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PATENT TROLLING—WHY BIO & PHARMACEUTICALS ARE AT RISK

*Robin Feldman & W. Nicholson Price II**

Patent trolls—also known variously as non-practicing entities, patent assertion entities, and patent monetizers—are a top priority on legislative and regulatory reform agendas. In the modern debates, however, the biopharmaceutical industry goes conspicuously unmentioned. Although biopharmaceuticals are paradigmatically centered on patents, conventional wisdom holds that biopharmaceuticals are largely unthreatened by trolls. This article shows that the conventional wisdom is wrong, both theoretically and descriptively. In particular, the article presents a ground-breaking study of the life science holdings of 5 major universities to determine if these might be attractive to monetizers.

This was deliberately a light, rather than an exhaustive, search. Nevertheless, we identified dozens of patents that could be deployed against current industries. These include patents on active ingredients of drugs; methods of treatment; screening methods to identify new drugs; manufacturing methods; dosage forms; and ancillary technologies that could be deployed in a “peddler’s bag” approach. The article describes the types of patents we found, including an example of each type.

In deciding whether to undertake this analysis, we lost sleep over whether the potential for harm outweighed the potential benefit. If reform efforts are not undertaken, our work could do no more than provide a handy road map for those who would follow. However, with scattered anecdotal evidence suggesting that monetization is moving into biopharmaceuticals, life sciences trolling is predictable and in its infancy. If reforms are implemented before the problem proliferates, legislators and regulators could cabin the activity before it becomes deeply entrenched and too much harm occurs.

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PATENT TROLLING: WHY BIO & PHARMACEUTICALS ARE AT RISK

INTRODUCTION

Patent trolling is at the top of legislative and regulatory reform agendas at many levels. In May of 2013, for example, the White House released an extensive report on patent assertion, along with a series of executive orders and recommendations for Congress.¹ Members of Congress were already showing interest in addressing the issue. A variety of bills have been introduced; the Chairmen of both the House and Senate Judiciary Committee have introduced bills on litigation reform, with hearings in the fall of 2013.² In addition, subcommittees of the Senate Energy Committee and the House Energy & Commerce Committee have held hearings on pre-litigation reform. The proposals address different aspects of a complex problem that will need to be addressed on many levels across a long period of time.

On the regulatory front, the Federal Trade Commission voted in September of 2013 to initiate a broad ranging Section 6(b) investigation into patent assertion entities. Under Section 6(b), the FTC has the power to conduct wide-ranging economic studies of businesses and practices that affect commerce.³ The FTC action followed a joint workshop held by the Federal Trade Commission and the Department of Justice in December of 2012 on the antitrust implications of patent assertion entities.⁴ The Patent and Trademark Office has initiated its own proposals, focused largely on sunshine rules. The PTO activities follow its own workshop in January of

¹ Executive Office of the President, Patent Assertion and U.S. Innovation (June 2013), available at http://www.whitehouse.gov/sites/default/files/docs/patent_report.pdf; White House Office of the Press Secretary, Fact Sheet: White House Task Force on High-Tech Patent Issues (June 04, 2013), available at <http://www.whitehouse.gov/the-press-office/2013/06/04/fact-sheet-white-house-task-force-high-tech-patent-issues>.

² Saving High-Tech Innovators from Egregious Legal Disputes Act of 2013, H.R. 845, 113th Cong. (2013); End Anonymous Patents Act, H.R. 2024, 113th Cong. (2013); Patent Quality Improvement Act of 2013, S. 866, 113th Cong. (2013); Patent Abuse Reduction Act of 2013, S. 1013, 113th Cong. (2013); Patent Litigation and Innovation Act of 2013, H.R. 2639, 113th Cong. (2013); Stopping the Offensive Use of Patents Act, H.R. 2766, 113th Cong. (2013); Innovation Act, H.R. 3309, 113th Cong. (2013); Patent Litigation Integrity Act of 2013, S. 1612, 113th Cong. (2013).

³ See generally OFFICE OF POLICY PLANNING, FTC, HISTORY OF SECTION 6 REPORT-WRITING AT THE FEDERAL TRADE COMMISSION(1981) [hereinafter HISTORY OF § 6], available at <http://www.ftc.gov/be/econrpt/231984.pdf>.

⁴ Press Release, Dep't. of Justice, Department of Justice, Federal Trade Commission to Hold Workshop on Patent Assertion Entity Activities (Dec. 7, 2012), available at http://www.justice.gov/atr/public/press_releases/2012/289873.htm.

2013, as well as the White House directives.⁵

Some states have entered the fray as well. Vermont passed legislation related to patent trolling, and the Vermont Attorney General's Office has initiated actions against entities under that legislation. Nebraska followed suit with its own actions, and other state legislatures are beginning to hold hearings.⁶ Even the Supreme Court has begun to nibble around the edges of the issue. The Court began the October 2013 term by granting certiorari in two cases that could have an impact on patent trolling, both related to awarding attorney's fees for baseless or exceptional patent cases that are rejected by the courts.⁷

The issue has attracted increasing attention from academics, the press, and companies in many sectors. Technology companies have led the way, with active lobbying campaigns in the United States and in Europe as well.⁸ This is not surprising, given that modern patent trolling has made a strong appearance in technology heavy industries, such as software,

⁵ Comments of the Antitrust Division of the United States Department of Justice and the United States Federal Trade Commission, In the Matter of Notice of Roundtable on Proposed Requirements for Recordation of Real-Party-in-Interest Information Throughout Application Pendency and Patent Term, No. PTO-P-2012-0047 (Feb. 1, 2013), *available at* <http://www.ftc.gov/os/2013/02/130201pto-rpi-comment.pdf>; *see supra* note 3.

⁶ Bad Faith Assertions of Patent Infringement Act 9 V.S.A. §§ 4195-99 (2013); Complaint, Vermont v. MPHJ Tech. Inv., LLC, No. 2:13-cv-00170-wks (May 8, 2013); Letter from Jon Bruning, Attorney General, Nebraska, to M. Brett Johnson, Partner, Farney Daniels LLP (July 18, 2013) (demanding that law firm "cease and desist the initiation of any and all new patent infringement enforcement efforts" with respect to patents held by its non-practicing-entity clients, pending a state investigation), *available at* http://www.ago.ne.gov/resources/dyn/files/1069534z3005a836/_fn/071813+Farney+Daniel+s+LLP+-+Cease+%26+Desist+Letter+and+Civil+Investigative+Demand.pdf; Press Release, Attorney General Lori Swanson Announces First-in-the-Nation Order to Stop Delaware Company from "Patent Trolling" in Minnesota (August 20, 2013), *available at* <http://www.ag.state.mn.us/Consumer/PressRelease/130820StopPatentTrolling.asp>; Press Release, Coakley Discusses Patent Trolling During Tour of Boston Startup LevelUp (Nov. 6, 2013), *available at* <http://www.mass.gov/ago/news-and-updates/press-releases/2013/2013-11-06-patent-trolling.html>; Informational Hearing on Patent Assertion Entities Before the California Assembly Select Committee on High Technology (October 30, 2013) (statement of Prof. Brian J. Love), <http://law.scu.edu/wp-content/uploads/Brian-Love-Testimony-Cal-Select-Comm-on-High-Tech-Hearing-on-PAEs-10-30-13.pdf>.

⁷ Octane Fitness, LLC v. ICON Health & Fitness, Inc., 496 Fed. Appx. 57 (Fed. Cir. 2013), *cert. granted*, 81 U.S.L.W. 3146 (U.S. Oct. 1, 2013) (No. 12-1184);

Highmark Inc. v. Allcare Health Management Sys., 687 F.3d 1300 (Fed. Cir. 2012), *cert. granted*, 81 U.S.L.W. 3562 (U.S. Oct. 1, 2013) (No. 12-1163).

⁸ Letter from adidas, AG, et al. to Member States of the European Union, et al. (Sept. 26, 2013), *available at* <https://docs.google.com/file/d/0BwxyRPFduTN2NkpoN29UVm11OWc>; Letter from the Alliance of Automobile Manufacturers, et al. to Harry Reid, Majority Leader, U.S. Senate, et al. (July 17, 2013).

smartphones, and computers. Retail companies have joined in as well, however, with brick and mortar stores like J.C. Penny Co. and adidas AG asking lawmakers to provide relief, and fighting back in the courts.⁹

In all of the noise, however, the life sciences industry has been silent. Conventional wisdom holds that patent trolling is a problem for the technology sector, not for biotechnology and pharmaceuticals. Indeed, in the debate leading up to the 2011 patent reform legislation known as the America Invents Act, the life sciences industry opposed reforms to patent damage calculations, reforms that might have helped curb some of the patent trolling activity that has exploded in the interim. Thus, any legislation or regulatory reforms that emerge are likely to be designed to bypass the life sciences industry.

We believe that the conventional wisdom is shortsighted. These industries are far more vulnerable to trolling than commonly acknowledged, and there are early indications that patent trolling is beginning to move into the life sciences arena. In a sign of things to come, for example, patent brokers are beginning to hear from pharmaceutical companies who are looking for monetizers that might be interested in buying their non-core patents.¹⁰ Similarly, two recent studies on patent demands against startup companies showed patent demands moving into the life sciences industry.¹¹

⁹ *Abusive Patent Litigation: The Impact on American Innovation and Jobs, and Potential Solutions, Before the Subcomm. on Courts, Intellectual Property & the Internet of the H. Comm. on the Judiciary*, 113th Cong. 9–112, 136–45, 236–60 (Mark Chandler, Senior Vice President and General Counsel of Cisco Systems; Janet L. Dhillon, Executive Vice President and General Counsel of J.C. Penny Co.; John G. Boswell, Senior Vice President and Chief Legal Officer of SAS Institute; and Dana Rao, Vice President and Associate General Counsel of Adobe Systems testifying before the House Committee on the need for patent reform in response to abusive patent litigation).

