REACH-THROUGH ROYALTIES IN BIOMEDICAL RESEARCH TOOL PATENT LICENSING: IMPLICATIONS OF NIH GUIDELINES ON SMALL BIOTECHNOLOGY FIRMS

by
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Reach-through royalty provisions in patent licenses for research tools have been blamed for decreasing innovation in the biomedical field. The competing interests of large pharmaceutical companies, universities, emerging biotechnology firms, and the government are at odds in the reach-through royalty controversy. The 1999 National Institutes of Health ("NIH") Guidelines regarding research tools further complicate the issue by applying the same limitations on reach-through royalties to small business and universities alike. The guidelines were meant to alleviate the bottleneck created by complicated exclusive license agreements, but they also have the effect of harming small businesses which are reliant on their ability to license their research tools. This is exacerbated by the inadequate and unequal enforcement of the guidelines. One solution is the elimination of the NIH Guidelines, and their replacement by regulations that differentiate between university and business concerns in the use of reach-through royalties.

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I. INTRODUCTION

Biomedical research tools are often patented and licensed to other parties whose research would benefit from the use of the tool. For example, a scientist may discover a receptor in the brain implicated in cognition and also discover that individuals with a genetic mutation in the receptor develop a neurological disorder. That scientist might patent her discovery as well as a method for screening compounds that interact with the receptor. A company might come along that wants to develop a therapeutic drug for the neurological disorder using the scientist's screen. The scientist and the company can enter into a license agreement so that the company can compensate the scientist for the use of her discovery.

Such license agreements for biomedical research tools often contain reach-through royalty provisions. These provisions are controversial because they require the licensee to provide the licensor with royalties for, or exclusive use of, future discoveries made with the tool. Many see the use of reach-through royalties as contributing to the decrease in the dissemination of tools among academics, subsequently causing a decrease in the sharing of scientific knowledge. Some see reach-through licensing as limiting innovation, and therefore as detrimental to the public good.

In 1999 the National Institutes of Health (NIH) published guidelines restricting the use of reach-through licensing by recipients of NIH grants.[1] These guidelines apply not only to non-profits and universities, but also to private companies receiving NIH funds. This includes all small businesses receiving grants from the NIH. Since most large companies do not receive NIH funds, small businesses are put at a disadvantage in this respect, especially when one considers that the market for research tools is the lifeblood of these small companies.

Reach-through licensing is a way for these companies to value and market tools that may or may not lead to the development of other commercial products. Thus, many small biotechnology companies rely on reach-through license provisions to market the research tools, which are their main source of income.

One of the largest obstacles in formulating a solution to the reach-through royalty problem is the nature of the competing interests of the entities involved. Universities, large pharmaceutical companies, and biotechnology companies all

[1] Principles and Guidelines for Recipients of NIH Research Grants and Contracts on Obtaining and Disseminating Biomedical Research Resources: Final Notice, 64 Fed. Reg. 72090 (Dec. 23, 1999) (hereinafter NIH Guidelines).

have different perspectives on the use of reach-through royalties. Even within a single entity, the view of reach-through royalties may differ depending upon whether the entity is the licensor or licensee of the tool.

Because of the complex nature of the problems facing reach-through licensing of research tools, it is difficult to formulate a solution that would be amenable to all the parties involved. However, the most equitable solution may be to promulgate regulations limiting the use of reach-through royalties by non-profits and universities while allowing their use by private companies whose primary goal is commercialization.

This Comment discusses the various competing interests involved in the reach-through licensing controversy and suggests a regulatory scheme that provides for the widespread dissemination of research tools among academics, while being sensitive to the concerns of small businesses whose survival depends on being able to accurately value their tools.

II. DISCUSSION

A. Research Tools, Reach-Through Royalties, and the Controversies Surrounding Them

Research tools are inventions used in the biomedical field as a means of finding compounds that may be commercialized for therapeutic uses.[2] More simply, they are tools that scientists use to further their research. By definition they are a means to an end in the scientific discovery process. However, to someone who holds a patent on a research tool, it is not just a means to an end, but a valuable resource in and of itself.[3] By licensing the research tool to another scientist who may develop and commercialize an end product using the tool, the patent holder is able to capitalize on the research tool itself. Thus, an entire industry has developed around the licensing of patented research tools.

There are several ways to value research tools in patent license agreements. Tools that have general applicability to laboratory techniques (such as the Polymerase Chain Reaction or PCR) do well with up front license fees.[4] However, some tools are only useful in the development of specific therapeutic targets. Problems arise in assessing the value of such downstream tools. For example, suppose you have cloned a novel receptor in the brain. You know a

[2] The NIH defines research tools as "the full range of tools that scientists use in the laboratory, including cell lines, monoclonal antibodies, reagents, animal models, growth factors, combinatorial chemistry and DNA libraries, clones and cloning tools (such as PCR), methods, laboratory equipment and machines." NIH Guidelines, *supra* note 1, at 72092 n.1.

[3] Janice M. Mueller, *No "Dilettante Affair": Rethinking the Experimental Use Exception to Patent Infringement for Biomedical Research Tools*, 76 WASH. L. REV. 1, 10 (2001).

[4] With PCR, that fee is passed on to researchers who use PCR in the purchase price of the reagents required to perform the polymerase chain reaction. *See* Roche Applied Science, PCR License, *available at* http://www.roche-applied-science.com/fst/legal.htm?/legal/pcr.htm (last visited April 18, 2005).

specific function for the receptor, but it also may be implicated in Parkinson's disease. Subsequently you patent its gene sequence, the receptor itself, and a method of screening ligands for the receptor. At this point there is no way of telling if a drug or treatment for Parkinson's disease will ever be developed, but there is potential, and any drug arising out of this patent could be extremely valuable. It is much easier to tell the value of an upstream tool with general applicability, for example a microscope. There is a competitive market for microscopes, and a wide variety from which to choose. Thus, it is relatively easy to judge its value. Downstream research tools such as patented receptors are much more difficult to value because of an extremely thin market. Where there are no good substitutes for the tool, and where it is uncertain whether or not its use will result in a researcher's ultimate discovery of a lucrative invention, valuation is not straightforward.

