developments in the field of biomedical research are vital to the development of new regenerative and therapeutic products.[52] Recognizing the integral role universities play at the research and development stage in biomedicine, Congress has taken progressive steps to stimulate innovation at this basic level. [53] As a result, government funding to universities has grown from $8 billion in 1980 to $19.2 billion in 2001,[54] and to a staggering $90 billion in 2009.[55] But with so much taxpayer money going into research, many are wondering whether the government should get something back in return.

Perhaps the most widely known example of revenue-sharing involving stem cell funding is the passage of Proposition 71—the California Stem Cell Research and Cures Bond Act.[56] This Act, which created the California Institute of Regenerative Medicine (CIRM), authorized the payment of $3 billion for stem cell research raised by the issuance of state bonds.[57] However, unlike the Bayh-Dole Act, CIRM requires non-profit grantees to share 25% of net exclusive licensing revenues in excess of $500,000 with the State of California.[58] Thus, California citizens get some tangible economic return back from their investment.

Many critics urge that this type of revenue-sharing policy should be applied to the Bayh-Dole Act to generate a greater net benefit for society.[59] The argument follows that allowing private firms to hold exclusive rights to inventions created at the public expense forces a double tax on the public for the same invention – once to support the research yielding the invention, and then again through higher prices and restricted supplies when the patented invention reaches the market.[60] Accordingly, critics argue that the government should take a share of the revenues generated by licensing the federally funded invention. However, the overall effect of revenue sharing may in fact discourage participation by researchers and the argument overlooks other non-tangible economic returns.

First of all, new medicines are costly to produce, and organizations are reluctant to invest in further research and development without some assurance of future product exclusivity.[61] Patents help cover this high, fixed research and development cost and are particularly useful in enabling biomedical companies to attract capital investments and eventually contract with other firms for commercialization of the inventions.[62] But, if more restrictions are added, such as a tax on the percentage of gross sales, more senior investment companies will look to other countries, such as Singapore and China, to pursue development of technologies.[63] Moreover, companies with exclusive rights to the inventions may charge a premium on their products in order to recoup losses due to revenue sharing.[64] Obviously, the exportation of research opportunities and the enforcement of a product premium are antithetical to what Congress was hoping to achieve by enacting the Bayh-Dole Act.

Secondly, the Act spurs real economic growth by creating new jobs and supporting existing research, which in turn reduces the cost of placing products in the marketplace.[65] A widely overlooked condition of the Act requires that the eventual product of a federally funded invention must be substantially manufactured in the United States.[66] This requirement restricts a company's desire to outsource their manufacturing needs to cheaper foreign countries, and instead requires them to maintain factories in the United States resulting in the creation of more jobs in the marketplace.[67] The purpose of this preference is to ensure that the American public and industry benefit from their own tax dollars.[68]

Finally, and most importantly, by making discoveries accessible to private, academic, and government entities, federal funds provide resources that result in practical products which give the United States a competitive edge in today's global market and thereby improve the quality of life for all Americans.[69] Life expectancy in the United States has increased from 47 years in 1900 to 78 years in 2009.[70] In May 2000, the U.S. Congressional Joint Economic Committee issued a report stating that the benefit of increased life expectancy in the U.S. as a result of advances in biomedicine creates an annual net gain of about $2.4 trillion.[71] If only 10% of this gain is due to NIH-funded medical research, that still suggests a payoff of about $240 billion, much more than then annual taxpayer investment.[72]

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IV. Conclusion

Over thirty years after its enactment, the Bayh-Dole Act is still seen as a practical piece of legislation designed to bridge the gap between invention and innovation. Because new knowledge cannot benefit the public unless it is put to practical use, the Bayh-Dole Act attempts to take the innovative aspect out of the researchers' hands and put into the control of entrepreneurs.

The Bayh-Dole Act provides the catalyst for the evolution of biotechnology by harnessing the potential associated with human embryonic stem cells. Not only is the Act essential to encourage scientists to delve further into uncharted hESC research, but it also provides a tool to monitor the progress made by organizations that utilize new technological advancements.

This Note demonstrates that the Bayh-Dole Act accomplishes two underlying purposes: It incentivizes businesses to take a chance on risky medicines by providing federal funds, and it wards off free-riding companies by allowing the businesses to secure an exclusive right to the invention. At the same time, the Act provides a means for the Government to supervise the commercialization of new technologies in a way that will best benefit the public.

About the Author

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Endnotes

1 Stevenson-Wydler Tech. Innovation Act of 1980, Pub. L. No. 96-480, § 2, 94 Stat. 2311 (1980).

2 *Id.* at § 2(8).

3 *See* H.R. Con. Res. 319, 109th Cong. (2005).

4 Act of Dec. 12, 1980, Pub. L. No. 96-517, § 6(a), 94 Stat. 3015 (amendment to the patent and trademark laws).

5 35 U.S.C. § 200 (2000).

6 *Id.*

7 *Innovation's Golden Goose*, The Economist, Dec. 12, 2002, http://www.economist.com/node/1476653.

8 *See* Arti K. Rai & Rebecca S. Eisenberg, *Bayh-Dole Reform and the Progress of Biomedicine*, 66 Law & Contemp. Probs. 289, 295 (2003).

9 35 U.S.C. § 261 (1982).

10 35 U.S.C. § 271 (1982)

11 *Id.*

12 35 U.S.C § 112 (2012).

13 2003 WL 22507757 (F.T.C.), 2.

14 *Id.* at 1.

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16 *Stem Cell Basics*, Nat'l Institutes of Health, (Apr. 28, 2009), http://stemcells.nih.gov/info/basics.

17 *Id.*

18 *Id.*

19 *Id.*

20 *Id.*

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24 *Id.*

25 Exec. Order No. 13,505, 74 Fed. Reg. 10,667 (Mar. 11, 2009).

26 National Institutes of Health Guidelines for Human Stem Cell Research, 74 Fed. Reg. 32,170, 32,170-02 (July 7, 2009).

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30 *Id.* at 14-17, 21.

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32 *The Promise of Human Embryonic Stem Cell Research: Hearing Before the S. Subcomm. on Labor, HHS, Educ. Appropriations*, 111th Cong. (2010) [hereinafter *Hearings:Collins*], *available at* http://www.hhs.gov/asl/testify/2010/06/t20100615e.html (statement of Francis S. Collins, M.D., Ph.D., Director, National Institutes of Health).