¹⁰ Lisa Shuchman, *The AIA's Impact on In-House Patent Processes*, Corporate Counsel (Feb. 7, 2014), <http://www.corpcounsel.com/id=1202641886062> (noting that intellectual property counsel in the pharmaceutical, biotechnology, and medical devices industries “are being called upon to monetize and get more value out of their company’s IP.”)

¹¹ Robin Feldman, *PATENT DEMANDS & STARTUP COMPANIES: THE VIEW FROM THE VENTURE CAPITAL COMMUNITY* 2, 36 (2013), http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2346338 (finding that 30% of venture capitalists in sample who have received patent demands have experienced them in the life sciences sector); Colleen Chien, *PATENT ASSERTION AND STARTUP INNOVATION* 11 fig. 1 (2013), http://www.newamerica.net/sites/newamerica.net/files/policydocs/Patent%20Assertion%20and%20Startup%20Innovation_updated.pdf (finding that 13% of bio/pharma or medical device venture capitalists in the sample reported receiving NPE demands against their portfolio companies). See also Jonathan Harris, Diane Ragosa, and Thara Russell, *When NPEs Target the Medical Device Industry*, Corporate Counsel (Feb. 4, 2014), <http://www.corpcounsel.com/id=1202641437461> (noting the growth of monetizer activity in the medical devices industry and their relatively high success rate against that industry).

Most important, as patent monetizers move towards purchasing portfolios from research universities, the risk to biotechnology and pharmaceutical companies that have existing products on the market increases exponentially. There is increasing pressure on universities to monetize their patents by transferring rights to assertion entities. In particular, the Association of University Technology Managers recently announced that it was re-examining its policies that had recommended against transferring rights to non-practicing entities.¹² Most important, some of the proposals would exempt universities and those working with universities from the reforms that are intended to curb abuses in patent monetization. It is critical for legislative drafters to understand the potential for problems within university portfolios in general and life science portfolios in particular. Without such recognition, patent monetization entities may be able to form joint ventures with universities or obtain sufficient exclusive licensing rights to university portfolios that would allow them to avoid any reforms enacted.¹³

Our goal in this article is to sound the alarm and to demonstrate the importance of taking action before the problem proliferates. In order to do this, we examined the patent portfolios of the 5 research universities that hold the largest number of patents. Following approaches taken by different types of monetizers in the technology field, we identified university patents that could be launched against types of products currently sold by biotechnology and pharmaceutical companies. This article describes a selection of those patents in order to demonstrate the risks that exist.

In deciding whether to undertake this analysis, we lost sleep over the question of whether the potential for harm from engaging in the analysis outweighed the potential benefit. As one of the authors has noted in the

¹² See Paul Baskin, *Under Financial Pressure, Universities Give Patent Buyers a Closer Look*, CHRONICLE OF HIGHER EDUCATION (Oct 25, 2013); see also Heidi Ledford, *Universities Struggle to Make Patents Pay*, NATURE (September 24, 2013) (documenting examples of federally funded university patents that have been transferred to patent monetization entities).

¹³ The Impact of Patent Assertion Entities on Innovation and the Economy Before the Subcomm. on Oversight & Investigations of the H. Comm. on Energy & Commerce, 113th Congress (2013), available at <http://energycommerce.house.gov/hearing/impact-patent-assertion-entities-innovation-and-economy> (statement of Robin Feldman, Director of Institute for Innovation Law at the University of California Hastings College of the Law, that leaving out universities and associated joint ventures could potentially create a loophole, if such provisions are not carefully framed to avoid gaming by NPEs, in response to inquiry by Congressman Ben Lujan); see also Saving High-Tech Innovators from Egregious Legal Disputes Act of 2013, H.R. 845, 113th Cong. (2013) (creating conditions to bring a patent infringement claim, among them that the party alleging infringement be: the original inventor, a university or technology transfer office, or have made substantial investment in the production or sale of an item covered by the patent).

past, if reform efforts are not undertaken, our work could do no more than provide a handy road map for those who would follow. Despite those concerns, however, we believe this is an important moment in the evolution of patent trolling. Technology trolling seeped in silently under the radar, growing to extraordinary dimensions before lawmakers had time to react. In contrast, life sciences trolling is predictable and in its infancy. If reforms are implemented before the problem proliferates throughout the industry, legislators and regulators have a chance to cabin the activity before it becomes deeply entrenched and before too much harm occurs.

PART I. WHAT IS PATENT TROLLING?

Patent assertion, and the strategic game-playing associated with it, is not new. Scholars have noted that the assertion of patents by those who do not use the patents themselves can be found scattered throughout the history of the US patent system.¹⁴ Similarly, agents who brokered sales of patents can be found as well, with such brokers earning the title of “patent sharks” in the 19th Century.¹⁵

In recent years, however, the market for patent trading and patent assertion has expanded dramatically, reaching an extraordinary scope and level of sophistication. Studies show that the percentage of patent litigation by those who do not make products has increased from roughly 25% in 2007 to almost 60% in 2012.¹⁶ In other words, as of 2012, the majority of litigation is filed by those whose core business involves asserting patents, rather than making products. This, of course, is only the tip of the iceberg.

¹⁴ Gerard N. Magliocca, *Blackberries and Barnyards: Patent Trolls and the Perils of Innovation*, 82 NOTRE DAME L. REV. 1809, 1809 (2007) (“[A]mong a host of dormant patents, some will be found which contain some new principle ... which the inventor, however, had failed to render of any use in his own invention. And some other inventor, ignorant that such a principle had been discovered ... had the genius to render it of great practical value ... when, lo! The patent-sharks among the legal profession, always on the watch for such cases, go to the first patentee and, for a song, procure an assignment of his useless patent, and at once proceed to levy black-mail upon the inventor of the valuable patent.”) (quoting Sen. Isaac Christiancy, 8 Cong. Reg. 307 (1878)).

¹⁵ See Naomi R. Lamoreaux, Kenneth L. Sokoloff, and Dhanoos Sutthiphisal, *Patent Alchemy: The Market for Technology in US History*, 87 BUS. HIST. REV. 3, 21 (2013) (documenting attorneys who served as patent brokers in the nineteenth century).

¹⁶ See Robin Feldman, Tom Ewing & Sara Jeruss, *The AIA 500 Expanded: Effects of Patent Monetization Entities* (forthcoming UCLA JOURNAL OF L. & TECH. 2014); see also Colleen V. Chien, *Patent Assertion Entities, Presentation to the DOJ/FTC hearing on PAEs*, SOCIAL SCIENCE RESEARCH NETWORK (December 10, 2012), http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2187314 (using data from RPX corporation and concluding that the percentage of litigation by non-practicing entities in 2012 has reached 62%).

Estimates suggest that 90% of patent demands never proceed to litigation, either because the target ignores the demand or because the target pays the demand to avoid the costs and risks of litigation, regardless of the merit of the claim.¹⁷

Complexity breeds opportunity, and the patent system is nothing if not complex. In fact, one of the authors has argued that patents themselves are best understood as an opportunity to bargain, rather than as a form of clear, definitive rights. It is tremendously difficult to know what the language of a patent covers, and it can cost as much as one to six million dollars to find out through a patent lawsuit.¹⁸ Moreover, if a product company challenges a patent and loses, in addition to the litigation costs, the company could be facing enormous damages, and even the possibility that its product could be shut down entirely. These are heady risks, and ones that rational companies might choose to avoid. The risks are not just the quantifiable costs of lawyers and experts. Recent academic work also documents the less tangible costs such as distraction to management, difficulty obtaining investors, and the need to retool the product.

Two other key issues in modern patent law have helped facilitate the rise of modern patent trolling. For some time, many of the most sophisticated players in the patent games, and many of those who owned large patent portfolios, were product companies. If a product company launched its patents against someone else, the target company would just launch its own set of patents in return, putting the original company's

¹⁷ According to figures in a 2013 White House report on patent assertion & U.S. innovation, conservative estimates place the number of patent demand threats in 2011 at a minimum of 60,000 and more likely at over 100,000. EXECUTIVE OFFICE OF THE PRESIDENT, PATENT ASSERTION & U.S. INNOVATION 6 (2013). Approximately 3,500 patent infringement lawsuits were filed in 2011. See Feldman, Ewing, Jeruss, *America Invents Act 500 Expanded: Effects of Patent Monetization Entities*, (forthcoming UCLA J.L. & TECH. 2014). Thus, just 3.50% to 5.83% of patent demands develop into patent litigation. See also Colleen V. Chien, *Patent Assertion Entities, Presentation to the Dec 10, 2012 DOJ/FTC Hearing on PAEs* at 23–27 (2012), SOCIAL SCIENCE RESEARCH NETWORK (December 10, 2012), http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2187314 (citing *In re Innovatio Ventures, LLC Patent Litigation*, 921 F. Supp. 2d 903, 907 (N.D. Ill. 2013) (noting that Innovatio had sent over 8,000 demand letters but brought only a few dozen suits)).

¹⁸ Tom Ewing, *Indirect Exploitation of Intellectual Property Rights by Corporations and Investors*, 4 HASTINGS SCI. & TECH. L.J. 1, 34, 63 (2012); Tom Ewing, *Practical Considerations in the Indirect Deployment of Intellectual Property Rights by Corporations and Investors*, 4 HASTINGS SCI. & TECH. L.J. 109, 119, 131

(2012); see also American Intellectual Property Association, 2011 Report of the Economic Survey (2011) (For a patent infringement claim that could be worth less than a \$1 million, median legal costs are \$650,000. When \$1 million to \$25 million is considered at risk, total litigation costs can hit \$2.5 million. For a claim over \$25 million, median legal costs are \$5 million.).

products at risk. Thus, a form of mutually assured destruction and common risk aversion acted as a natural break on patent demands. In the new market for patent monetization, monetizers do not make products and may be organized to hold few assets. Thus, they are free to initiate a patent attack, knowing that there is little to launch in return.