Herein lies the power of the reach-through license agreement. Basically, it is a license agreement which includes terms requiring only a minimal amount of money to be paid up front to license the tool, but if a product is commercialized using the tool, then a certain amount of royalties earned off that product will be paid to the owner of the tool.[5] This is beneficial to the licensee because there is very little upfront cost and they only have to pay if they are able to produce a useful end product using the tool.

However, reach-through royalties in license agreements are controversial for several reasons. First, reach-through provisions are usually found in exclusive license agreements. Tools that historically would have been traded freely are now often exclusively licensed.[6] This is the case even where licensing the tool nonexclusively might be more beneficial to the patent holder because he or she would have access to a variety of chemical libraries.[7] For example, the patentee of a receptor might enter into an exclusive license agreement with a company that is interested in developing a drug for that

[5] Rebecca S. Eisenberg, *Reaching Through the Genome*, *in* PERSPECTIVES OF THE HUMAN GENOME PROJECT 209, 214 (F. Scott Kieff ed.) *available at* http://law.wustl.edu/Academics/Faculty/Bios/Kieff/HGPIP/Final/GEN_50_CH10.pdf (last visited March 6, 2005) (hereinafter Eisenberg, *Reaching Through the Genome*); REBECCA S. EISENBERG, *Bargaining Over the Transfer of Proprietary Research Tools: Is This Market Failing or Emerging?*, in EXPANDING THE BOUNDARIES OF INTELLECTUAL PROPERTY: INNOVATION POLICY FOR THE KNOWLEDGE SOCIETY 223, 230 (R.C. Dreyfuss et al. eds. 2001) (hereinafter Eisenberg, *Proprietary Research Tools*).

[6] Arti K. Rai & Rebecca S. Eisenberg, *Bayh-Dole Reform and the Progress of Biomedicine*, 66 LAW & CONTEMP. PROBS. 289 (2003); John M. Golden, *Biotechnology, Technology Policy, and Patentability: Natural Products and Invention in the American System*, 50 EMORY L. J. 101, 175 (2001).

[7] John P. Walsh & Wesley M. Cohen, *Research Tool Patenting and Licensing and Biomedical Innovation*, forthcoming in PATENTS IN THE KNOWLEDGE-BASED ECONOMY 28 (W.M. Cohen & S. Merrill eds.) *available at* http://sippi.aaas.org/utt/WalshetalAAAS.pdf (last visited March 6, 2005). However, Walsh also introduces an interesting counter-argument suggesting that exclusive licenses to biotech start-ups may actually increase innovation because while a large pharmaceutical company will not pay much for a non-exclusive license, and therefore does not have an incentive to try very hard to develop anything using the license, a start-up with an exclusive license has a huge incentive to innovate since that license may be the only intellectual property the company has. *Id.* at 26.

target, but whose chemical library is limited. The patentee might have a better chance of finding the right drug by licensing to several companies with diverse libraries.[8] However, the licensee often demands exclusivity. The patentee, in return may demand a reach-through provision. In this way, exclusive licenses with reach-through provisions may have the effect of reducing innovation.[9]

Second, problems arise in infringement cases when courts try to assess damages. In research tool infringement cases where reach-through provisions are implicated, a court awarding damages for infringement must speculate what the parties would have agreed to had they actually negotiated.[10] This becomes especially cumbersome if the infringement suit is filed before a product is commercialized.[11] A court must not only consider what type of agreement would have been entered into, but also the probability that a product would be commercialized.[12]

Third, as complications with reach-through royalties in license agreements increase, patentees are beginning to attempt to obtain reach-through claims in the patents themselves. For example, a patentee may try to claim both a method for selectively inhibiting a receptor's activity and chemical compounds that can be found using the screen, without actually describing a specific compound.[13] Reach-through claims pose even greater problems than reach-through royalty provisions.[14] One of the biggest issues has been whether such claims are even allowed under 35 U.S.C. § 112 ¶ 1, which requires the written description of an invention that is claimed in a patent to describe the invention in terms that establish that the patentee was actually in its possession.[15] So far the Patent and Trademark Office (PTO) has not been uniform in its application of this requirement.[16] An additional concern is that reach-through claims reduce the incentive for third parties to develop improvements on the original patent, thus decreasing innovation.[17]

1. The Various Users of Research Tools Have Competing Interests

There are four major players who have interests in the use of reach-through licensing for biomedical research tools: the government, universities

[8] *Id.* at 28.

[9] *Id. See also* Golden, *supra* note 6, at 175 (explaining how "industry-inspired restrictions, both on the disclosure and use of patented inventions, have become non-trivial interferences with normal scientific practice. . .").

[10] Donald Ware, *Research Tool Patents: Judicial Remedies*, 30 AIPLA Q.J. 267, 281 (2002).

[11] *Id.* at 286 (discussing SIBIA Neurosciences, Inc. v. Cadus Pharm. Corp. 225 F.3d 1349 (Fed. Cir. 2000)).

[12] *Id.*

[13] *See e.g.*, Univ. of Rochester v. G.D. Searle & Co., 358 F.3d 916, 918 (Fed. Cir. 2004).

[14] *See generally* Stephen Kunin, et al., *Reach-Through Claims in the Age of Biotechnology*, 51 AM. U. L. REV. 609 (2002).

[15] *Univ. of Rochester*, 358 F.3d at 926; *see also In re* Vaeck, 947 F.2d 488 (Fed. Cir. 1991); Kunin, *supra* note 14, at 630.

[16] Kunin, *supra* note 14, at 619.