33 *Fueling Local Economies: Research, Innovation and Jobs: Hearing Before the U.S. Cong. J. Econ. Comm.,* 111th Cong. (2010) [hereinafter *Hearings:Litan*], *available at* http://www.brookings.

edu/research/testimony/2010/06/29-research-innovation-litan (statement of Robert E. Litan, Vice President of Research and Policy at the Kauffman Foundation).

34 *See generally* Rebecca S. Eisenberg, *Public Research and Private Development: Patents and Technology Transfer in Government-Sponsored Research*, 82 Va. L. Rev. 1663, 1666-67 (1996).

35 U.S. Patent No. 6,200,806 (filed June 26, 1998).

36 *See Sherley v. Sebelius*, 776 F. Supp. 2d 1, 5 (D.D.C. 2011) (discussing that in 1998 scientists from WARF "first succeeded in isolating and culturing stem cells from human embryos").

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40 *See* Wisconsin Alumni Research Foundation's Brief in Opposition to Geron Corporation's Fed. R. Civ. Pro. 12 (c) Motion for Judgment on the Pleadings at 47-48, WARF v. Geron Corp., No. 01-C-0459-C (W.D.Wis. Oct. 30, 2001), 2001 WL 36058828 at *47-48. As a consequence of public and political scrutiny, WARF and Geron decided to grant rights free of charge to academic and government scientists to use their stem cell patents for research. *See Wisconsin Alumni Research Foundation Changes Stem Cell Policies to Encourage Greater Collaboration*, WiCell Your Lab Partner (Jan. 22, 2007), http://www.wicell.org/home/about-wicell/news-room/12207/12207.cmsx.

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42 35 U.S.C. § 202(c)(4) (2011).

43 35 U.S.C § 202 (2000).

44 *Hearings:Freire*, *supra* note 31.

45 *Id*.

46 *About NIH*, National Institutes of Health (Dec. 5, 2011), http://www.nih.gov/about/.

47 *See* 35 U.S.C. § 203(a)(1) (2011).

48 *Id.* at § 200.

49 *See* Rights to Inventions Made by Nonprofit Organizations and Small Business Firms, 52 Fed. Reg. 8552-01 (March 18, 1987) (to be codified at 37 C.F.R. pt. 401).

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52 *See* 15 U.S.C. § 3701(2) (2001).

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56 *See* California Stem Cell Research and Cures Act, Cal. Health & Safety Code § 125290.10 (West 2004).

57 *Id.* at § 125291.30.

58 Cal. Code Regs. tit. 17, § 100308(b) (2007).

59 *See, e.g.,* Eisenberg, *supra* note 34 at 1666-67; *The University And Small Business Patent Procedures Act: Hearing Before the Senate Committee on Judiciary*, 96th Cong. (1979) (statement of Admiral H.G. Rickover, U.S. Navy).

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61 *See Hearings:Freire*, *supra* note 31.

62 *Hearings:Collins*, *supra* note 32.

63 *Id.*

64 *Id.*

65 *Innovation's Golden Goose*, *supra* note 7; *see also* Rooksby, *University Initiation of Patent Infringement Litigation*, 10 J. Marshall Rev. Intell. Prop. L. 623, 625 (2011) (discussing that in the fiscal year of 2009 alone, university patent licensing and technology transfer helped create over 500 start-up companies in the U.S.).

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68 48 C.F.R. § 27.302(a) (2007).

69 *See Statement:Bayh*, *supra* note 50, at 6.

70 *See About NIH*, Nat'l Inst. Health, (Feb. 6, 2013), http://www.nih.gov/about/.

71 Joint EconomicComm'n, Benefits of Medical Research and the Role of the NIH (May 2000), http://www.faseb.org/portals/0/pdfs/opa/2008/nih_research_benefits.pdf (report from the office of the Chairman, Connie Mack).

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Inter Partes Review Under the AIA—A Practitioner's Perspective

By R. Michael Azzi

On September 16, 2011, the Leahy-Smith America Invents Act ("Act") went into law, substantially changing many aspects of the United States patent system. While these changes touch a number of substantive and procedural areas of patent law, of particular note are the new post-grant review procedures the Act provides. Prior to the Act, *inter partes* and *ex parte* reexamination were the only mechanisms for third parties to have substantive involvement in the challenge of issued patents, with third-party involvement in the review process relatively limited after the prior art that served as the basis for review was submitted to the United States Patent and Trademark Office ("USPTO").[1] The Act eliminated *inter partes* reexamination, replacing it with two new procedures: post-grant review ("PGR") and *inter partes* review ("IPR").[2]

While both PGR and IPR provide third parties with new procedures to challenge issued patents, PGR only applies to patents (other than covered business method patents) having an effective filing date of March 16, 2013 or later.[3] Consequently, as a practical matter, it will take additional time before a significant number of PGR challenges proceed at the USPTO, and PGR will therefore not be the focus of this Article. In contrast, IPR is available to challenge any issued patent, with 167 IPR review petitions being filed within the first six months of IPR being available.[4] This Article seeks to identify issues, advantages, and disadvantages practitioners should consider when counseling clients as to whether IPR should be used to challenge a patent, particularly as compared to traditional federal court litigation, where alleged infringers generally assert invalidity as a defense in an infringement action, or seek declaratory relief that a patent at issue is invalid after being threatened with a patent infringement lawsuit. As explained below, both IPR and more traditional federal court litigation have advantages depending on a patent challenger's goals, and practitioners should be aware of these issues when counseling clients.

Inter Partes Review—An Overview of the Process

As a preliminary matter, to determine whether IPR or federal court provides the optimal venue to mount a patent challenge, an understanding of the IPR process is essential. This Section provides a summary of some of the more important aspects of the IPR process when making recommendations on how to proceed in attempting to invalidate claims in a patent.