Modern patent assertion begins by exploiting the high costs and risks of patent litigation. Offer a settlement comfortably below the point of cost and risk, and a rational company may choose to settle. The techniques can be even more effective with a group of patents. Suppose I claim that your smartphone infringes my patent on gumballs. That may seem pretty far-fetched to you, and you may be unlikely to settle. Suppose, however, I threaten to throw a hundred patents at you as well. The simple process of determining whether any of the patents might have a valid claim against your product is costly, let alone the costs and risks of litigating the entire lot. Under these circumstances, a rational company might choose to settle, regardless of the merits of the claims. I think of these as peddler's bag monetizers.

In a variant on that theme, some monetizers try to assert their patents widely against large numbers of targets, asking for moderate settlement amounts, and hoping to reap a healthy profit in the aggregate. I think of this as an assault rifle approach, aiming rapid fire at a wide number of targets at the same time.

Some of the assault rifle trolls have begun to target the end users of products, rather than those who make products themselves. For example, coffee shops and hotels have received demand letters from monetizers, asking for payment for the fact their locations have wifi installed, which allegedly infringes a patent the monetizer holds related to wifi equipment. Similarly, small businesses have received demand letters asking for payment based on their use of office equipment such as scanning to a fax machine. Information and resource asymmetries make this type of monetization particularly troubling. Small mom-and-pop stores are unlikely to have the resources and experience with patenting to even be able to investigate the validity of the claim. While larger end users, such as hotels, may have more resources, they are likely to lack experience with the technology asserted in a way that would allow them to easily evaluate the merits.

Targeting really large end users can have the effect of vastly increasing a monetizer's returns, given the way that damages are calculated. For example, suppose I hold a patent that I want to assert against those who make software related to tracking bank customers. If I sue the software company, my damages may be calculated as a percentage of the software sales, for example, fifty million dollars. If I sue each of the banks'

customers, however, I may be able to get damages calculated on the base of sales for all of the combined business of the banks, which could be five hundred million. Although in theory, damages should be rationalized to the actual value contributed by the patent, in reality, damages can be based more loosely on the percentages of products and revenue.¹⁹ This multiplies the risk and the settlement value when dealing with large end users.

In contrast, some patent monetizers operate along the lines of what one scholar has described as “lottery ticket trolls.”²⁰ Less interested in large indiscriminate portfolios and quick settlements, they are interested in higher value patents that can bring larger settlements from blockbuster companies. This approach, as well as other modern monetization approaches, is aided by the proliferation of software and business method patents. Problems with this type of patent are discussed in detail in *Rethinking Patent Law*, but a brief explanation is the following. As computer related inventions proliferated in the 1970s and 1980s, inventors tried to find ways that the PTO and the courts would accept that these inventions were patentable. Early Supreme Court forays suggested that the key to patentability lay in avoiding anything that looked like math or formulas. Rather, one should describe the invention in simple industrial terms. Thus, we have settled into a system in which software and business method patents simply name in abstract terms what the invention does, without specifying how the inventor actually accomplished it.²¹ For example, the goal in *Diehr* was curing rubber;²² the goal in *Flook* was operating hydrocarbon machinery;²³ the goal in *LabCorp* was treating patients with vitamin B12 and folic-acid

¹⁹ See Christopher B. Seaman, *Reconsidering the Georgia-Pacific Standard for Reasonable Royalty Patent Damages*, 2010 B.Y.U. L. REV. 1661, 1702 (2010) (“The likely scenario in such a case is then this: A jury, when presented with portfolio licensing exemplars under which royalties may be as high as 5-8% of the licensee’s revenues, will combine these high rates with evidence showing total sales of a successful, complex product and reach a conclusion on damages that bears no reasonable relationship to the value of an individual patented component.”); see also *ClearValue, Inc. v. Pearl River Polymers, Inc.*, 735 F. Supp. 2d 560, 577 (E.D. Tex. 2010) *aff’d in part, rev’d in part*, 668 F.3d 1340 (Fed. Cir. 2012) (citing *SmithKline Diagnostics, Inc. v. Helena Labs. Corp.*, 926 F.2d 1161, 1167 (Fed. Cir. 1991) (“[T]he factual determination of a reasonable royalty . . . need not be supported, and indeed, frequently is not supported by the specific figures advanced by either party.”)).

²⁰ Mark A. Lemley & A. Douglas Melamed, *Missing the Forest for the Trolls*, 113 COLUM. L. REV. 1001, 1010 (2013).

²¹ See Robin Feldman, *RETHINKING PATENT LAW* 111–13, 130–35 (2012). Mark Lemley refers to this as “functional claiming.” Mark Lemley, *Software Patents and the Return of Functional Claiming* 7 (Stanford Pub. Law, Working Paper No. 2117302, 2012), available at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2117302.

²² *Diamond v. Diehr*, 450 U.S. 175, 188 (1981).

²³ *Parker v. Flook*, 437 U.S. 584, 586, (1978).

deficiencies.²⁴ Framing in that manner does not provide much in the way of a dividing line for separating what is patentable from what is unpatentable.²⁵

Patents such as these have an extraordinary reach into many types of inventions, particularly if they are drafted broadly. They can wreak havoc when later asserted in the market place after companies have already developed products.

Yet another version of patent monetization involves product companies themselves. As monetization has taken off, many product companies have begun spinning off non-core assets to monetizers, who then assert those patents against other product companies. The activity can be a rational form of asset management. However, it can also be a more troubling behavior known as privateering.²⁶ With privateering, a product company transfers assets to a monetizer in an attempt to raise its rivals' costs of operation, thereby damaging them as a competitor. In other words, as a product company, if I launch patents at my competitor, the competitor is likely to counter-sue, putting my own projects at risk. If I transfer the patents to a third-party monetizer with no products, keeping a license for myself, that monetizer can launch against my competitors, and I am safe. If the transfer agreement is structured so that I receive a return on the monetizer's assertion campaign, I can raise my rival's costs and directly profit from the activity, all from a safe distance.

Even more complex and sophisticated variations on these themes have emerged. For example, suppose a product company has a group of patents related to a particular technology. Rather than transferring the group of patents to one monetizer, the company divides the patents up among ten monetizers. I refer to this tactic as disaggregation. With disaggregation, the company can multiply the returns from the group of patents, as well as multiplying any damage to a competitor.

Many of these patents were never intended to directly earn a profit. The companies developed them as a method of protecting the operating space around their core technology. Now, however, those patents are being stripped off, repurposed and launched in ways that can multiply their damage in the marketplace.

This echoes the more general problem with modern monetization. The patent office has very little time to spend reviewing any individual

²⁴ *Metabolite Labs., Inc. v. Lab. Corp. of Am. Holdings*, 370 F.3d 1354, 1361 (Fed. Cir. 2004).

²⁵ See Robin Feldman, *RETHINKING PATENT LAW* 111–13, 130–35.

²⁶ Tom Ewing, *Indirect Exploitation of Intellectual Property Rights by Corporations and Investors*, 4 *HASTINGS SCI. & TECH. L.J.* 1 (2012).

patent.²⁷ Estimates suggest that the patent office may spend only 18 hours spread over a period of two years on a patent application.²⁸ Thus, individual patents, and individual claims within each patent, may be problematic.²⁹ For some time, this posed little difficulty. The vast majority of patents never earned any direct return, and society could take comfort in the fact that important patents would have their claims tested in court. Now that patents are being traded as commodities and grouped for new purposes, the sheer volume of active patents of uncertain value and scope is straining the patent system.³⁰

With any invention, the ability to scale and mass produce opens new possibilities for market expansion and proliferation. Patent monetization is no different. The sheer amount of patent demand activity is staggering, as is the variety of models and approaches. The impact on companies is dramatic as well. Although difficult to measure with any accuracy, scholars have estimated that patent demands are costing US companies over twenty billion dollars a year.³¹

In theory, a market for patent monetization could be a positive force. A market that matched inventors with those who could translate the inventions into a saleable product would provide a benefit for society consistent with goals of the patent system. The market for modern market for patent monetization, however, is not playing out in that manner. There are almost no new products emerging from this extraordinary amount of money changing hands. Rather, patent monetization seems to be operating primarily as a tax on current products. Worse yet, studies suggest that much of the money changing hands never makes it to inventors but is absorbed by the monetizers themselves.³² Thus, in economic terms, the patent monetization system is operating as a tremendously leaky bucket, one that appears to be harming consumers and innovation.

²⁷ Robin Feldman, *Intellectual Property Wrongs*, 18 *Stan. J.L. Bus. & Fin.* 250, 264 (2013).

²⁸ *Id.*

²⁹ *Id.* (“[W]ith the limited amount of time patent examiners have to spend on each application, the patent office is unlikely to catch all of the claims that reach too far.”).

³⁰ *Id.* at 265 (“The modern combination of Magnification and monetization is playing out in ways that are inconsistent with the goals of the patent system.”).

³¹ James Bessen, Jennifer Ford, & Michael J. Meurer, *The Private and Social Costs of Patent Trolls*, 34:4 *REGULATION* 26 (Winter 2011–2012).

³² James E. Bessen & Michael J. Meurer, *The Direct Costs from NPE Disputes*, 99 *CORNELL L. REV.* (forthcoming 2014), available at www.bu.edu/law/faculty/scholarship/workingpapers/2012.html; see also Joe Mullin, *Newegg on trial: Mystery company TQP rewrites the history of encryption* (Nov. 21 2013, 2:00 PM), <http://arstechnica.com/tech-policy/2013/11/newegg-on-trial-mystery-company-tqp-re-writes-the-history-of-encryption> (the monetizing entity TQP has earned \$45 million through patent licensing settlements while the original patentee has earned only \$585,000).