[17] Walsh & Cohen, *supra* note 7, at 7.

and non-profit research institutions, large pharmaceutical companies, and smaller biotechnology companies. A solution to the controversy surrounding reach-through royalties is complicated because each of these entities has competing interests when it comes to the regulation of reach-through provisions.[18] Furthermore, how a particular entity views reach-through royalties can change according to whether they are the licensor or licensee in a particular transaction.[19]

a. Large Pharmaceutical Companies

Large pharmaceutical companies that own patents on research tools that they would like to license view reach-through royalties favorably because they can make money from someone else's expenditure of labor and resources in putting a drug on the market. However, most pharmaceutical companies are primarily focused on drug discovery, not the marketing of research tools, so any tools that they happen to invent are usually developed in the course of their own drug discovery projects and are thus secondary to the end product. Pharmaceutical companies are not likely to want to license a tool they have developed to someone they perceive as their competitor on a similar project. As a result, they are not often interested in marketing their research tools. Therefore, most of the benefits of reach-through royalties are lost on them.

When it comes to licensing a research tool from another party (usually a university or biotech company), pharmaceutical companies try to avoid reach-through license provisions whenever they can. Some pharmaceutical companies flat out refuse to enter into reach-through license agreements.[20] Pharmaceutical companies' income is derived primarily from commercialization of drugs; because it takes considerable amounts of time and money to develop new drugs, they do not want to have to share the fruits of their labor with research tool providers who have done nothing but provide the tool. This is exacerbated when one takes into account stacking royalties.[21] That is, because it takes multiple tools in the development and commercialization of a drug, if a company had to pay several licensors reach-through royalties for use of their tools, the company's profits would be severely diminished.[22] Pharmaceutical companies believe that a better measure of the value of a tool is the amount of money it took to develop it.[23] They are therefore often willing to pay a licensing fee upfront, factoring in this amount rather than having to pay royalties on future discoveries.[24]

Because pharmaceutical companies are the least likely to benefit from licensing research tools to others and most likely to be harmed by having to pay

[18] Eisenberg, *Proprietary Research Tools*, *supra* note 5, at 235.
[19] *Id.* at 239.
[20] Ware, *supra* note 10, at 292.
[21] *Id.* at 295.
[22] *Id.*
[23] Eisenberg, *Proprietary Research Tools*, *supra* note 5, at 243.
[24] *Id.*

reach-through royalties, they are the most hostile to the use of reach-through royalties, and would be most likely to support regulations limiting their use.[25]

b. Universities and Other Non-profits

Universities that own patents on research tools view reach-through royalties favorably because they are now able to profit from drugs that are developed by pharmaceutical companies using their tools. This is especially pertinent given that until the advent of the biotechnology industry, research tools were primarily invented by academic scientists. Passage of the Bayh-Dole Act in 1980 gave universities a better opportunity to patent and capitalize on their discoveries, and tools that were once freely traded because they were not marketable became a potential source of profits for universities. Thus, universities have increased their use of reach-through provisions in their licensing agreements. The caveat to this arrangement is the NIH Guidelines published in 1999 that limit the use of reach-through provisions.[26] These guidelines are discussed at length *infra*.

When universities seek to license research tools, they often have conflicting interests. On one hand, they do not mind reach-through royalty provisions because they can use research tools for academic purposes without having to worry about hefty licensing fees, since development of a marketable product has not historically been the goal of academia.[27] On the other hand, they do not like the patenting of research tools in general because they now might have to pay for research tools that once would have been freely exchanged.[28] These differing viewpoints can be reconciled when you consider that the former view is often expressed by technology transfer managers while the latter view is expressed most often by scientists.[29]

As universities become more aligned with industry interests, complications arise when they, as publicly funded institutions, have to share profits with private companies. There is a perception that a motivation to patent and profit from research tools has induced universities to require unreasonable license agreements that deter the wide dissemination of these tools and reduce

[25] For example, Pfizer's research and development technology office manager, Lauren Miller, supports nonexclusive licensing of research tools as encouraged by the NIH Guidelines. Eugene Russo, *Regulating Researchers' 'Picks and Shovels': Scientists Continue to Review NIH Research Tool Guidelines*, THE SCIENTIST 14[9]:8, May 1, 2000 *available at* http://www.the-scientist.com/yr2000/may/russo_p8_000501.html (last visited March 6, 2005).

[26] NIH Guidelines, *supra* note 1.

[27] Eisenberg, *Reaching Through the Genome*, *supra* note 5, at 216.

[28] *Id.*; *see also* Walsh & Cohen., *supra* note 7, at 36 ("'Things are becoming more bureaucratic. [Material Transfer Agreements], they are crazy. Before, whenever someone wanted a plasmid from my lab, I would just send it. Now, the university says they own it and I have to go through the IP office. It goes back and forth between the two offices and it takes a long time. Before, we would just send it in the mail, and you would have it and could use it.'" (quoting an academic researcher)).

[29] *See* Eisenberg, *Proprietary Research Tools*, *supra* note 5 at 231; Russo, *supra* note 25, at ¶ 8, noting MIT's technology licensing office director's "wait and see" attitude towards the NIH guidelines.

innovation.[30] As a result, the 1999 NIH regulations limit the use of provisions, such as reach-through royalties, for research tools discovered using NIH funds.

c. Small and Emerging Biotechnology Firms

Small biotechnology companies have interests that are different from both pharmaceutical companies and universities because they blend many of the attributes of both entities. While they are private businesses engaged in biomedical research for profit, they often are founded by academic scientists, have strong scientific and financial ties to universities, and rely upon government grants for funding.[31] Moreover, they are the primary source of research tools meant for commercialization, so they have the greatest at stake in the reach-through royalty controversy. In addition to being major licensors of research tools, biotechnology companies are also significant licensees of research tools. In fiscal year 2002, a survey by the Association of University Technology Managers of its members calculated that 68% of all patent licenses were granted to small biotechnology companies or start-ups.[32] As such, small biotechnology companies hold a significant stake in any regulation of research tools.

As research tool patent holders seeking to license their products, biotechnology firms enjoy all of the benefits of reach-through royalty provisions. Because such firms have limited resources, they are unable to see a drug developed from beginning to end. Most often they must partner with a large pharmaceutical company in order to see an end product developed from their tool. Reach-through royalties provide a vital source of income to these biotech companies because they are able to get a "slice of the pie" of a successful drug without having to expend all of the resources necessary for its development.