Standing and the Petition

Anyone may institute IPR to request cancelling as unpatentable one or more claims in an issued patent, so long as the person has not previously challenged the patent's validity in a civil action.[5] When the Act was passed, a person could not institute *inter partes* review until nine months after the patent was issued or the date PGR concluded, but the Act was recently amended to permit challenges any time after the patent's issuance.[6] To challenge an issued patent, a person must (1) file a petition identifying all real parties in interest; (2) identify each claim being challenged and the basis for any such challenge; (3) provide copies of the evidence relied on and why it is relevant; (4) articulate a claim construction for each challenged claim; and (5) pay the required filing fee, which is currently $27,200, to challenge up to 20 claims.[7] In addition to providing the prior art serving as the basis for the challenge, the petitioner may also file declarations, including expert declarations, relevant to the challenge.[8] However, an IPR petition may only challenge a patent claim under Sections 102 and 103, with the challenge further limited only to prior art consisting of patents or printed publications.[9] Validity challenges under Sections 101 and 112 are unavailable in IPR proceedings, as are challenges based on prior art outside of patents and printed publications.[10]

The Patent owners Preliminary Response

After a party files a petition, the patent owner has three months to file a response, although the patent owner has no obligation to do so, as the Patent Trial and Appeal Board (the "Board") undertakes an independent review of the petition regardless of whether a response is filed.[11] Unlike the petitioner, the patent owner is precluded from filing declarations or other evidence to rebut the petitioner's arguments, and must limit its petition response to argument addressing why IPR should not be granted in the first instance.[12] After the three-month response period closes, the Board reviews the application (and any filed response), instituting IPR if the petitioner demonstrates "a reasonable likelihood of prevailing on at least one claim challenged in the petition."[13]

The Board—Whether to Grant IPR Review

When considering an IPR petition, the Board gives each challenged claim "its broadest reasonable construction in light of the specification of the patent in which it appears," which, as noted above, may be informed by the petitioner's proposed claim construction.[14] To prevail under the "reason-

able likelihood standard," the petitioner must demonstrate that it is likely to prove by a preponderance of the evidence that the claim at issue is invalid—a markedly different standard than district court litigation, which requires clear-and-convincing evidence to invalidate a claim.[15]

Board decisions as to whether to institute *inter partes* review are not appealable.[16] Currently, the average time for this decision is approximately 7 weeks following the patent owner's response, with a response being filed in 94 percent of proceedings to-date.[17] As of March 16, 2013, 23 *inter parties* review petition decisions had been published, with the Board instituting inter partes review proceedings in 22 cases—a 96 percent grant rate.[18]

Proceedings After the Board Grants an IPR Petition

If the Board grants a petition, it will generally enter a scheduling order governing the proceedings, with default rules governing deadlines in the absence of any such order. Discovery is permitted, but is limited to depositions of witnesses that submitted affidavits and/or declarations in support of the petition, information related to inconsistent positions either party has taken leading up to or during the proceeding, and anything else the Board considers "otherwise necessary in the interest of justice" on motion from the party seeking additional discovery."[19] As discussed in more detail below, discovery in Board proceedings is more limited than discovery generally available in federal court litigation.

Once the Board grants a petition, the petitioner has one month from when the Board grants IPR to file a motion to submit supplemental information in further support of its original petition, which will only be granted if the petitioner can demonstrate the information is "relevant to a claim for which the trial has been instituted."[20] Motions to supplement information filed outside this one-month "grace period" will only be granted if the petitioner can demonstrate the information to be supplemented could not reasonably have been obtained earlier, and granting the motion would be in "the interests-of-justice."[21]

Additionally, a patent owner has the opportunity to "file a response to the petition addressing any ground for unpatentability not already denied," including affidavits, declarations, or other evidence it seeks to submit.[22] The default rule provides for three months to file a response, which the Board may modify.[23] This response provides the patent owner with its first opportunity to submit substantive evidence on the validity of its patent claims.

Furthermore, the patent owner has the right to file one motion to amend the patent at issue to narrow or cancel claims in an effort to avoid the cited prior art references contemporaneous with or prior to filing its written response.[24] Before filing this Motion, the patent owner is required to confer with the board.[25] Moreover, amendments are limited in two key respects. First, only amendments that "respond to a ground of unpatentability involved in the trial" may be made.[26] Second, amendments cannot in any way "enlarge the claims of the patent or introduce new subject matter."[27]

At any time before the Board enters a final decision in an IPR proceeding, the parties may terminate IPR, typically by entering a settlement.[28] Any settlement that resolves a proceeding must be filed with the USPTO, but can be filed under seal with leave of the Board.[29] Notably, proceedings that are settled prior to a final decision do not provide a basis for estoppel to be asserted in subsequent IPR proceedings or related federal court litigation, in contrast to IPRs that are decided on the merits, which estop a petitioner from asserting any invalidity argument in a later IPR or federal court litigation that was "raised or reasonably could have [been] raised during that [IPR]."[30]

The Board must enter a final decision on the petitioner's challenge no later than one year from when the petition was filed, unless the Board extends the deadline for cause shown, which may be done for up to an additional six months.[31] As of the date this Article went to print, no Board decisions on the merits of an IPR petition had been entered, with the first substantive IPR hearing taking place on April 17, 2013.[32]

Inter Partes Review v Federal Court Litigation – Understanding the Differences and What to Consider When Advising Your Client

As the above summary of IPR illustrates, IPR provides a completely new procedure for mounting challenges to issued patents, supplanting *inter partes* reexamination and providing interested parties with a potential alternative to more traditional patent litigation. As explained below, however, the new procedure does not necessarily present a clearly superior alternative to federal court litigation, but rather depends on a client's goals in challenging the patent and needs during the process. This Section delves into some of the considerations practitioners and their clients should carefully balance when determining how to proceed with respect to a patent they wish to challenge on invalidity grounds.

Understand the Options Available and Timing Considerations

Generally, a client's desire to mount a validity challenge against an issued patent arises in one of three situations: (1) the patent owner sued the client for patent infringement; (2) the patent owner threatened the client with a patent infringement lawsuit, but has not yet filed in hopes of reaching a settlement; or (3) the client wants to develop a particular product or idea, but a key patent provides a concerning impediment in the technology space. While each of these situations provide a compelling reason for challenging an issued

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patent, the particular situation will likely inform what tact the client takes, and indeed may limit a client's options when considering whether to pursue IPR or federal court litigation. The procedural posture of a particular case will determine whether IPR is even available to a potential challenger.