As concerns have escalated over the problem of patent trolling, everyone has scrambled to define terms. In this highly charged atmosphere, no one wants to be branded a bad guy, and if patent trolls are bad guys, everyone wants the definition to point somewhere else. And, indeed, numerous definitions—and variations on those definitions—have been offered to define the notion of patent trolling. Many use the term non-practicing entity, or NPE, in reference to entities that do not use the patents they own to create anything. In the code-like language of patents, using the ideas in the patent to create a product is called “practicing the patent,” and thus, those who do not create products are called “non-practicing.” Among many others, Congress has used the term NPE in directing the non-partisan General Accounting Office to study the topic.³³

Problems with the term include the question of whether to include universities in the definition. Universities are in the business of scientific research and education, and they generally do not engage in the production of products from their inventions.³⁴ Thus, they do not actually practice the ideas in their patent portfolios. In addition, a term that references only entities is also problematic. Some of the most famous modern examples of those who do not practice the ideas in their patents, but use the patents to demand license fees from others, are individuals.³⁵

One of us has argued elsewhere that the key definitional question is not the identity of the acting entity—corporation, individual, university, or

³³ See Pub.L. No. 112-29 § 34 (2011) (directing the nonpartisan General Accounting Office to study the consequences of litigation by non-practicing entities); see also 157 CONG. REC. S5441 (daily ed. September 8, 2011) (statement of Sen. Patrick Leahy) (discussing the General Accounting Office’s requirements under § 34 of the Leahy-Smith America Invents Act to study the “nature and impact of lawsuits brought by non-practicing entities”).

³⁴ *Madey v. Duke Univ.*, 307 F.3d 1351, 1362 (Fed. Cir. 2002) (University-sanctioned research projects “further the institution’s legitimate business objectives, including educating and enlightening students and faculty participating in these projects” as well as “increas[ing] the status of the institution and lur[ing] lucrative research grants, students and faculty.”). *But cf.* *id.* at n.7 (“Duke’s patent and licensing policy may support its primary function as an educational institution. . . . Duke, however, like other major research institutions of higher learning, is not shy in pursuing an aggressive patent licensing program from which it derives a not insubstantial revenue stream.”)

³⁵ See, e.g., Michael Risch, Patent Troll Myths, 42 Seton Hall L. Rev. 457, 470 (2012) (referencing Ronald A. Katz as a well-known and high-profile NPEs); David Segal, *Has Patent, Will Sue: An Alert to Corporate America*, NEW YORK TIMES (JULY 13, 2013) (profiling Erich Spangenberg), available at <http://www.nytimes.com/2013/07/14/business/has-patent-will-sue-an-alert-to-corporate-america.html>

otherwise—but the activity engaged in.³⁶ We define the relevant activity broadly, to include not only litigating patents but also engaging in patent-based demands, which is likely to have similar economic effects on industry, if not on the judicial system.³⁷ We also think that including only those who purchase and then assert patents narrows the relevant activity too far; practicing firms which generate patents not intended for commercialization may assert them themselves, spin off sub-entities to assert their patents, or license them for assertion.³⁸ Similarly, classical patent assertion entities could get into the business of filing patents not intended for commercialization to avoid any fixed definition relying on patent purchase.³⁹ However, these are complex issues, and need not be fully resolved here. To address the questions at hand broadly, we will use the term “monetizers” as one of us has previously proposed, which includes all entities and individuals “whose core business involves licensing and litigating patents, rather than making products.”⁴⁰

PART II. CONVENTIONAL WISDOM AND THE CURRENT LANDSCAPE

The variety and complexity of the players, and the range of behavior involved, in the market for patent monetization makes the issue difficult to tackle. Moreover, innovation is never an easy issue to predict or incentivize, and it remains the driving force of the US economy. The challenge is finding ways to deter abusive behavior without inadvertently harming innovation.

Despite the challenges, legislators and regulators at both the state and federal level are working on proposals to mitigate problems from patent monetization.⁴¹ The discussion has centered largely on issues related to technology, however, with biotech and pharmaceuticals on the sidelines.

This is not surprising. Conventional wisdom holds that patent monetization is a problem for high-technology, but not for biotechnology or

³⁶ Robin Feldman, *Patent Demands & Startup Companies: The View from the Venture Capital Community*, 11–19, available at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2346338 (2013).

³⁷ *Id.* at 12–13.

³⁸ *Id.* at 13–19.

³⁹ *Id.* at 16–17.

⁴⁰ *Id.* at 19.

⁴¹ *See, e.g.*, Saving High-Tech Innovators from Egregious Legal Disputes Act of 2013, H.R. 845, 113th Cong. (2013); End Anonymous Patents Act, H.R. 2024, 113th Cong. (2013); Patent Quality Improvement Act of 2013, S. 866, 113th Cong. (2013); Patent Abuse Reduction Act of 2013, S. 1013, 113th Cong. (2013); Patent Litigation and Innovation Act of 2013, H.R. 2639, 113th Cong. (2013); Stopping the Offensive Use of Patents Act, H.R. 2766, 113th Cong. (2013); Innovation Act, H.R. 3309, 113th Cong. (2013); Patent Litigation Integrity Act of 2013, S. 1612, 113th Cong. (2013).

pharmaceuticals, and that any solutions must be designed to avoid impacting bio and pharma. The section below describes the conventional thinking, and explores its weaknesses.

A. *Never the Twain Shall Meet*⁴²

A cost comparison between the bio/ pharmaceutical and high-tech industries reveals a stark contrast in both spending levels and business philosophy. Drug companies spend large sums on research and development, often facing daunting failure rates. In contrast, the technology industry seems to reward those companies that spend less on research and development, a trend that has encourage a proliferation of low-end software markets that lower the barrier to entry for smaller companies.

For example, pharmaceutical industry statistics suggest that the average cost of developing a successful new drug in 2007 fell between \$800 million and \$1 billion,⁴³ and the cost has risen to \$1.3 billion in 2012.⁴⁴ Outside studies using drug industry data suggest that the figure has grown even higher in 2013.⁴⁵ Although scholars have disputed the derivation of these figures,⁴⁶ it is clear that drug development is not for the faint of heart.

A significant factor in these skyrocketing costs is the impact of the

⁴² Rudyard Kipling, *The Ballad of East and West*, in *A VICTORIAN ANTHOLOGY*, 1837-1895 (Edmund Clarence Stedman, Ed.) (Riverside Press 1895)(containing the famous line, “Oh, East is East, and West is West, and never the twain shall meet”).

⁴³ PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA (PHRMA), *Drug Discovery and Development: Understanding the R&D Process*, INNOVATION.ORG 1b (numberless page immediately following 1) (Feb. 2007), http://www.innovation.org/drug_discovery/objects/pdf/RD_Brochure.pdf. See also PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA, *About Us*, INNOVATION.ORG (last visited Oct. 9, 2013) (explaining that Innovation.org is a “project of the Pharmaceutical Research and Manufacturers of America”), http://www.innovation.org/index.cfm/About/About_Us.

⁴⁴ See, e.g., Amy O’Connor, *Football - By the Numbers*, LILLYPAD: THE PLACE FOR PERSPECTIVES ON POLICY AND HEALTH CARE INNOVATION (Feb. 3, 2012), <http://lillypad.lilly.com/entry.php?id=1583> (Blog entry for Eli Lilly stating that the cost of developing a new drug had risen to \$1.3 billion, and making various football-related comparisons regarding what that amount could buy, such as the number of Superbowl ads).

⁴⁵ Matthew Herper, *The Cost Of Creating A New Drug Now \$5 Billion, Pushing Big Pharma To Change*, FORBES: PHARMA & HEALTHCARE (Aug. 11, 2013), <http://www.forbes.com/sites/matthewherper/2013/08/11/how-the-staggering-cost-of-inventing-new-drugs-is-shaping-the-future-of-medicine/>.

⁴⁶ Donald W Light & Rebecca Warburton, *Demythologizing the high costs of pharmaceutical research*, 6 *BIOsocieties* 34 (2011) (criticizing the study underlying these figures for excluding tax credits for research and development and including cost of capital, that is, the amount companies could have made by investing the money, rather than spending it on R&D).

expenses that follow the development of a drug once it has been discovered. For example, clinical trials for high-profile drugs can cost as much as \$100 million alone.⁴⁷ Indeed, for some drugs the “combined cost of manufacturing and clinical testing [alone] . . . has added up to \$1 billion.” Further adding to R&D expenses is the fact that certain costs continue to add up even after a drug hits the market.⁴⁸ For example, companies customarily monitor reports of a successful drug’s side effects to ensure safety, an endeavor that requires massive amounts of manpower and organization.⁴⁹ Johnson & Johnson’s safety infrastructure alone employs nearly 1,000 people, an infrastructure that the company’s Co-Chairman of Pharmaceuticals Paul Stoffels has noted is enough people to form an entire biotech company.⁵⁰

Drug companies also cite the unavoidably high failure rate of drug research as a key factor in the high Research & Development costs. According to a recent industry publication, “[f]or every 5,000-10,000 compounds that enter the research and development . . . pipeline, ultimately only one receives approval.”⁵¹ An August 2013 Forbes study concluded that 19 out of every 20 drugs being developed ultimately fails, a 95 percent failure rate.⁵² All of these factors combine to make drug development an expensive and risky endeavor.

To compare costs between the biotech/pharmaceutical industry and the technology industry – particularly its most successful players – is to compare two fundamentally different strategies on R&D spending. Success in the technology industry has come to those who target their R&D sparingly toward the creation of new markets.

Indeed, most studies of the technology industry have shown that technology companies cannot spend their way toward success. For example, in 2011, software giant Microsoft pumped more than any other company in the technology industry into R&D, at \$9.0 billion (just behind Pfizer, holding steady at \$9.1 billion) or 12.9 percent of its sales.⁵³ The results of these expenditures, however, were primarily evolutionary upgrades to its existing Windows operating system and Office software, updates that were seen as largely incremental.⁵⁴ During this period, the

⁴⁷ *Id.*

⁴⁸ *Id.*

⁴⁹ *Id.*

⁵⁰ Herper, *supra* note 45.

⁵¹ *Drug Discovery and Development*, *supra* note 43.

⁵² Herper, *supra* note 45.

⁵³ Max Nisen, *The 20 Biggest Corporate R&D Spenders In The World*, BUSINESS INSIDER (Oct 31, 2012), <http://www.businessinsider.com/biggest-research-and-development-spender-2012-10>.