There are, however, two problems facing biotech start-ups that wish to license tools with reach-through license provisions. First, many start-up companies rely on Small Business Innovative Research (SBIR) grants sponsored by the NIH as a valuable source of income separate from venture capital.[33] These grants are given to small businesses that are engaged in biomedical research and whose purpose is commercialization of any discoveries. These grants are vital to many start-ups because they allow them to engage in innovative and sometimes risky research that otherwise would not likely be funded by more conservative venture capitalists. The caveat is that the 1999 NIH Guidelines for dissemination of research tools expressly limit the use of reach-through royalties in license agreements for tools developed using

[30] Rai & Eisenberg, *supra* note 6, at 292.

[31] Eisenberg, *Proprietary Research Tools*, *supra* note 5, at 227.

[32] THE ASSOCIATION OF UNIVERSITY TECHNOLOGY MANAGERS, INC., AUTM LICENSING SURVEY, FY 2002: A SURVEY SUMMARY OF TECHNOLOGY LICENSING (AND RELATED) PERFORMANCE FOR U.S. AND CANADIAN ACADEMIC AND NONPROFIT INSTITUTIONS, AND PATENT MANAGEMENT AND INVESTMENT FIRMS, at 15 (2003) (the data cited includes non-research tool patents as well).

[33] SBIR grant award data can be found at http://grants.nih.gov/grants/funding/award_data.htm (last visited March 8, 2005).

NIH funding.[34] This means that start-ups must either forgo NIH funding, a vital source of income, or forgo reach-through royalties on their tools, a potentially lucrative source of income.

The second is the unequal bargaining power between start-ups and the large pharmaceutical companies to whom they seek to license their tools.[35] This is especially a concern given pharmaceutical companies' reluctance to enter into agreements using reach-through royalties. With their considerable leverage in negotiating the use of these tools, biotechnology companies may not always be able to negotiate the full value of their tool.[36] A further concern is that these large pharmaceutical companies might use their political weight to convince the Commerce Department or Congress to promulgate regulations or a statute further restricting the use of reach-through royalties.

Biotechnology companies seeking to license research tools from others have mixed feelings about reach-through royalties. The companies do not mind them because it means they have access to tools they would not necessarily be able to afford if they had to pay licensing fees up front. [37] With reach-through royalties they only have to pay if they successfully find something marketable. But they also must contend with issues of stacking royalties and reduced profits, which are even more relevant to smaller companies with limited resources relative to pharmaceutical companies.

d. Government Interests

The federal government's interest in this issue can best be described as a tension between two goals. Passage of the Bayh-Dole Act ("Bayh-Dole") [38] in 1980 was the result of an effort to increase innovation by allowing recipients of government funding to patent and commercialize their inventions.[39] But the NIH sees that the repercussions of Bayh-Dole have spiraled out of control to the point that innovation is actually diminished by the increased commercialization of scientific discovery. Thus, it is increasingly difficult to see a way of achieving the government's ultimate goal, which ought to be a policy regarding biomedical research tool dissemination that most benefits the American people. A more thorough discussion of this tension follows below, but the solution may be to eliminate the current NIH Guidelines and promulgate regulations through the Commerce Department, the administrator of Bayh-Dole.[40] These regulations could be written in such a way to encourage free dissemination of tools by universities, while allowing small biotech firms more freedom to utilize license provisions including reach-through royalties, regardless of the receipt of government funding. Furthermore, passage by Congress of a formal experimental use exception for biomedical research tools

[34] NIH Guidelines, *supra* note 1 at 72,093.

[35] *See* Eisenberg, *Reaching Through the Genome*, *supra* note 5, at 215.

[36] *Id.*

[37] *Id.*; Eisenberg, *Proprietary Research Tools*, *supra* note 5, at 239.

[38] 35 U.S.C. §§ 200−212 (2000).

[39] 35 U.S.C. § 200 (2000).

[40] 35 U.S.C. § 208 (2000) (giving the Commerce Department authority to regulate licensing of patents on inventions made with federal assistance).

may help to achieve the goal of increasing scientific knowledge while also compensating the research community for any perceived disparate treatment between universities and private industry.[41]

It should be noted that in the last thirty years large pharmaceutical companies have, for the most part, been profitable enterprises, while biotechnology firms have not.[42] If this is because they have thus far been unable to recover the full value of their research tools, it argues that biotechnology firms, especially small and emerging firms, should not be limited in their ability to use reach-through royalty provisions in their license agreements.[43]

2. An Historical Overview of Research Tool Patent Licensing

Historically, research tools were disseminated in a casual manner among academics.[44] Scientists would often just call their colleagues at other institutions and have them send various reagents that would be helpful in their research. In 1980, the Supreme Court ruled that genetically engineered organisms were patentable as "anything under the sun that is made by man."[45] Additionally, the Federal Circuit also loosened the stringency of its test for utility and non-obviousness.[46] Subsequently, it became easier to patent all manner of research tools.[47]

Also in 1980, Congress passed the Bayh-Dole Act.[48] Its purpose was to allow the patenting of inventions produced with government funding.[49] It was thought that this would increase public access to cutting edge technology by producing an incentive for scientists to market their inventions. As a result, universities began using reach-through royalties in their licenses.[50] An unfortunate consequence is that it has become increasingly complicated for scientists to gain access to research tools because they now have to enter license agreements to get reagents that used to be freely traded among colleagues.[51] Furthermore, the pharmaceutical industry, which previously viewed academics as benign, now sees them as potential competitors.[52] This often leads to protracted negotiations and frequent denial of transfer of technology that further decreases the dissemination of scientific knowledge.[53]

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[41] *See generally* Mueller, *supra* note 3 for a discussion on broadening the experimental use exception.

[42] Eisenberg, *Reaching Through the Genome*, *supra* note 5, at 228.

[43] *Id.*

[44] Rai & Eisenberg, *supra* note 6, at 289.

[45] *Id.* at 290 (citing Diamond v. Chakrabarty, 447 U.S. 303, 309 (1980)).