When a patent holder sues an alleged infringer for patent infringement, the alleged infringer may assert invalidity as an affirmative defense and/or file a counterclaim seeking to invalidate the patent at issue. As noted above, the standard for prevailing based on invalidity in district court litigation is significantly higher than in an IPR proceeding, as the former applies a clear-and-convincing evidence standard while the latter only requires the challenger to prove invalidity by a preponderance of the evidence. Accordingly, when sued for patent infringement, the alleged infringer may be best served by filing an IPR seeking to invalidate the patent under Section 102 and/or 103, as the invalidity standard is substantially more favorable when proceeding with IPR. The alleged infringer may seek to institute IPR any time within a year after served with a complaint for infringement, with the litigation and IPR proceeding in parallel.[33] As further discussed below, costs, discovery needs, and the facts of a particular case will likely inform the decision on how to proceed, but a client should be made aware of the opportunity to proceed on this "dual track" basis, particularly when invalidity provides a strong basis to invalidate the claims at issue.

Declaratory judgment actions also provide a common basis for seeking to invalidate a patent. However, if a potential infringer decides to institute a declaratory judgment action prior to filing an IPR petition on invalidity grounds, IPR is no longer an available alternative, with the civil lawsuit barring a petition from being filed.[34] Accordingly, before filing a declaratory judgment action, it should be determined if an IPR provides a preferable course of action. If so, the IPR petition should be filed before, or contemporaneous with, any declaratory judgment action.

Finally, in some situations, a client may have infringement concerns regarding a particular patent, or want to develop a particular technology or product, but does not wish to do so given a particular patent's current scope. While both are important concerns, they often do not provide a basis to file a declaratory judgment action, as no "actual controversy" exists that provides a basis to institute such an action.[35] In this situation, IPR may provide an attractive alternative, enabling a challenge to an issued patent without any actual controversy requirement.[36]

Time and Cost Considerations

In addition to determining at the outset whether IPR is available and the effect proceeding with a federal court action may have on that availability, costs and timing are also important factors to consider when formulating a comprehensive case strategy. Under the AIA, the Board is required to render a final decision on the merits of an IPR no later than one year after a petition is filed (extendable by six months for sufficient cause). In contrast, federal court litigation generally takes years to resolve, causing great uncertainty for both parties involved, but particularly the alleged (or potential infringer). IPR provides a more expeditious basis to challenge an issued patent, enabling the petitioner to tailor its behavior based on the outcome.

Moreover, IPR will likely provide a more cost-effective basis to challenge a patent's validity. As explained below, discovery during IPR is more limited than that available in federal court litigation, significantly reducing the costs associated with proceeding to trial. Additionally, given the one-year statutory requirement for final decisions, parties are less likely to pursue extensive motion practice, as time simply does not permit it. Similarly, the Board may be more amenable to more informal procedures for resolving discovery disputes and related issues, permitting the parties to deal with the issues through a telephonic conference, rather than the often burdensome and costly motion practice.

While the overall cost of IPR may be less expensive than federal litigation with respect to validity challenges, however, there are significantly more up-front costs associated with the former over the latter. In addition to the $27,200 filing fee, IPR petitions generally include expert declarations and much more substantive claim construction and invalidity arguments than a declaratory judgment complaint.[37] While some cases may support this additional front-end cost, many will not, impeding ability to reach settlements for relatively small transaction costs early in the adversary proceeding process.

Claim Construction and Amendment—Know How Your Client's Interests May Best Be Served

Other potentially important (and related) issues to consider is the different potential experience and familiarity with applicable patent law that the Board and a court possess, as well as the ability of the patent holder to amend claims while an IPR proceeding remains pending, in contrast to federal court litigation, where such amendments are not permitted.

As noted above, under the AIA, the Board is required to

give a challenged claim its broadest reasonable interpretation. The Board is comprised of three-person panels, which consist of individuals that are relatively well-versed in patent law and claim construction, given the Board's regular purview over such issues. In contrast, the parties usually pose competing constructions in a Markman hearing to a Court that may not necessarily have the experience and familiarity with the applicable patent law the Board possesses, with the Court ultimately considering the claim construction in light of "how those skilled in the art would interpret the claims."[38] The different experience of the decision makers available, as well as the substantially different invalidity standards, may provide certain advantages or disadvantages in a particular case, depending on the facts of a particular case.

Moreover, during IPR, a patent owner is entitled to file a motion to amend its claims to narrow them in light of the petitioner's challenge, which may enable a petitioner to tailor its claims to avoid the prior art while maintaining a strong infringement position. In contrast, once district court litigation commences, a patent owner must litigate based on the claims as drafted, forced to rely on reexamination procedures to modify claim scope. Depending on the claims and the petitioner's invalidity position, a challenger may wish to proceed in federal court, where the claims cannot be modified to avoid particularly damaging prior art.

Discovery—How Much Information Do You Need from the Other Side?

Another important consideration is the broader scope of discovery available in federal court litigation when compared to IPR. In federal court, discovery, including depositions, interrogatories, document production requests, and subpoenas, is generally permissible when "reasonably calculated" to lead to admissible evidence relevant to one or more claims or defenses in a pending case.[39] Consequently, federal court litigation enables both the patent owner and alleged infringer to engage in relatively expansive discovery. This reality enables a patent owner to determine the full breadth of the infringer's use of a potentially infringing design, including first use, potential knowledge of the patent at issue, and products sold that incorporate the infringing design. Conversely, the alleged infringer may engage in discovery to determine potential limits to a patent owner's claims based on estoppel, related litigation, and subpoena third parties for potentially relevant prior art, which may better enable the alleged infringer to not only prevail on a non-infringement theory, but advance a more informed and complete invalidity argument under Section 102 and/or 103.

In contrast, IPR proceedings provide for comparatively less discovery, limited to deposing witnesses that submitted declarations in support of the IPR petition and the patent owner's response, conducting discovery as to information that is inconsistent with a position that a party has previously taken, and anything else the Board considers "otherwise necessary in the interest of justice." As for this last category, the Board has taken a relatively narrow view of its scope, recently articulating factors to be considered in *Garmin v. Cuozzo,* Case No. IPR2012-00001 (PTAB March 5, 2013).