⁵⁴ Adam Hartung, *Top 20 R&D Spenders - Not Good Investments*, FORBES (Nov. 5,

company's attempts to reestablish its former dominance in mobile phones have been largely unsuccessful, and outgoing CEO Steve Ballmer has admitted that his company now has "almost no share" in that market.⁵⁵

The opposite has been true for Microsoft's rival, Apple. With a net income of \$41.7 billion in 2012, Apple remains not only the most profitable technology company in the U.S. but also the second-most profitable company in the world, behind Exxon.⁵⁶ Despite its dramatic success, Apple spends significantly less on R&D than its competitors. In 2012, Apple spent \$3.4 billion on R&D, only 2 percent of its sales – a percentage that remained the same as in 2011.⁵⁷ Indeed, the company has stated that this level of targeted spending is a key element of its business strategy: "[Apple] continues to believe that focused investments in R&D are critical to its future growth and competitive position in the marketplace."⁵⁸

Apple's success in the iPhone and iPad products, and its policies regarding compatible products, has helped spark a revolution in the software industry. Indeed, the application economy that has arisen as a result of consumers' demand for mobile applications has facilitated the development of the lower end of the software industry. Barriers to entry are low enough that it is easier and cheaper than ever for small companies to enter the market and create apps without substantial investment. In a recent report, the Government Accountability Office offered a passing anecdote that exemplifies this newfound ease of market entry and development: "[R]epresentatives from one small software company we spoke with said that they could develop a product in a little as 2 months with only a few programmers."⁵⁹

Within platform ecosystems like Apple's, established technology

2012), <http://www.forbes.com/sites/adamhartung/2012/11/05/top-20-rd-spenders-not-good-investments/>.

⁵⁵ Tom Warren, *Ballmer sees Microsoft's 'almost no share' in mobile as an opportunity, regrets mistakes*, THE VERGE (Sep. 19, 2013), <http://www.theverge.com/2013/9/19/4750086/ballmer-almost-no-mobile-share-microsoft-opportunity>.

⁵⁶ BLOOMBERG, *Most Profitable in Technology in U.S.: Companies*, <http://www.bloomberg.com/visual-data/best-and-worst/most-profitable-in-technology-in-u-dot-s-companies> (last visited Oct. 9, 2013); BLOOMBERG, *Top 20 by Profits Worldwide: Companies*, <http://www.bloomberg.com/visual-data/best-and-worst/top-20-by-profits-worldwide-companies> (last visited Oct. 9, 2013).

⁵⁷ Josh Lowensohn, *Apple R&D spending up nearly 40 percent in 2012*, CNET (Oct. 31, 2012), http://news.cnet.com/8301-13579_3-57543370-37/apple-r-d-spending-up-nearly-40-percent-in-2012/.

⁵⁸ Apple Inc., Annual Report (Form 10-K) 36 (Oct. 31, 2012).

⁵⁹ UNITED STATES GOVERNMENT ACCOUNTABILITY OFFICE, INTELLECTUAL PROPERTY: ASSESSING FACTORS THAT AFFECT PATENT INFRINGEMENT LITIGATION COULD HELP IMPROVE PATENT QUALITY, GAO-13-465, at 35 (2013).

companies actively encourage other companies to create products that build upon their own innovations, an inherently interdependent business model that makes it a lot easier to enter the industry. For example, the company makes it easier for software developers to create iPhone applications by giving them free access to the iPhone's underlying technology through its developer tools.⁶⁰ This makes it much simpler for a developer to implement certain basic features found in all mobile apps that most users take for granted, such as the ability to have animated buttons that react to the user's touch.⁶¹ A startup company looking to create the next great iPhone application does not have to expend nearly as much time or energy creating the underlying technologies needed for their app to function properly as they would otherwise have to. Smaller developers that would not otherwise have the resources to enter the software development market can now do so.

Platform-steward companies such as Apple also provide the underlying infrastructure for delivering applications and transacting payments for those applications on their respective app stores.⁶² Thus, smaller developers, since they can offer their products to consumers through a sales portal built into each device – a feature that makes the devices themselves more compelling as well.

Overall, the rise of the application economy and the degree to which it has facilitated the proliferation of small software businesses is indicative of a broader trend in the technology industry toward lower costs and easy access. This stands in sharp contrast to R&D-heavy industries like pharmaceuticals, in which smaller companies cannot easily enter the market because each player must shoulder heavy development costs. In other words, you cannot do biotech in your garage, but you can certainly write a software application—or even found a computer company.⁶³

The costs of entry and the structure of the industry affect conventional wisdom about the industry's relative safety from patent trolling. The long lead time and extensive financial investment necessary for a bio/pharmaceutical product creates the sense that all relevant patents

⁶⁰ See APPLE INC., *About Xcode*, https://developer.apple.com/library/ios/documentation/ToolsLanguages/Conceptual/Xcode_Overview/About_Xcode/about.html (last visited Oct. 9, 2013).

⁶¹ See APPLE INC., *About the iOS Frameworks*, <https://developer.apple.com/library/ios/documentation/Miscellaneous/Conceptual/iPhoneOSTechOverview/Introduction/Introduction.html> (last visited Oct. 10, 2013).

⁶² Press Release, Apple Inc., *Apple Announces iPhone 2.0 Software Beta* (Mar. 6, 2008) (available at <http://www.apple.com/pr/library/2008/03/06Apple-Announces-iPhone-2-0-Software-Beta.html>) (“Apple will cover all credit card, web hosting, infrastructure and DRM costs associated with offering applications on the App Store.”).

⁶³ Daniel Terdiman, *Road Trip kickoff: The garage where the HP legend began*, CNET (June 19, 2009, 11:55 AM), http://news.cnet.com/8301-13772_3-10268615-52.html.

will have emerged. As one commentator noted, “Before biotech companies decide to go into the market, they might be more cognizant or concerned about whether they have time to operate, because they’re going to invest a lot of time and money to get there. . . . biotech takes so long to get into any commercial embodiment that people know about the patent to begin with.”⁶⁴

Similarly, the difficulty of entering the bio/pharmaceutical product market suggests that there will be fewer patents floating around that monetizers can acquire and fewer targets for them to go after. “It’s a different life cycle between the patents and technology development. It reduces the number of targets for infringement because [the commercialization pathway] reduces the number of people who are going to get on the market.”⁶⁵ With fewer possible patents and fewer targets, trolling in the bio/pharmaceutical industry could be less lucrative on the whole.

The numbers limitation also applies to the products themselves. Technology products tend to have multiple components. This makes it more likely that a patent monetizer can find a patent that relates to some part of the product somehow. The method by which courts assess patent infringement damages also makes multiple component products a more appealing target. Under some damages approaches, a small component can command a large share of the revenue, leading to greater leveraging power when demanding a license.⁶⁶ As one scholar noted, monetizers are less troublesome in the pharmaceutical sector because pharmaceutical products have one patent for one arduously researched chemical.⁶⁷

The type of patents in the biotechnology and pharmaceutical industries also reduce the appeal of monetization in comparison to patents in high technology. Technology patents tend to be broader, particularly in the software arena. As described above, in an attempt to avoid being labeled as an unpatentable mathematical formula, software patents are drafted in prose language that describes what the software does, rather than how the inventor accomplished it.⁶⁸ This leads to the happy coincidence of broad patents with unclear boundaries and a remarkably wide potential reach. In

⁶⁴ See Alex Philippidis, *New Gene Patent Suit Sparks Talk of Trolls*, GENENGENEWS.COM, <http://www.genengnews.com/insight-and-intelligenceand153/new-gene-patent-suit-sparks-talk-of-trolls/77899863>.

⁶⁵ See *id.*

⁶⁶ See ROBIN FELDMAN, *RETHINKING PATENT LAW* 49 (Harvard 2012) (describing problems in modern patent damage calculations).

⁶⁷ See Stu Hutson, *Pharma ‘patent trolls’ remain mostly the stuff of myth*, 15 NATURE MEDICINE 1240 (2009), available at <http://www.readcube.com/articles/10.1038/nm1109-1240a>.

⁶⁸ For a history of how modern software patenting has developed and a description of the resulting problems, see FELDMAN, *supra* note 66, at 104–24.

contrast, patents in the biotechnology and pharmaceutical space are more limited, hewing somewhat better to the more traditional restriction that a patent should describe not just the idea but how to implement the idea. Once again, broad patents have a wider reach and provide better weapons to launch in a monetization campaign—which suggests that monetizers will choose to populate the technology industry, rather than biotechnology and pharmaceuticals.

Finally, biotechnology and pharmaceutical companies have been less concerned about patent trolling because it they have yet to experience it—at least not to the extent of the technology industry. Early studies suggested that patent trolling activity was largely concentrated in the technology sector, rather than biotechnology and pharmaceuticals.⁶⁹ The relative lack of patent trolling activity in the biotechnology and pharmaceutical sectors leads to the sense that, “if it is not on my doorstep, I have nothing to fear.”

B. Fallacies in the Conventional Wisdom

There is much truth to the conventional wisdom. Biotechnology and pharmaceutical research does involve a greater investment of time, money and expertise. This results in fewer patents, fewer targets, and a longer lead time for problems to emerge. In addition, developments in product type and patent rules affect the opportunities for patent demands. Biotech and pharmaceutical products tend to have fewer components, and patents in the field tend to be less broad than the software and business method patents that proliferate in the technology industry.

However, the conventional wisdom suffers from three weaknesses. First, it ignores the role that regulation plays in making some pharmaceutical patents harder to invent around, thus raising the potential hold-up costs of what patents are available to monetize. Second, it assumes a classical model of patent bargaining, rather than the strategic bargaining and suit filing adopted by modern monetizers. Third, it assumes that monetizers will confine themselves to a relatively narrow set of technological targets; while high-tech may be low-hanging fruit, the proliferation and increasing sophistication of monetizers means that other industries are likely to be targeted in the near future.