[46] Rai & Eisenberg, *supra* note 6, at 290.

[47] *Id.*

[48] 35 U.S.C. §§ 200−12.

[49] 35 U.S.C. § 200.

[50] Rai & Eisenberg, *supra* note 6, at 291.

[51] Eisenberg, *Proprietary Research Tools*, *supra* note 5, at 225.

[52] Rai & Eisenberg, *supra* note 6, at 294.

[53] *Id.*; Golden, *supra* note 6, at 175; Eisenberg, *Proprietary Research Tools*, *supra* note 5, at 225.

Thus, the purpose of Bayh-Dole—increased public access to technology—has been undermined by the overzealous commercialization of universities' discoveries.

Although Bayh-Dole's purpose was to promote the widespread utilization of inventions by permitting inventors to patent their inventions made using federal funding,[54] some see the push to patent as limiting the widespread use of these inventions.[55] One of the problems is that Bayh-Dole does not differentiate between inventions that are close to commercialization from upstream discoveries that may or may not lead to a marketable product.[56] This is what popularized the use of reach-through provisions in the first place.

A second problem is that because the Commerce Department is the agency that has the authority to promulgate regulations concerning licensing under Bayh-Dole,[57] the NIH has very limited authority over whether research tools are patented and can only prevent patenting in "exceptional circumstances."[58] Bayh-Dole also gives the funding agency march-in rights to compel licensing to the agency,[59] but only if the funding recipient is not attempting to achieve its practical application or in matters relating to public health.[60] This procedure is sufficiently cumbersome that to date the NIH has never attempted to exercise these rights.[61] Instead, it issued guidelines on the proper way that NIH grant recipients should disseminate their research tools.[62]

These guidelines, although permissible under Bayh-Dole, have almost the opposite purpose of Bayh-Dole. Where Bayh-Dole promotes the free patentability and licensing of inventions made with government funds and limits the ability of agencies to curtail patenting, the NIH Guidelines seek to curtail patenting, exclusive licensing, and use of reach-through royalties in an effort to increase the free dissemination of resources, thus increasing innovation.[63] There is concern among some that by issuing these guidelines the NIH has overstepped its bounds.[64] While the guidelines do not have the force of law, grant recipients must agree to follow them as a condition of funding.

As discussed above, the problem with these guidelines as they pertain to small businesses is that they not only apply to universities and non-profits, which are the primary targets of the guidelines, but they also apply to small

[54] 35 U.S.C. § 200; Rai & Eisenberg, *supra* note 6, at 291.

[55] Eisenberg, *Proprietary Research Tools*, *supra* note 5, at 226.

[56] Rai & Eisenberg, *supra* note 6, at 291.

[57] 35 U.S.C. § 208; *see also* 37 C.F.R. § 401 (2003).

[58] 35 U.S.C. § 202(a) (2000).

[59] 35 U.S.C. § 203(a) (2000).

[60] *Id.*

[61] Rai & Eisenberg, *supra* note 6, at 294.

[62] NIH Guidelines, *supra* note 1, at 72,093.

[63] *Id.*; Rai & Eisenberg, *supra* note 6, at 307−09; Ware, *supra* note 10, at 291.

[64] Russo, *supra* note 25, at ¶ 9 (paraphrasing William Haseltine, CEO of Human Genome Sciences as "saying that the guidelines might as well be regulations since NIH grantees, nervous about losing funding , will likely follow the agency's recommendations to the letter. 'I believe that by administrative fiat, [the NIH] has done something they oughtn't do . . . .'").

businesses that receive SBIR or other grants from the NIH.[65] The comments the NIH received after the initial notice of the guidelines indicated a concern that the interests of non-profits and universities are different from those of small businesses that receive SBIRs, because the goal of an SBIR grant is commercialization of discoveries.[66] Additionally, it can be argued that the reduction of dissemination of research tools is more of a problem with universities than with small businesses that must be able to successfully negotiate license agreements in order to survive. However, the NIH stated that it did not see a conflict in the dual purpose of disseminating resources and promoting commercialization, and so the guidelines apply to private companies and universities alike.[67]

Another difficulty inherent in the NIH Guidelines is that they do not have the force of law.[68] The Commerce Department is in charge of issuing regulations under Bayh-Dole.[69] The NIH does have the power to sanction or withhold future funding from those who violate the guidelines.[70] However, this is rarely done.[71] In fact, while the NIH has the ability to sanction or withhold funding from violators, it is not easy to understand the exact procedure followed in order to impose sanctions. There is some concern that they might not be evenly enforced to all NIH grant recipients.[72] This could be due to NIH's lack of resources for investigating breaches, or more disconcerting, it could be a function of how well connected one is to the NIH.[73]

3. Emerging Trends in the Use of Reach-Through Royalty Provisions

a. The Association of University Technology Managers

The Association of University Technology Managers (AUTM) is a coalition of technology transfer managers from around the nation, seeking ways to increase the benefits to universities in the dissemination of their resources. Some commentators have noted that they have a reputation of encouraging universities to hardball negotiate each license agreement, adding in reach-through royalties, milestone payments, and renegotiation options that unnecessarily complicate licenses.[74] Such licenses often become deal breakers and lead to the slow down in the transfer of resources with which the NIH is so concerned. One commentator thinks that the reasons institutions like MIT are so successful is because they realize that only one in 300 of these licenses will

[65] NIH Guidelines, *supra* note 1, at 72,091.

[66] *Id.*

[67] *Id.*

[68] See 35 U.S.C. § 203 (granting march-in rights); 35 U.S.C. § 208 (giving regulatory authority to the Commerce Department); Rai & Eisenberg, *supra* note 6, at 308−09.

[69] 35 U.S.C. § 208.

[70] E-mail from Dr. George Stone, Chief, Extramural Inventions and Technology Resources Branch, NIH, personal communication (Oct. 27, 2003) (on file with author).

[71] *Id.*

[72] Interview with a Patent Attorney representing Biotechnology Start-ups who did not give permission to use his name in this Comment.

[73] *Id*.