In *Cuozzo,* the patent owner served the petitioner with written discovery during IPR that generally would be considered typical in federal court litigation, consistently of relatively broad (and at times vague) interrogatories directed at a number of issues likely to arise in litigation.[40] The petitioner objected to many of the discovery requests.[41] The Board found in favor of the petitioner, concluding the discovery was unduly broad, and did not constitute the "routine discovery" generally permitted, but rather "additional discovery" that did not meet the "interest of justice" standard under the applicable procedural rules.[42] In reaching this holding, the Board articulated five factors that are considered when determining whether particular information is discoverable in IPR proceedings:

1. Whether the requester of information is "already . . . in possession of a threshold amount of evidence or reasoning tending to show beyond speculation that something useful will be uncovered." Absent this "threshold" being met, discovery is not warranted, placing the requester in a difficult position, as if the requester already has information, it may be difficult to demonstrate a need for added discovery, but an absence of desired information may preclude discovery.
2. Whether the information requested is intended to compel a party to divulge litigation positions or the underlying basis of their claim or defense that are not advanced in affidavits or declarations. Unlike district court litigation, which often permits such discovery, the Board generally will not.
3. Whether the information requested can be ascertained through other means available to the requesting party. Particularly, the Board noted that the requester of information is not entitled to conduct discovery as to a party's views as to the state of the prior art or independent analyst's opinions, as the requester is positioned to adequately conduct this analysis on its own.
4. In the case of written discovery, whether the instructions accompanying the interrogatories and/or document production requests are easy to understand. While such instructions are oftentimes convoluted in

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federal court litigation, similar issues in Board proceedings may preclude discovery on the issues.

5. Whether the requests are unduly burdensome. In *Cuozzo,* the patent owner estimated responding to the petitioner's written discovery would cost in excess of $50,000, which the Board concluded was too burdensome given the one-year statutory bar for decisions, IPR's intended purpose to provide a more cost effective and streamlined alternative to litigation, and the lack of a "genuine need" for the discovery requested.[43]

In sum, the discovery needs and potential strategic considerations related to discovery play an important role in deciding whether litigation or IPR provides the best option for challenging the validity of a particular patent. If a potential challenger is in possession of strong prior art and does not require much discovery to make its case for invalidity, IPR likely provides an attractive alternative to federal court litigation. In contrast, if more extensive discovery is needed to invalidate a patent, particularly from third parties that may possess relevant prior art, federal court litigation may prove the best approach.

Basis for Review and Estoppel

When determining whether to proceed in federal court or with an IPR proceeding (or both, provided timing limitations are adhered to as set forth above), the effect of possible estoppel should be considered. As noted above, IPR can only be instituted under Section 102 or 103 based only on issued patents or printed publications. If a validity challenge falls outside of this definition, IPR cannot provide a basis for the challenge, and proceeding in federal court is required. However, if a petitioner decides to institute IPR, and the review proceeds through final judgment from the Board, the decision has important estoppel implications, preventing either party from relitigating any invalidity challenge that was brought or reasonably could have been brought during IPR in either a later IPR or federal court litigation. Moreover, an alleged infringer's failure to institute IPR within a year of being served with a patent infringement complaint bars an IPR on invalidity grounds as to the patent, with the infringer being forced to litigate the issue in federal court.

Practitioners should be aware of these estoppel implications, particularly as related to the preclusive effect IPR final decisions are given in pending litigation, when advising clients on potential courses of action. Additionally, the fact that settlement during an IPR does not necessarily estop an invalidity challenge in related federal court proceedings is also an important consideration.

Proceeding Before the Board – IPR Strategy

As outlined above, many factors go into deciding whether to proceed in federal court or before the Board. If IPR is instituted, both the petitioner and patent owner should be prepared to move quickly, given the one-year statutory mandate for final Board decisions to be rendered. Petitioners should make sure to provide thorough and relatively exhaustive IPR petitions, including expert declarations and reports in support of their interpration of the prior art at issue when compared to the claims being challenged. Indeed, to date, 68 percent of petitions have included expert declarations, with the Board oftentimes heavily relying on these declarations in their decision to grant IPR.[44]

Once a petition is filed, a patent owner must carefully weigh its options on whether to file a preliminary response. The default approach seems to be to file a response, with 94 percent of patent owners filing a preliminary response.[45] However, despite this high preliminary response rate, IPR have been granted 96 percent of the time, with 82 percent of these petitions being granted in their entirety (as opposed to in-part).[46] Based on this preliminary data, a patent owner may want to reconsider filing a response, given the relatively low success rate, costs associated with a preliminary response, and the fact that by responding, a patent owner is in essence giving a free preview of its defense strategy with little potential benefit. The patent owner's resources may be better spent at the substantive response phase and during discovery.

Patent owners should also consider their options regarding amendments in view of the prior art at issue. A claim amendment might avoid the prior art while still providing a patent owner with strong protection that is not readily susceptible to a design around. To the extent known and ongoing infringement exists, the patent owner may wish to amend its claims to avoid the prior art while still providing a basis for an infringement action. Amending early in the process may also avoid incurring substantial additional costs defending the action, which may prove to be a strong incentive for more cost-sensitive clients.

Finally, in stark contrast to *inter partes* reexamination, settlement at any time prior to a final Board decision remains

available. This enables parties to arrive at business solutions that address the issues between the parties, any may help the patent owner avoid a damaging invalidity decision that would provide a basis for estoppel in future litigation. The possibility of settlement—and the prospect of completing the IPR absent a final decision—should not be overlooked.

While not an exhaustive list, practitioners should be mindful of the above issues when proceeding before the Board, and keep their client's goals in mind when navigating the process.

Conclusion

IPR provides a new and unique mechanism for challenging issued patents. While still in its infancy, IPR cannot be overlooked, and should be considered when advising clients as to not only options to pursue patent invalidity, but also when providing counsel related to patent enforceability and potential litigation and invalidity risks in the future. As IPR petitions continue to proceed to hearing and final decisions are rendered, the contours of this review process will be brought into focus. But having a fundamental understanding of IPR, including the potential upside and downside when compared to district court litigation, is important.

About the Author

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Endnotes

1 35 U.S.C. § 314 (pre-AIA provision governing *inter partes reexamination).*

2 The Act also includes a transitional post-grant review procedure for covered business method patents and a supplement examination procedure available to patent owners. The former is available for any issued business method patent (with some exceptions) that is the basis for an infringement action in federal district court, with the latter having many similarities to the current *ex parte* reexamination procedure. While both forms of review are important for practitioners to remain cognizant of in practice, they are not addressed in this Article.

3 35 U.S.C. § 321. Covered business method patents include those that were issued under the first-to-invent statutory regime, and can be subject to PGR.

4 Harness Dickey, Harnessing Patent Office Litigation, Vol. 1, http://ipr-pgr.com/wp-content/uploads/2013/04/PRNTFNL_Harnessing-Innovation_IPR-PGR.pdf (last visited May 27, 2013) [hereinafter the "Harness Dickey Litigation Analysis"].