⁶⁹ Colleen Chien, Patent Assertion and Startup Innovation, NEW AMERICA FOUNDATION (September 15, 2013), http://newamerica.net/sites/newamerica.net/files/policydocs/Patent%20Assertion%20and%20Startup%20Innovation_updated.pdf (finding that 88% of the technology venture capitalists surveyed (N=66) had experienced demands from non-practicing entities, as compared to 13% of bio/pharma or medical device venture capitalists surveyed (N=23)).

1. Regulatory barriers to inventing around in biopharmaceuticals⁷⁰

Conventional wisdom ignores the ways that regulatory barriers make patent holdup particularly costly in biopharmaceuticals by increasing the cost of “inventing around.” The idea of inventing around is simple: if someone holds a patent on one aspect of a product, someone wishing to make that product must either a) license the patent or b) change the product or production method to avoid using the patented technology. The second path is the process of “inventing around.”⁷¹

In the context of patent litigation or negotiations, the costs of inventing around the patent are a crucial factor. Setting aside damages and litigation costs—which may be significant—the hold-up value of a potential injunction depends on the difficulty of inventing around. The manufacturer has an expectation of profits based on the status quo; a monetizer (or a competitor) who can assert a blocking patent should be able to extract no more than the value of keeping the status quo over shifting to another aspect of production—that is, inventing around the blocked technology and implementing that invention. If the costs of inventing around are very low (for example, switching one off-the-shelf for another off-the-shelf part), the value of avoiding the injunction may be very low. If the costs are very high (for example, if the technology covers a key technology to the product), the value of avoiding the injunction is correspondingly high. For example, RIM was willing to settle for \$612.5 million when the alternative was an injunction preventing it from using the central technology in its BlackBerry communications devices.⁷²

⁷⁰ See generally Janet Freilich, *Patent Infringement in the Context of Follow-On Biologics*, 16 STAN. TECH. L. REV. 9, 13–20 (2012); Jonathan Stroud, *The Illusion of Interchangeability: The Benefits and Dangers of Guidance-Plus Rulemaking in the FDA's Biosimilar Approval Process*, 63 ADMIN. L. REV. 599, 624 (2011) (“[T]he burden of evidence for generic biologics applicants could be far higher than it is for generic drugs . . .”); Islah Ahmed et al., *Follow-On Biologics: Impact of Biologic Product Life Cycle and European Experience on the Regulatory Trajectory in the United States*, 34 CLINICAL THERAPEUTICS 400, 400–19 (2012) (“In theory you can develop technology sensitive enough to establish clinically relevant thresholds of heterogeneity such that Hatch-Waxman type structure could be applied. In practice, this is extremely challenging because it is difficult to establish a correlation between biophysical differences and clinical effects.”).

⁷¹ See generally *Texas Instruments, Inc. v. U.S. Int'l Trade Comm'n*, 805 F.2d 1558, 1572 (Fed. Cir. 1986) (“[T]he incentive to innovation that flows from ‘inventing around’ an adversely held patent must be preserved.”); *London v. Carson Pirie Scott & Co.*, 946 F.2d 1534, 1538 (Fed. Cir. 1991) (“Although designing or inventing around patents to make new inventions is encouraged, piracy is not. Thus, where an infringer, instead of inventing around a patent by making a substantial change, merely makes an insubstantial change, essentially misappropriating or even ‘stealing’ the patented invention, infringement may lie under the doctrine of equivalents.”).

⁷² See Rob Kelley, *BlackBerry maker, NTP ink \$612 million settlement*, CNN Money

The FDA's regulatory apparatus strengthens many patents in the biopharmaceutical industry by adding regulatory barriers to the technological and marketing costs of inventing around a blocked technology.⁷³ In the strongest case, it is essentially impossible to invent around a composition-of-matter patent covering the active pharmaceutical ingredient of a drug, because changing the active pharmaceutical ingredient of a drug necessarily changes the drug itself and generally requires an entirely new FDA approval process, including new clinical trials.⁷⁴ Such a patent would therefore provide a very strong blocking patent. Accordingly, a patent monetizer holding a previously unknown but valid patent covering a drug's active pharmaceutical ingredient could potentially extract a large portion of the value of the drug.

FDA approval processes provide similar—though less drastic—regulatory barriers to inventing around patents on methods of manufacturing drugs,⁷⁵ particular dosage forms, or methods of treatment. Firms can still potentially invent around such patents, but the costs of doing so are significantly increased by regulatory costs associated with such changes.

2. The assumption of classical patent bargaining and suits

The conventional wisdom is also premised on a model of patent bargaining in which the value and relevance of each patent in relation to a potential infringing product is carefully weighed, the spurious demands drop out, and the more meritorious claims advance to a court for determination. It is a world in which the relevant players are evident, and a certain level of discipline is imposed by the fear that one's target could launch its own patent stockpile back at you, threatening your own products.

(March 3, 2006, 7:29 PM), http://money.cnn.com/2006/03/03/technology/rimm_ntp/

⁷³ See, e.g., Benjamin N. Roin, *Unpatentable Drugs and the Standards of Patentability*, 87 Texas L. Rev. 503, 570 n.243 (2009) (“If a drug only has one active ingredient and that ingredient is patented, then the patent will be difficult for generics to design around even if it is narrow since any change the generic firms make to the active ingredient would likely trigger the FDA's clinical-trial requirements.”).

⁷⁴ *Id.* Some very small particular changes might not require a completely new regulatory package. For instance, if a very narrow patent were asserted against a brand-name drug, the brand-name company could potentially make small alterations sufficient to avoid infringing the patent and then apply for approval using an Abbreviated New Drug Application as a generic version of the brand-name drug. But even in this case, production or sale of the original drug would still be blocked by the patent; the replacement process would merely be somewhat easier.

⁷⁵ See W. Nicholson Price II, *Making Do in Making Drugs: Innovation Policy and Pharmaceutical Manufacturing*, B.C. L. Rev. (forthcoming 2014), available at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2311682, 25–31.

Modern patent monetization is an entirely different ballgame. Much of monetization operates effectively from leverage available through the costs and risks of patent litigation. In some cases, that leverage is achieved by the simple costs of challenging the license. With patent cases costing \$1 million to \$6 million dollars,⁷⁶ it may be cheaper for a company to settle against a determined monetizer. That leverage is magnified when patents are grouped together. A company that is tempted to fight off one patent may not have the stomach, or the litigation budget, to fight off 150 patents. In larger groupings, the validity of each individual patent become less important, and effective strategies can include a group of questionable patents—or patents that may not truly apply in this case—with one or two higher value patents thrown in.

Multiplicity has another benefit for increasing leverage. Under current rules and practices, patent holders do not need to articulate the basis for their assertion that a target is infringing their patent. They do not need to even identify which claim in the patent is being infringed, in their view, or which aspect of product infringes.⁷⁷ As a result, the burden of investigating a patent demand falls entirely on the company receiving the demand, while the monetizer can spend very little. When a company is faced with a claim that they are infringing 50 patents from a monetizer with a reputation for tough tactics and determination, a rational company may choose to settle, rather than engage in the considerable expense of even studying those patents in the first place.

The same lack of specificity exists for patent lawsuits, as well as patent demands. In most federal cases, heightened pleading standards now require a certain level of specificity when filing a complaint. These standards were imposed by two Supreme Court cases, *Twombly* and *Iqbal*, which are sometime colloquially referred to as “*Twiqbal*.”⁷⁸ Federal Circuit

⁷⁶ Tom Ewing, *Indirect Exploitation of Intellectual Property Rights by Corporations and Investors*, *supra* note 19 at 63; Tom Ewing, *Practical Considerations in the Indirect Deployment of Intellectual Property Rights by Corporations and Investors*, *supra* note 119, 131; *see also* American Intellectual Property Association, 2011 Report of the Economic Survey (2011) (For a patent infringement claim that could be worth less than a \$1 million, median legal costs are \$650,000. When \$1 million to \$25 million is considered at risk, total litigation costs can hit \$2.5 million. For a claim over \$25 million, median legal costs are \$5 million.).

⁷⁷ *See* Dennis Crouch, Patent Reform 2013: Demand Letter Transparency Act of 2013, PatentlyO (Nov. 20, 2013), <http://www.patentlyo.com/patent/2013/11/patent-reform-2013-demand-letter-transparency-act-of-2013.html>; Demand Letter Transparency Act of 2013, H.R. 3540, 113th Cong. (2013) (requiring, inter alia, that patent infringement demand letters identify each patent and each claim asserted, each allegedly infringing instrumentality by name and model number, and whether each instrumentality infringes literally or under the doctrine of equivalents).

⁷⁸ *See* Dennis Crouch, Pleading Requirements: Patent Reform through the Supreme

case law, however, has ruled that these cases and their heightened pleading standards do not apply to patent lawsuits, which can be filed according to bare bones pleading forms established in 1934. Thus, patent holders can proceed to discovery with very little on the table.

Not all monetizers are interested in the leverage of multiplicity. One scholar refers to “lottery-ticket trolls,” who are looking for one patent that can strike fear into the hearts of an entire industry.⁷⁹ Even in those cases, however, leverage plays an important role. Given difficulties in the doctrines related to calculating patent damages, a patent that makes a small contribution to the overall product can yield a payoff well beyond its proportionate value to the eventual product.⁸⁰

In addition to damages, injunctions are still a real threat. A company could find itself completely enjoined from making or selling its product, a potential disaster if the product at issue holds the company’s profitability. At one point, injunctions were routinely granted under Federal Circuit precedent upon any successful infringement claim. The Supreme Court changed this practice in the case of *eBay v. Mercexchange*, ruling that courts in patent cases must apply the same 4-part test as in other injunction cases.⁸¹ Although the percentage of injunctions granted since *eBay* has declined, injunction is still a threat in the Federal Courts. In addition, the ITC has declined to apply the *eBay* principles to its cases.⁸² The threat of

Court and Judicial Conference, Patently-O (Feb. 11, 2014) (contrasting pleading standards for patent lawsuits with standards for other federal cases and using the term, “Twiqbal”), <http://patentlyo.com/patent/2014/02/heightened-requirements-conference.html>

⁷⁹ Mark A. Lemley & A. Douglas Melamed, *Missing the Forest for the Trolls*, 113 COLUM. L. REV. 2117, 2126 (2013).