[74] *Id*.

ever make them money. Therefore, they are much more focused on the quantity of agreements into which they enter, rather than trying to make millions of dollars on each one.[75] They are much more interested in the ease of the transaction and licensing as many things as possible. Unfortunately, most institutions do not have the same philosophy as MIT. These institutions are the ones that the NIH was most concerned with when promulgating its guidelines.[76]

b. NIH Guideline Enforcement

It has been nearly five years since the NIH issued its guidelines, yet it is still uncertain what impact they are actually having. In light of the NIH Guidelines, institutions might choose to forgo public funding rather than be restricted in their ability to negotiate licenses.[77] Even the NIH sends mixed signals, saying that institutions may be sanctioned for not following the guidelines, but also saying "It's not 'thou shalt,' it's not 'you must,' it's 'here are some ways to do it.'"[78] However, it may be more likely that these guidelines are simply ignored and universities and start-ups will just bet on the NIH not sanctioning them.[79] If this is true, then it argues that the NIH Guidelines should be revoked all together. First, they do not have their intended effect on universities and unfairly include small business in the same category. Second, they may not be evenly enforced, thus increasing the likelihood of unfairness depending on how well connected one is to the NIH. Third, if the guidelines are simply ignored, then none of their potentially positive effects could ever come to fruition. Finally, because of the considerable political clout of the pharmaceutical industry, there is some concern that they might put pressure on the NIH to more strictly enforce the guidelines which they themselves are not required to follow.

A more effective means of achieving widespread dissemination of tools while preserving small business interests would be Commerce Department regulations restricting the use of exclusive licensing and reach-through provisions for non-profit recipients of government funding that does not include private business recipients of SBIR or similar funding.

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[75] *Id*.

[76] *See* Eisenberg, Proprietary Research Tools, *supra* note 5, at 231: "[T]he more serious bottleneck to research is the growing burden of negotiating numerous agreements . . . . Taken individually, none of these agreements is likely to yield commercially valuable results. Nonetheless, in the aggregate, they create significant administrative delays that slow the pace of research."

[77] Thomas J. Kowalski & Christian M. Smolizza, *Reach-through Licensing: A US Perspective*, J. Comm. Biotech. 1, 9 (July 14, 2000) *available at* http://pharmalicensing.com/features/disp/963567614_396edffe132c5 (last visited April 7, 2005).

[78] Russo, *supra* note 25, at ¶ 10, quoting Barbara McGarey, NIH deputy director of the office of technology transfer.

[79] Interview with unnamed patent attorney, *supra* note 72 (commenting that he still writes reach-through provisions into license agreements for his clients. He advises them that they could be sanctioned, but they are usually willing to take the risk.); Kowalski & Smolizza, *supra* note 77, at 9.

c. Reach-Through Damage Awards

As discussed *supra*, complications arise when awarding damages for patent infringement on research tools that conceivably would have been licensed with reach-through royalties had the parties actually negotiated.[80] This is because it is purely speculative as to what the parties would have actually agreed.[81] For example, in *SIBIA Neurosciences, Inc. v. Cadus Pharmaceutical Corp.*,[82] the court struggled with the amount of damages that should be awarded because the infringement case was brought before an actual drug had been developed. Not only did the court have to speculate as to what the terms of the license agreement would have been, but they also had to determine the relative probability that a lead compound discovered using the tool would actually ever be commercialized.[83] Similarly, in *Integra Life Sciences I, Ltd. v. Merck KGaA*[84] the court suggested that the district court should consider on remand whether reach-through royalties and royalty stacking would have been a factor in a hypothetical negotiation between the parties when assessing damages.

Additionally, some commentators note that some firms may just infringe on the research tool patent, hoping that they will not get caught, and that they will not have to pay damages unless they actually develop something marketable.[85] For these reasons, some have suggested a modified research exemption for research tool damage liability.[86] Such an exemption would mean that it would be unnecessary to pay for licensing unless you produce something marketable. At that point you would be liable for damages if you failed to pay.[87] Here again the court would be required to speculate as to the amount of such damages. However, the problems of speculation might be alleviated if reach-through royalties became an industry norm.[88] The marketplace itself would dictate what is normally reasonable for any given license agreement.[89] Because it is unlikely that courts will be able to completely avoid the issue of reach-through royalties when determining cases like *SIBIA* there is an

[80] Ware, *supra* note 10, at 286 (discussing *SIBIA*).

[81] *Id.*

[82] 225 F.3d at 1354 (*rev'd on other grounds*).

[83] *Id.*

[84] 331 F.3d 860, 871 (Fed. Cir. 2003).

[85] Rai & Eisenberg, *supra* note 6, at 298 n.49; Eisenberg, Proprietary Research Tools, *supra* note 5, at 233−34; Walsh & Cohen, *supra* note 7, at 42 (stating that University researchers regularly infringe on upstream research tools, but firms are reluctant to pursue infringement actions because of the prohibitive cost of a lawsuit relative to the amount of compensatory damages, as well as the bad publicity one might incur by suing a non-profit institution); Walsh & Cohen, *supra* note 7, at 44−45 (noting that infringement by private firms is pervasive, and that many firms wait to see if the research looks promising before seeking a license if necessary).

[86] *See* Mueller, *supra* note 3.

[87] Eisenberg, Reaching Through the Genome, *supra* note 5, at 217; Mueller, *supra* note 3, at 55.

[88] Ware, *supra* note 10, at 282.

[89] *Id.*

additional reason to encourage small businesses to continue using reach-through licenses, rather than try to ban them completely.