5 35 U.S.C. §§ 311(a), 315(e)(2) (2012); 37 C.F.R. § 42.101 (2012).

6 *Compare* 35 U.S.C. § 311(c) *and* 37 C.F.R. § 42.102 (2012), *with* 37 C.F.R. § 42.102 (Mar. 23, 2013).

7 35 U.S.C. § 312; 37 C.F.R. §§ 42.15, 42.104. The filing fee permits a person to challenge up to 20 claims, with $600 for each additional claim.

8 *Compare* 35 U.S.C. § 312(3)(B). To date, expert declarations have accompanied approximately 68 percent of petitions. Harness Dickey Litigation Analysis, *supra* note 2.

9 35 U.S.C. § 311(b); 37 C.F.R. § 42.104(b)(2).

10 35 U.S.C. § 311(b); 37 C.F.R. § 42.104(b)(2).

11 37 C.F.R. §§ 42.107, 42.108(c).

12 *Compare* 35 U.S.C. § 312(3)(B) *with* C.F.R. § 42.107(c) ("The preliminary response shall not present new testimony evidence beyond that already of record, except as authorized by the Board.").

13 35 U.S.C. § 314(a);37 C.F.R. § 42.108.

14 37 C.F.R. § 42.100(b). It is unclear what weight, if any, the Board provides to any such proposed construction that the petitioner is required to provide under the applicable procedural regulations, given that the regulations must provide the "broadest reasonable construction" permissible.

15 *Compare* 35 U.S.C. § 316(e) (preponderance standard) *with e.g., Adenta GmbH v. OrthoArm, Inc.*, 501 F.3d 1364, 1371 (Fed. Cir. 2007) (clear-and-convincing standard) (citations omitted).

16 35 U.S.C. § 314(d).

17 Harness Dickey Litigation Analysis, *supra* note 2. For the Harney Dickey Litigation Analysis, a sample size of 26 decisions was available as of March 16, 2013, with the statistics being drawn from this study.

18 Harness Dickey Litigation Analysis, *supra* note 2.

19 35 U.S.C. § 316(a)(5).

20 37 C.F.R. § 42.123(a).

21 37 C.F.R. § 42.123(b).

22 35 U.S.C. § 316(a)(8); 37 C.F.R. § 42.120.

23 37 C.F.R. § 42.120(b).

24 35 U.S.C. § 316(d); 37 C.F.R. § 42.121. Again, the Board may modify this due date, and may grant leave to amend outside of this period if good cause is shown, or the petitioner and patent owner file a joint motion to amend for the purposes advancing settlement. 37 C.F.R. § 42.121(c).

25 37 C.F.R. § 42.121(a).

26 37 C.F.R. § 42.121(a)(2)(i).

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27 37 C.F.R. § 42.121(a)(2)(ii). To date, little evidence is readily available on how this limitation has affected IPR, as the USPTO's online search system for IPR proceedings is not up and running, requiring a case-by-case review of pleading histories for known IPR proceedings.

28 35 U.S.C. § 317(a).

29 35 U.S.C. § 317(b).

30 35 U.S.C. § 317(e).

31 35 U.S.C. § 316(a)(11); 37 C.F.R. § 42.121.

32 Ryan Davis, Law360, *1st AIA Review Hearing Less Like a Trial than Expected*, www.law360.com/articles/430910 (Apr. 17, 2013); *see also* Law360, *AIA's 1st Trial Was More of a Hearing—No Surprise There*, www.law360.com/articles/434718 (Apr. 18, 2013).

33 35 U.S.C. § 315.

34 *Id.*

35 *MedImmune v. Genentech, Inc.,* 549 U.S. 118, 126 (2007).

36 *Id.*

37 *See infra.*

38 *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 974 (Fed. Cir. 1995), *aff'd,* 517 U.S. 370 (1996).

39 Fed. R. Civ. P. 26(b)(1).

40 *Garmin v. Cuozzo,* Case No. IPR2012-00001 (PTAB March 5, 2013)

41 *Id.*

42 *Id.*

43 *Id.; see also* Eugene T. Perez & Gerald M. Murphy, Jr., *Inter Partes Review and Limited Discovery: Garmin v. Cuozzo,* http://postgrantproceedings.com/topics/IPR_Garmin_v_Cuozzo.html (last visited May 20, 2013) (discussing five factors articulated by the Board).

44 Harness Dickey Litigation Analysis, *supra* note 2.

45 Harness Dickey Litigation Analysis, *supra* note 2.

46 Harness Dickey Litigation Analysis, *supra* note 2.

New Frontiers for Copyright Infringement: Law Firms?

By Catherine T. Dobrowitsky[1]

Do law firms risk liability for copyright infringement when they gather non-patent literature ("NPL") in connection with the representation of clients in proceedings before the U. S. Patent and Trademark Office ("USPTO")? Publisher John Wiley & Sons, Inc. ("Wiley") and other plaintiffs pose that question in a federal copyright infringement lawsuit against the law firm Schwegman, Lundberg & Woessner, P.A., currently pending in U.S. District Court for the District of Minnesota (hereinafter the "*Wiley Case*").[2] If this lawsuit and other similar cases[3] are successful, the impact upon law firms will be widely felt: Professor Dennis Crouch estimates that law firms and other applicants submit at least 500,000 articles each year to the USPTO, creating a potential licensing market of $50 million.[4]

In the *Wiley Case*, the Plaintiffs are publishers and owners of federal copyright registrations for scientific articles.[5] Plaintiffs allege that the defendant law firm impermissibly copied the articles without a license in the course of prosecuting patent applications before the USPTO.[6] Specifically, the infringement occurred when the law firm downloaded NPL from the USPTO's "Private PAIR" system, made internal electronic copies for the firm's case management system, and also sent copies of a few of the articles to clients or foreign patent attorneys in connection with a patent application file.[7] Because a copyright owner has the exclusive right to make copies of a protected work, Plaintiffs claim that the making of these unauthorized copies constituted infringement.[8] Notably, these actions are typical of many law firms in the course of patent prosecution.