⁸⁰ See FELDMAN, *supra* note 76, at 84-86 (describing problems in patent damages calculations). (“In particular, the details of determining the proper royalty rate and base of sales provide little assurance of an accurate outcome . . . One practitioner describes the Georgia Pacific test as more often involving the talents of a conjurer than those of a judge. This hypothetical, or some would say mythical, bargaining is intended to lead to a reasonable approximation of the damages from infringement. Nevertheless, scholars and commentators have complained that it all too often leads to ridiculous results.); Mark A. Lemley & A. Douglas Melamed, *supra* note 92, 2143 (“[F]or both legal and practical reasons damages in patent infringement suits . . . are not only somewhat unpredictable but, as a general matter, excessive.”).

⁸¹ See *eBay v. Mercexchange*, 547 U.S. 388, 391 (2006) (detailing the four-part test as requiring a plaintiff to demonstrate, “(1) that it has suffered an irreparable injury; (2) that remedies available at law are inadequate to compensate for that injury; (3) that considering the balance of hardships between the plaintiff and defendant, a remedy in equity is warranted; and (4) that the public interest would not be disserved by a permanent injunction”).

⁸² *Spansion, Inc. v. Int’l Trade Comm’n*, 629 F.3d 1331, 1359 (Fed. Cir. 2010) (“[T]his court holds that *eBay* does not apply to Commission remedy determinations under Section 337.”).

out-sized damages and a downright shutdown of the product creates enough leverage that companies may choose to settle, irrespective of the merits of the claim. Again, a determined monetizer with a strong reputation can create the leverage to make companies settle.

The point is simply the following: the success of the modern monetization business method is not necessarily based on the value of the patent. That success is, in many ways, attributable to the leverage derived from the costs and risks of litigation. Biotechnology and pharmaceutical companies are not immune to the power of that leverage. In fact, those fields have additional leverage points. A company that is on the cusp of FDA approval for a drug—following a decade of developing the product and engaging in medical trials—may be particularly vulnerable to threats of patent litigation.

3. The assumption of tightly clustered targets for monetizers

The conventional wisdom suffers from a third weakness as well. It is based on the premise that patent trolls will only go after the best and most lucrative market. It is certainly true that technology provides better trolling grounds than biotechnology and pharmaceuticals. Smartphones, which may involve tens of thousands of patents, provide a much better target than a drug, whose key patent involves a single chemical composition. Even the classic unitary patent setting, however, will involve peripheral patents. The processes of experimentation, production, and distribution involve the use of numerous technologies, all of which could be vulnerable to patent claims. Again, imagining that one's product is safe because the core product is a chemical compound, ignores the potential for peripheral risk.

Most important, the allure of patent monetization is drawing an increasing number of players onto the field, and generating an increasingly complex array of business models. The field is more crowded and traditional troll "customers," such as the technology companies who buy licenses from them, may reach the saturation point. In this context, markets that are merely good rather than spectacular, become appealing. Even if the market were not expanding, one could not rest assured that being a second best target means one is safe. One may simply be farther down on the list of potential customers.

Finally, the wolf appears to be at the doorstep—or at least the troll does. Although the modern version of monetization may have started largely in the technology sector, it has expanding to other sectors such as retail, and there are signs that monetization is headed for biotechnology and pharmaceuticals. For example, press reports note that one of the largest aggregators holds patents for purifying nucleic acids in its portfolio, and

IPNav, a notorious patent monetization entity founded by Erich Spangenberg, describes its platform as “equally effective for patents in all scientific and technology fields.”⁸³ Pharmaceutical company counsel are facing internal pressure to monetize IP assets which are not being used in marketed products.⁸⁴ In addition, as noted above, patent brokers are beginning to hear from major pharmaceutical companies interested in shopping their noncore patents to monetizers, and studies of patent demands against startup companies show monetizers moving into the life science space.⁸⁵ Most important, there are increasing signs that universities are transferring rights to monetizers.⁸⁶

It is universities, of course, that are the focus of the study we have undertaken. Part of the narrative that biotechnology and pharmaceuticals are safe from patent trolling involves the relative lack of appropriate inventory. We should note, of course, that there are plenty of biotechnology and pharmaceutical patents outstanding. Nevertheless, while software patents may be easy to develop, a patent relevant to the biotechnology and pharmaceutical industry will be tougher to develop.

We wondered, however, how university patents could potentially affect this calculus. This vast storehouse of patents sits largely unused in the form of extensive portfolios that are rarely licensed or commercialized in any form. In fact, reports suggest that only 5% of the vast patent holdings of universities are subject to licensing.⁸⁷ More recently, the Association of University Technology Managers is reexamining a 2007 pledge not to sell to monetizers, driven by financial considerations.⁸⁸ Our suspicion was that these university holdings would provide a fertile hunting ground for monetizers.

⁸³ See Alex Philippidis, *New Gene Patent Suit Sparks Talk of Trolls*, GENENGENEWS.COM, <http://www.genengnews.com/insight-and-intelligenceand153/new-gene-patent-suit-sparks-talk-of-trolls/77899863>.

⁸⁴ See Shuchman, *supra* note 10.

⁸⁵ See *supra* notes 11–11. With respect to the closely related medical devices industry, a publication directed to life sciences corporate counsel recently noted that “NPEs now seem to be setting their sights on the medical device industry. . . . Further, relatively large NPEs are aggregating medical device patents at a rapid clip.” Harris, Ragosa, and Russell, *supra* note 11. Such litigation has had higher success than against other industries, with median damages of \$20 million. *Id.*

⁸⁶ Heidi Ledford, *Universities Struggle to Make Patents Pay*, 501 NATURE 471 (2013).

⁸⁷ Heidi Ledford, *Universities Struggle to Make Patents Pay*, *supra* note 86 at 472 (2013).

⁸⁸ Paul Basken, *Under Financial Pressure, Universities Give Patent Buyers a Closer Look*, CHRON. HIGHER ED. (Oct. 25, 2013), <http://chronicle.com/article/Under-Financial-Pressure/142613>.

PART III. A BRIEF SURVEY OF UNIVERSITY PATENT HOLDINGS

As a proof of concept, we sought to identify a subset of university-held patents potentially attractive to monetizers.⁸⁹ This examination was not intended to be comprehensive; instead, we sought to see what would emerge from a relatively quick skim through university patent holdings performed by individuals with moderate knowledge but little experience and no sophisticated analytical tools. If, as we suspected, patents of potential interest to monetizers targeting the biopharmaceutical industry were relatively common, we would expect them to appear during our search.⁹⁰ Our suspicions were borne out—we found many patents that could potentially provide the basis for a suit by monetizers against the biopharmaceutical industry, or at least bargaining leverage.

A. Approach and methods

We skimmed the patent holdings for four of the of five university systems with the highest number of patents issued in fiscal year 2011: the University of California system, the University of Texas system, MIT, and CalTech.⁹¹ We added as a wild-card the University of South Florida, the school among the top 10 in 2011 patent grants which had the lowest ratio of license revenues to research expenditures. We searched for patents assigned to those universities.

It is important to emphasize the deliberate limitations of this search. The search was performed by one author and one research assistant, each with a significant scientific background but no extensive experience in intellectual property litigation or patent prosecution. We spent under 30 total hours identifying potential target patents, briefly skimming the patent claims, and occasionally looking to other readily available Internet sources to see whether the patent might be of use to a monetizer. Rather than attempting to devise sophisticated methodologies based on the search

⁸⁹ A large-scale empirical analysis of university-held patents potentially of interest to monetizer's might provide useful results. However, such a study is far outside the parameters of this project.

⁹⁰ Note that this search could provide support for our hypothesis only asymmetrically; the absence of monetizer-worthy patents in our relatively unsophisticated search would not provide proof that such patents do not exist.

⁹¹ *Sortable Table: Universities With the Most Licensing Revenue, FY 2011*, THE CHRONICLE OF HIGHER EDUCATION (Aug. 30, 2012), <http://chronicle.com/article/Sortable-Table-Universities/133964>. The University of Wisconsin/Wisconsin Alumni Research Fund (WARF) was also among the top 4 research institutions by number 2011 patents granted, but we excluded it as a target because WARF behaves differently from a typical university research system and has a long history of actively seeking to commercialize university research. *Id.*

strategies of extant monetizers,⁹² we simply looked for patents assigned to the selected universities in what seemed to be relevant subject classes, such as drugs, chemical reactions, and methods of manufacture, and selected those patents whose titles seemed promising.⁹³ We also deliberately did not try to identify available patents which clearly covered a current commercial product, as this fell too close to our concern of providing a precise roadmap for monetizers.⁹⁴

We also spent approximately 8 hours trying a sample more targeted search. One broad form of patent covers chemical classes by claiming them using “Markush” claim language,⁹⁵ which typically include chemical compositions with a base structure and one or more variable elements, to be filled from a list of possibilities included in the claim language. We searched for Markush claims assigned to the universities listed above.⁹⁶ Many had already been noted in the broad initial skim, but some additional composition-directed patents appeared which had been missed earlier. This quick but targeted search yielded an additional 22 targets.

The patents identified in this fashion were then read to determine whether they could plausibly be used as the basis for suit or negotiation by a biopharmaceutical-targeting monetizer. Because the vast majority of suits

⁹² See also IPNav, *Best Practices in Patent Monetization* 2-3 (June 2012), <http://www.ipnav.com/linkservid/6BB9DE27-5056-9000-03661B5708AD47ED/> (last visited November 23, 2013) (discussing the criteria used by one patent monetization firm in selecting patents to monetize, those criteria including a patent’s value, whether the patent is being infringed, the strength of the patent, and whether the patent covers core or non-core technology); cf. John R. Allison, Mark A. Lemley & Joshua Walker, *Extreme Value or Trolls on Top? The Characteristics of the Most-Litigated Patents*, 158 U. Pa. L. Rev. 1, 28-29 (2009) (“[T]he most-litigated patents have different, clearly identifiable characteristics,” including, “more claims, more prior art citations, more forward citations, a higher likelihood of assignment between issue and litigation, and larger numbers of continuation applications.” These patents “are disproportionately owned by nonpracticing entities”).