Unfortunately, the Federal Circuit has recently reiterated its interpretation of a narrowly construed experimental use exemption. In *Madey v. Duke Univ.*,[90] the court ruled that Duke University could not rely on the common law experimental use exemption as a defense to Madey's patent infringement claim simply because it was an academic institution.[91] The court stated that the exemption should be "limited to actions performed 'for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry.'"[92] On remand, the district court was instructed to see if Duke's use of the patented inventions could be viewed as furthering a legitimate business interest and therefore did not qualify for the research exemption defense.[93]

In light of the court's narrow construction of the common law experimental use exemption, any broadening would need to be achieved through legislative action. If a formal research exemption were passed, Congress could at the same time set statutory damages as an alternative to compensatory damages for researchers incurring liability through commercialization, thus alleviating some of the difficulty courts may have in assessing damages for reach-through licensing provisions.[94]

d. Reach-Through Claims and Patent Misuse

Inventors, with increasing frequency, have been trying to avoid reach-through licensing problems by working the reach-through provision into the patent claims themselves.[95] This means they can circumvent fruitless negotiations with pharmaceutical companies that are reluctant to enter into reach-through license agreements because the reach-through provision is already a part of the patent. For instance, an inventor patenting a receptor may claim the gene sequence, the receptor itself, and a method for screening for ligands of the receptor. However, as of late, they also might try to patent as yet unidentified ligands for the receptor, thus reaching through to compounds yet to be developed.[96] There are serious concerns as to whether such claims should be allowed under 35 U.S.C. § 112 ¶ 1, which requires a written description of the patented invention to "describe the claimed subject matter in terms that establish that [the applicant] was in possession of the . . . claimed invention, including all of the elements and limitations."[97] The Federal Circuit's holding in *University of Rochester v. G.D. Searle & Co.* that the University's patents

[90] 307 F.3d 1351 (Fed. Cir. 2002) (*cert. denied* in Duke Univ. v. Madey, 539 U.S. 958 (2003)).

[91] *Id.* at 1363.

[92] *Id.* at 1362 (quoting Embrex Inc. v. Service Eng'g Corp., 216 F.3d 1343, 1349 (Fed. Cir. 2000)).

[93] *Id.* at 1363.

[94] Mueller, *supra* note 3, at 62.

[95] Kunin, *supra* note 14, at 619.

[96] *Id.* at 620.

[97] 35 U.S.C. § 112 ¶1 (2000); Univ. of Rochester v. G.D. Searle & Co., 358 F.3d 916, 926 (Fed. Cir. 2004) (quoting Hyatt v. Boone, 146 F.3d 1348, 1353 (Fed. Cir. 1998)).

failed the written description requirement,[98] should curtail the use of reach-through claims. However, the Patent and Trademark Office has so far not been uniform in disallowing such claims.[99]

A recent case, *Bayer AG v. Housey Pharmaceuticals*,[100] highlights some of the problems with reach-through claims. In *Bayer*, the plaintiff argued that the patentee had impermissibly broadened the scope of the patent by seeking to extract royalties on drugs not yet discovered. The plaintiff argued that this was patent misuse. Yet, the court ultimately held that because the plaintiff never actually licensed the tool from the patentee, the license could not be said to be conditioned on royalties for drugs not yet covered by the patent.[101] However, to do this the court once again needed to speculate as to how the parties would have negotiated a license. This speculation is but one of the problems with reach-through claims.

Reach-through claims are also troublesome because of their potential to deter innovation.[102] With reach-through claims, third parties have little incentive to develop targets that are covered by the reach-through claim.[103] Any innovation must therefore come from the original patent holder rather than a variety of third parties seeking to use the research tool. Since it is unlikely that the patent holder is able to think of all of the possible applications of its invention, the progress of science is thereby hindered. This too suggests that while the PTO should be able to limit reach-through claiming, perhaps an equitable compromise is the continued allowance of reach-through license provisions.

B. A Proposal that Considers Small Biotechnology Firms' Interests

1. The NIH Guidelines Should Be Eliminated

The largest problem in the controversy surrounding reach-through royalties is that each of the players involved has competing interests. Thus, the interests of biotechnology companies must be balanced with those of large pharmaceutical companies, universities, and non-profits. Ultimately, any solution must promote widespread dissemination of biomedical resources for the public good, while keeping in mind the various goals of the entities involved.

Although the NIH Guidelines were issued with the noble purpose of encouraging the widespread dissemination of research tools, they must be eliminated and replaced with a more equitable and effective means of achieving that same goal. The provisions in the guidelines restricting the use of reach-through royalties are best applied to universities and non-profits, not to biotechnology firms, which depend on their intellectual property as their

[98] *Univ. of Rochester*, 358 F.3d at 929.
[99] Kunin, *supra* note 14, at 619.
[100] 228 F. Supp. 2d 467 (D. Del. 2002).
[101] *Id.* at 470.
[102] Walsh & Cohen, *supra* note 7, at 13.
[103] *Id.*

lifeblood. Contrary to the NIH's view, biotechnology firms that are recipients of federal funding do not and should not have the same mission as universities and non-profits, and should not be treated as though they do. Biotechnology firms rely on reach-through royalties as a fair way to value their proprietary research tools. Furthermore, they are not as susceptible to the bogging down of transfer agreements as universities are because it is in their best interest financially to make sure the deals go through. This is in contrast to a university that has numerous sources of income. Small businesses should be encouraged to commercialize as much as possible, as was the original intent of the Bayh-Dole Act.

The NIH Guidelines should be eliminated because they are not equally enforced. There is no set procedure for imposing sanctions, and the guidelines do not have the force of law. Additionally, the NIH does not have the resources to sanction every violator. This is a formula for the irregular and potentially unfair enforcement of the guidelines. More troublesome is the possibility that large pharmaceutical companies may use their political clout to put pressure on the NIH to start cracking down on violators. With political pressure also comes the concern that enforcement will not be fair.