In response, the defendant law firm invoked the defense of fair use. The firm countered that the copying of NPL is "necessary and incidental" to the filing and prosecution of a U.S. patent application, and therefore cannot constitute copyright infringement.[9] Defendants pointed to federal regulations and USPTO guidelines which require the identification and submission of NPL to the USPTO in the course of patent prosecution.[10] Specifically, applicants have the duty to disclose "all information material to patentability," and in doing so, must provide a "legible copy" of each document to the USPTO.[11] The copies of NPL submitted in the course of prosecution become a part of the publicly-available file history, which serves important notice functions regarding the patent and strengthens the integrity of the patent system.[12]

In July 2012, the USPTO moved to intervene as a defendant.[13] The USPTO requested intervention "to ensure that

the Court has the benefit of the Government's view about how the balancing required by the fair use statute should play out" under the circumstances, not to "exonerate all instances of law firm copying of scientific articles."[14] The Court granted the USPTO's motion, and permitted the USPTO to file a counterclaim for declaratory judgment of non-infringement based on fair use.[15] All parties have filed competing motions for summary judgment, which are set for hearing in June 2013.[16]

For now, the scope of law firm liability for copyright infringement based on the use of NPL in connection with USPTO proceedings is uncertain. It is no secret that publishers and other copyright owners currently scan filed patent applications for NPL citations, and some law firms are taking steps to protect themselves from the next round of cases.[17] If interpreted broadly, potential target defendants could include other law firms, litigators, corporations, individual applicants, or patent agents. And at the moment, there seem to be no easy solutions: a Copyright Clearance Center (CCC) license or other similar service can be expensive and might not cover all uses of NPL by law firms.[18] Until the courts provide some guidance as to the merits of the publishers' claims, the consequences of copying NPL in the course of representing clients before the USPTO remain uncertain.

About the Author

Catherine Dobrowitsky *is the founding member of Rivenoak Law Group, P.C., a boutique law firm focused on strategic intellectual property protection, agreements, and enforcement. She graduated cum laude from University of Michigan Law School and is admitted to practice in both Michigan and Massachusetts. Catherine has litigated trademark, copyright, patent, false advertising, unfair competition, and general commercial matters. She counsels clients in various aspects of intellectual property and manages trademark registration portfolios worldwide for corporations, non-profit organizations, and individuals. She currently serves as a Venture Coach for Blackstone LaunchPad, a collaborative entrepreneurial incubator sponsored by Walsh College and Wayne State University, as Secretary of the Mental Health Association of Michigan, and on the Diversity Committee of the Federal Bar Association of the Eastern District of Michigan. She also serves on the Intellectual Property Litigation Committee and the Solo & Small Firm Committee of the American Bar Association and is a member of the International Trademark Association (INTA), Oakland County Bar Association (OCBA) and Michigan Intellectual Property Lawyers Association (MIPLA). She can be contacted at (248) 677-1045 or by email at ctd@rivenoaklaw.com.*

Endnotes

1 Founding member of Rivenoak Law Group, P.C. The author would like to thank Sarah Thompson for her contributions to this article.

2 John Wiley & Sons and Am. Inst. Physics v. Schwegman, Lundberg & Woessner, No. 12-cv-00528 (D. Minn.) (hereinafter, the *"Wiley Case").*

3 Wiley has also filed a copyright infringement lawsuit based on the unlicensed use of NPL in the course of patent prosecution against a law firm based in Illinois. *See John Wiley & Sons v. McDonnell Boehnen Hulbert & Berghoff*, No. 12-cv-01446 (N.D. Ill.).

4 Dennis Crouch and Jason Rantanen. "*The New Choice: Inequitable Conduct or Copyright Infringement*," http://www.patentlyo.com/patent/2012/01/copyright-license-for-ids-submissions.html, Jan. 23, 2012 (last visited May 15, 2013).

5 *See* Pl. Br. Supp. Mot. Partial Summ. J. at 13, *Am. Inst. Physics v. Schwegman, Lundbery & Woessner*, No. 12-cv-00528 (D. Minn Feb. 27, 2013). Note that the Defendant claims that Plaintiffs lack standing because at the time the lawsuit was filed, they owned copyright registrations for the journals in which the articles appeared, but not for the articles themselves. See Def. Br. Supp. Mot. Summ. J. at 21-23, *Am. Inst. Physics v. Schwegman, Lundbery & Woessner,* No. 12-cv-00528 (D.Minn. Apr. 12, 2013). Plaintiffs subsequently obtained copyright registrations for 12 of the 18 articles at issue. *Id.* at 22.

6 *See* Pl. Br. Supp. Mot. Summ. J. at 6, *Am. Inst. Physics v. Schwegman, Lundbery & Woessner*, Case No. 12-cv-00528 (D. Minn, Feb. 27, 2013) ("[T]he publishers have 'established markets for users… to conveniently license those articles.'")

7 *See* USPTO Br. Supp. Mot. Summ. J. at 4-5, *Am. Inst. Physics v. Schwegman, Lundbery & Woessner*, No. 12-cv-00528 (D.Minn. Apr. 12, 2013).

8 *See* 17 U.S.C. § 101 ("Subject to sections 107 through 122, the owner of copyright under this title has the exclusive rights to do and to authorize any of the following: … (1) to reproduce the copyrighted work in copies or phonorecords.") "Copies" includes reproduction in electronic and paper formats. *Id.*

9 *See* Def. Br. Supp. Mot. Summ. J. at 1-2, *Am. Inst. Physics v. Schwegman, Lundbery & Woessner*, No. 12-cv-00528 (D.Minn. Apr. 12, 2013).

10 *See* Def. Br. Supp. Mot. Summ. J. at 4, *Am. Inst. Physics v. Schwegman, Lundbery & Woessner,* No. 12-cv-00528 (D.Minn. Apr. 12, 2013).

11 *See* 37 C.F.R. §§ 1.56, 1.98, *see also* Def. Br. Supp. Mot. Summ. J. at 4, *Am. Inst. Physics v. Schwegman, Lundbery & Woessner*, No. 12-cv-00528 (D.Minn. Apr. 12, 2013).

12 *See* Def. Br. Supp. Mot. Summ. J. at 4-5, *Am. Inst. Physics v. Schwegman, Lundbery & Woessner*, No. 12-cv-00528 (D.Minn. Apr. 12, 2013) (citing 37 C.F.R. §1.56 and noting that the public interest is best served "when [the] USPTO 'is aware of and evaluates all teachings of all information material to patentability'").