Some suggest that there should be fewer regulations altogether and that the negotiating parties should be free to decide what they would like in their license agreements.[104] According to this view, not only should the NIH Guidelines be done away with, but nothing should be put in their place. The market would dictate the terms of license agreements. But this argument is deficient for several reasons. The NIH Guidelines are not all bad. They intend to encourage the dissemination of resources by the use of non-exclusive material transfer agreements. Their intent is ultimately for the public good by increasing innovation. The problem is that they are not working, and that they have unnecessary negative effects on small businesses. The absence of any regulation at all, however, would put small businesses at the mercy of the much more powerful pharmaceutical industry. Some have observed a practice of pharmaceutical companies already offering miniscule lump sum fees.[105] This could be because they believe that small businesses and universities will take them in light of the NIH Guidelines.[106] Only when small companies absolutely require reach-through royalties do the large companies agree.[107]

Other commentators suggest that the NIH be given more power to regulate patent licenses under Bayh-Dole.[108] Professors Arti Rai and Rebecca Eisenberg argue that the use of non-exclusive license agreements such as AUTM's model material transfer agreement should become the norm.[109] But, there are several problems with this solution as well. First, Professors Rai and Eisenberg focus so much on the issues surrounding universities that they fail to consider

[104] Interview with unnamed patent attorney, *supra* note 72.
[105] Kowalski & Smolizza, *supra* note 77, at 9.
[106] *Id.*
[107] *Id.*
[108] Rai & Eisenberg, *supra* note 6, at 310.
[109] *Id.* at 301.

whether giving the NIH more power will completely disable emerging businesses because of its unwillingness to differentiate between the academic missions of universities and the commercial nature of biotechnology firms. Second, while non-exclusive licenses make sense for research tools that are significantly upstream to be of general applicability in a variety of research products, the same may not be true for a downstream tool that only a few labs are interested in studying to begin with. Reach-through royalties make significantly more sense for such downstream tools. Furthermore, it may be virtually impossible to value a tool at the outset of a project, especially where any commercialized discoveries would not have been made but for the use of the research tool.[110]

One idea is to promulgate a regulation that compromises by saying that upstream tools must use upfront licensing fees, while downstream tools may use reach-through royalties. The test for upstream versus downstream would be a "but for" test. That is, a research tool is considered downstream if the commercialized product would not have been developed but for the use of the research tool. The problem with this idea is that it may be very difficult to prove "but for", especially in situations where the tool is not used for drug discovery, but for other purposes such as safety trials.[111]

In other contexts, transparency is often a viable solution where there are competing interests at work. In an ideal situation, holders of research tool patents could be made to list their technologies and terms in a repository. While they would still be able to demand reach-through royalties, the transparency would ensure that competition would drive prices down. However, because of the unique nature of research tools, this solution would only work with upstream tools, not downstream ones. The problem is that downstream tools are one of a kind, and cannot be substituted by someone else's product. For example, if you wanted to conduct a project using a receptor implicated in Parkinson's disease, you cannot use a different target receptor for that same project.

2. New Regulations Should Be Promulgated that Consider Small Business Interests and Congress Should Expand the Experimental Use Exemption

The Commerce Department should issue regulations that allow small businesses to continue using reach-through royalties regardless of whether they are recipients of government funding. These regulations could at the same time restrict the use of reach-through royalties by universities and non-profits in a manner that is consistent with the original intent of the NIH Guidelines. These regulations would have the force of law, and should include procedures ensuring that they are fairly enforced. Such regulations would have the advantages of reducing many of the bottleneck issues that concern both pharmaceutical companies and the NIH, and they would provide relief for smaller biotech companies by affording them the full benefits of the Bayh-Dole Act. Thus, they could potentially embody a compromise that both

[110] Kowalski & Smolizza, *supra* note 77, at 3.
[111] Ware, *supra* note 10, at 279.

pharmaceutical companies and biotechnology companies can live with. Universities, while not being able to freely negotiate as many exclusive license agreements as they may like, would actually benefit by ensuring the widespread dissemination of resources, and increasing the number of license agreements that are executed, thus increasing their chances of profiting. At the very least, if such regulations cannot be promulgated, the NIH should amend their guidelines on the dissemination of research tools such that small business recipients of SBIRs or STTRs are not subject to the restriction against reach-through royalties.

Additionally, Congress should pass a statute formalizing a broad construction of the experimental use exemption for biomedical patents as outlined by Janice Mueller.[112] Professor Mueller likens such an exemption to the equivalent of the Fair Use Doctrine in copyright law.[113] Such an exemption would have the effect of promoting the free dissemination of research tools for research purposes, thus achieving many of the goals outlined in the NIH Guidelines. Under Professor Mueller's model, using a tool for research would incur no liability, but if a marketable product was discovered using the tool, the party would be liable to the research tool's patent owner.[114] Damages could be assessed using reach-through royalties, but in instances where that is not feasible, statutory damages could be awarded.[115]

The combination of Congressional expansion of the experimental use exemption coupled with Commerce Department regulations that implement the goals intended by the NIH Guidelines, while still permitting reach-through royalties for businesses, strikes a balance between competing interests. Universities benefit from the broadened exemption for their research activities. Pharmaceutical companies would not necessarily be harmed by a broadened research exemption; there is evidence that they are reluctant to pursue most infringements by universities because of the prohibitive cost and potentially bad publicity.[116] Small biotechnology companies benefit by still being able to negotiate reach-through royalties in their license agreements. Government interests are furthered both by promoting the dissemination of scientific knowledge and resources, while also protecting the biotechnology industry.

III. CONCLUSION

The use of reach-through royalties in research tool license agreements is controversial because they are seen as being partially responsible for the reduction in the dissemination of such tools, thereby causing a decrease in innovation. Further complicating the issue are the competing interests of large pharmaceutical companies, universities, emerging biotechnology firms, and the government. The 1999 NIH Guidelines regarding research tools worsen the

[112] Mueller, *supra* note 3.
[113] *Id.* at 42.
[114] *Id.* at 54.
[115] *Id.* at 62.
[116] Walsh & Cohen, *supra* note 7, at 42.

problem by applying the same limitations on reach-through royalties to small business and universities alike. While they were meant to help alleviate the growing bottleneck that complicated exclusive license agreements cause, they potentially harm small businesses that rely on reach-through provisions for their livelihoods. This is exacerbated by the inadequate and unequal enforcement of the guidelines. One solution is the elimination of the NIH Guidelines, and its replacement by regulations that differentiate between university and business concerns in the use of reach-through royalties in license agreements, coupled with a statutory broadening of the experimental use exemption for biomedical patents.