13 *See* USPTO Mot. Intervene at 1, *Am. Inst. Physics v. Schwegman, Lundbery & Woessner*, No. 12-cv-00528 (D.Minn. Jul. 2, 2012)

14 *See* Def. Br. Supp. Mot. Summ. J. at 2, *Am. Inst. Physics v. Schwegman, Lundbery & Woessner*, No. 12-cv-00528 (D.Minn. Apr. 12, 2013)

15 *See* Order granting Mot. Intervene, *Am. Inst. Physics v. Schwegman, Lundbery & Woessner*, No. 12-cv-00528 (D.Minn. July 11, 2012); see also USPTO Answer and Counterclaim, Am. Inst. Physics v. Schwegman, Lundbery & Woessner, No. 12-cv-00528 (D.Minn. Nov. 21, 2012).

16 *See* Notice of Resetting of Motions Hearing, DE# 206, *Am. Inst. Physics v. Schwegman, Lundbery & Woessner*, No. 12-cv-00528, (D.Minn. May 14, 2013).

17 Dennis Crouch, "*Copyright: Lawfirms Sued for Submitting Prior Art to the USPTO*," http://www.patentlyo.com/patent/2012/03/copyright-lawfirms-sued-for-submitting-prior-art-to-the-uspto.html, Mar. 2, 2012 (last visited June 7, 2013) (noting Oblon Spivak's recent procurement of a firm-wide license to "avoid the annoyance of a lawsuit").

18 Dennis Crouch. "*Patent Prosecutors Licensing of Copyrights for Prior Art Submissions,*" http://www.patentlyo.com/patent/2012/11/patent-prosecutors-licensing-of-copyrights-for-prior-art-submissions.html. Nov. 29, 2012 (last visited May 15, 2013); Dennis Crouch, "*Copyright: Lawfirms Sued for Submitting Prior Art to the USPTO*," http://www.patentlyo.com/patent/2012/03/copyright-lawfirms-sued-for-submitting-prior-art-to-the-uspto.html, Mar. 2, 2012 (last visited June 7, 2013) (noting that academic authors generally receive no compensation for publication).

Opportunities Provided by the Elijah J. McCoy-Detroit Satellite Office

By Karl T. Ondersma

Earlier this planning year, the IPLS council had the pleasure of welcoming Dr. Ram Shukla, Resource SPE from the Elijah J. McCoy-Detroit Satellite Office, to one of its meetings. Dr. Shukla was appointed the Regional Manager of the Detroit Office in June 2013. The meeting was to open a dialogue between the Detroit office and our section regarding how we might partner together to benefit the Detroit office and our members. As discussed below, Dr. Shukla provided an update to the council regarding the status of the Detroit office and outlined areas of possible future opportunities.

Currently, the Detroit office has three managers on detail for internal operations and outreach, with the outreach efforts including meetings with universities, companies and other organizations to promote awareness of that office. The Detroit patent examiners are focused in the 3600 and 3700 technology centers. In the future, the Detroit office may utilize additional resources from the Alexandria office. IPLS members may arrange for interviewing cases in Alexandria utilizing the Detroit office's video conferencing resources.

Dr. Shukla discussed an existing 6-8 week unpaid externship program conducted in Alexandria for undergraduate and law students. The program provides students with an introduction to patent examination and insight regarding how the Patent Office works. A similar program may be instituted in Detroit in the future. A possible opportunity for our members to provide service to the Detroit office would be to participate in the externship program by providing training or conducing workshops.

The USPTO also seeks help from practitioners and individuals within industry to provide technical training to examiners. These include Tech Fairs to provide state of the art training to examiners and Patent Examiner Technical Training programs. The Technical Training programs are not conducted at set times, but instead are arranged on an ad hoc basis and may even involve one or more individuals providing an hour or two of training on topics such as general technology or state of the art awareness. Some of the Tech Fairs are not open to the public, just examiners. At other times, however, programs may be scheduled for practitioners to receive updates from the Patent Office. The next Tech Fair is currently being planned for sometime in the November 2013 to January 2014 timeframe.

Tech Fairs and Technical Training programs are not currently in place in Detroit, but are being considered. This may include conducting programs in Detroit that are then broadcast to Alexandria, as the training provided at the Detroit office would also be appropriate for examiners in Alexandria. Thus, potential future collaboration opportunities may be available in this regard as well.

In terms of providing assistance to inventors, Dr. Shukla commented on a program administered by the USPTO in

which law schools apply for certification to enable students working through their law school to assist inventors in submitting patent applications. Depending on participation by law schools in Michigan, our IPLS members may also be able to get involved with the law schools in this area. Still further, the IPLS is currently investigating a pro bono program at the encouragement of the USPTO.

The Detroit office also has a public search room with two terminals having access to the East and West databases. Searching assistance provided by office personnel can be available to visitors. It would be recommended to contact the Detroit office in advance to determine what assistance may be available. This supplements resources historically available at the Patent and Trademark Resource Center ("PTRC") at the Detroit Public Library, which provides help to inventors and searching capabilities through the West database. Possibilities for IPLS members to provide assistance in this area also exist in the form of conducting workshops discussing patent classification and searching, specification writing and claim drafting.

Additional educational opportunities provided through the Detroit office for our IPLS members were also discussed, including the possibility of Detroit office personnel providing presentations or continuing legal education. Dr. Shukla also discussed an Inventor Assistance Program conducted through the Patent Office's Office of Development Assistance in which conferences for inventors and attorneys are provided on topics such as claim drafting, searching, and responding to office actions. The IPLS council will be investigating these opportunities for future seminars and programs.
Finally, Dr. Shukla noted that the Patent Office has an "IP Awareness Assessment Tool" on its website for inventors intended to provide guidance based on the individual's particular circumstances. It currently includes sixty questions in ten different categories. IPLS members may be able to aid in this regard by working through the Solicitors Office to evaluate and/or add a module.

We are excited about the opportunities provided by the historic addition of the Detroit Office to Michigan, and will keep our members apprised of new developments toward partnering with the Detroit Office. If you have questions or ideas about how you might get involved, please contact an IPLS council member.


IP Overview: Patents, Trademarks, Copyrights, & Trade Secrets in 60 Minutes or Less
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2:00 p.m.-3:00 p.m.
A basic overview of the acquisition and enforcement of patent, trademark, copyright, and trade secret rights.
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• Kristen Murphy, Rader, Fishman & Grauer, Bloomfield Hills
Registration is requested to allow for proper facilities planning. Visit the Bar's Annual Meeting page (www.michbar.org/annualmeeting) for more details.
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