⁹³ The database searched included a total of 21,231 patents across five university systems, including 7,481 patents in broadly relevant categories. Of these, we skimmed the text of 179 and identified 48 as potential targets.

⁹⁴ This choice leaves open the possibility that although we found many promising patents, none might actually be commercially relevant. Given the diversity and ambiguity among the patents we identified, we think this result unlikely.

⁹⁵ “A Markush-type claim recites alternatives in a format such as ‘selected from the group consisting of A, B and C.’” MPEP § 803.02 (8th ed. Rev. 8, Aug. 2012) (citing *Ex parte Markush*, 1925 Dec. Comm’r Pat. 126 (1924)). See also *Abbott Labs. v. Baxter Pharm. Prods., Inc.*, 334 F.3d 1274, 1280-81 (Fed. Cir. 2003); *In re Harnisch*, 631 F.2d 716, 716-17 (C.C.P.A. 1980).

⁹⁶ Specifically, we searched the USPTO Full Text Database for claims (“ACLM”) including the terms “‘selected from the group consisting’ AND ‘drug’” or “‘selected from the group consisting’ AND ‘pharmaceutical’ ANDNOT ‘drug,’” in patents assigned (“AN”) to the University of California system, the University of Texas system, MIT, CalTech, or the University of South Florida.

by monetizers do not depend on proceeding to actual validity or infringement determinations, we did not attempt to evaluate the patent's validity, and did not attempt careful claim construction. We also did not attempt to identify specific industry targets likely to infringe the patents, for reasons both of resource limitations and of not wishing to provide too straightforward a target list for potential monetizers. Finally, we did not—and feasibly could not—determine the licensing situation of these patents. It is possible that some subset of the patents we have identified are in fact licensed by universities to the relevant potential infringers. Given the secrecy of licensing arrangements, this is an unavoidable limitation a study of this kind; however, considering the broad range of industry and university players, we consider it unlikely that licensing of even *potentially* relevant patents is so widespread as to render all industry players safe from monetizers.

B. Results

We found dozens of potentially assertable patents in several categories. The parameters of our search mean there are almost certainly many more to be found by monetizers, who have more time and expertise in searching. However, the patents we found in our non-intensive search support our hypothesis: the patent holdings of universities do indeed appear to hold many patents of potential interest to monetizers seeking to target the biopharmaceutical industry. Potentially relevant patents cover drugs' active ingredients; methods of treatment; screening methods to identify new drugs; manufacturing methods; dosage forms; and plausibly related ancillary technologies (a catchment category including patents useful in a “peddler's bag”/“kitchen sink” approach but otherwise of relatively attenuated relationship to industry procedures). This section describes each of the several types of patents we found, including an exemplar of each type.

1. Active ingredient patents

Every drug relies on active pharmaceutical ingredients, and patents covering those active pharmaceutical ingredients are clearly the dominant form of patent in the biopharmaceutical industry. When policy or scholarship discusses “drug patents” without further elaboration, this type of patent is meant. Such patents are particularly strong due to the FDA approval process, as described above; essentially, they cannot be invented around. Because active pharmaceutical ingredient patents are central to the patent strategy of drug companies, such patents covering marketed drugs would be of tremendous use to monetizers, especially of the “lottery-ticket

troll” variety. They could be potent litigation weapons both before and after approval, and would provide powerful bargaining tools.

These patents are also the least likely to be found. Typically, the PTO will not grant multiple patents covering a single chemical, since once the chemical is disclosed in a patent, the second patent would be barred for lack of novelty. That said, there is a substantial amount of error at the PTO, and initial examination involves few resources.⁹⁷ Drug companies also do particularly extensive diligence seeking patents that cover potential active pharmaceutical ingredients, since the patentability of a drug’s active pharmaceutical ingredient is a key question in approving the drug’s development.⁹⁸ However, some patents are likely to slip past these efforts as well, particularly in light of the broad combinatorial nature of Markush claims for chemical classes.⁹⁹

Although our search found relatively few composition patents which appear to cover active pharmaceutical ingredients for a class of commercially viable or currently marketed drugs, we did find some.¹⁰⁰ For example, Patent no. 6,437,105, filed November 2, 1999 and assigned to the University of Texas System, covers a large set of anthracycline-based antitumor agents.¹⁰¹ Anthracyclines are a widely used class of powerful

⁹⁷ Mark A. Lemley, *Rational Ignorance at the Patent Office*, 95 Nw. U. L. Rev. 1495 (2001).

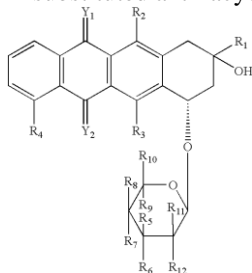
⁹⁸ See, e.g., Benjamin Roin, *Unpatentable Drugs and the Standard of Patentability*, 87 TEX. L. REV. 503, 512–13 (2009).

⁹⁹ See note 95, *supra*.

¹⁰⁰ As described above, we did not attempt to find or demonstrate specific instances of infringement.

¹⁰¹ The patent’s only independent claim, Claim 1, claims:

A substituted anthracycline having the formula:



wherein

R^1 is a hydroxyl group ($-\text{OH}$), a methoxy group ($-\text{OCH}_3$), an alkoxy group having 1-20 carbon atoms, an alkyl group having 1-20 carbon atoms, an aryl group having 6-20 carbon atoms, a fatty acyl group having the structure $-\text{O}-\text{CO}(\text{CH}_2)_n\text{CH}_3$, wherein n =an integer from 1 to about 20, or a fatty acyl group having the structure $-\text{O}-\text{CO}(\text{CH}_2)_l(\text{CH}=\text{CH})_m(\text{CH}_2)_n\text{CH}_3$, wherein l is an integer between 1 to 3, m is an integer between 1 and about 6, and n is an integer between 1 to about 9;

each of R^2 and R^3 is, independently of the other, a hydrogen ($-\text{H}$) group, a

chemotherapy drugs used to treat several cancers, including lymphomas, leukemias, and cancers of the breast, uterus, and lung.¹⁰² They include doxorubicin (Adriamycin) and daunorubicin (Daunomycin).¹⁰³ Other patents we found in this category covered a broad range of analogs to the natural antimicrobial agent indolicidin¹⁰⁴ and a range of C-substituted diindolylmethane compounds; the latter are used to treat a respiratory disease and to prevent certain cancers.¹⁰⁵

2. Methods of treatment

Another relevant patent type covers methods of treatment—that is, the use of a drug by a doctor, patient, or anyone else to treat a disease. For instance, Pfizer holds a patent covering the use of its blockbuster drug Lipitor to treat high cholesterol, as well as covering the active

hydroxyl group (—OH), a methoxy group (—OCH₃) or a double bonded oxygen moiety;

R⁴ is a hydrogen (—H) group, a hydroxyl group (—OH), a methoxy group (—OCH₃) or a halide;

each of Y¹ and Y² is, independently of the other, a hydrogen (—H) group; a hydroxyl group (—OH); a methoxy group (—OCH₃); or a double bonded oxygen, sulphur, or nitrogen group;

R⁵-R¹² are, independently, —H, —OH, a halide, —OR¹³, —SH, —SR¹³, —NH₂, —NHR¹³, —N(R¹³)₂; R⁵-R¹² can additionally independently be a saccharide; or R⁹ can additionally be CH₃, with the proviso that:

both of R⁶ and R⁷ or both of R⁵ and R⁸ or both of R⁵ and R¹¹ or both of R⁶ and R¹² are involved in forming a three ring structure; wherein said three ring structure contains three heteroatoms selected from the group consisting of O and N and the rings of said three ring structure have 5 or 6 members; or

either of R⁵ and R⁶ is independently a mercapto-haloalkyl group; an ether alkyl group containing an easy leaving group; an alkyl group containing an easy leaving group or an ether alkyl group containing an aziridine, oxirane, thirane, oxetane or thietane ring; and

R¹³ is a methyl group, an alkoxy group having 1-20 carbon atoms, an alkyl group having 1-20 carbon atoms, an aryl group having 6-20 carbon atoms, a fatty acyl group having the structure —CO(CH₂)_nCH₃, wherein n=an integer from 1 to about 20, or a fatty acyl group having the structure —CO(CH₂)_l(CH=CH)_m(CH₂)_nCH₃, wherein l is an integer between 1 to 3, m is an integer between 1 and about 6, and n is an integer between 1 to about 9.

¹⁰² Giorgio Minotti et al., *Anthracyclines: Molecular Advances and Pharmacologic Developments in Antitumor Activity and Cardiotoxicity*, 56 PHARMACOL. REV. 185 (2004)

¹⁰³ Note that, although we did not perform a full infringement analysis, it is unlikely that doxorubicin or daunorubicin themselves actually infringe the '105 patent, which discloses a 3-ring structure not present in either of those drugs.

¹⁰⁴ Patent No. 6,524,585, filed October 12, 1999 and assigned to the University of California.

¹⁰⁵ B.J. Wiatrak, *Overview of current respiratory papillomatosis*, 11 CURRENT OPS. IN OTOLARYNGOLOGY, HEAD, AND NECK SURGERY 433 (2003).

pharmaceutical ingredient of Lipitor itself.¹⁰⁶ New uses of an already marketed drug can also be patented, like the use of minoxidil (Rogaine) to treat male pattern baldness, discovered years after its initial development as a treatment for high blood pressure.¹⁰⁷

This type of method of treatment claim could be asserted by monetizers against the industry. For instance, consider a counterfactual story in which the use of minoxidil in treating baldness was discovered not by Upjohn, the drug's maker, but by MIT researchers, who published the results and simultaneously applied for a patent. Doctors relying on the study could prescribe minoxidil to treat baldness, and Upjohn could share the study in an effort to increase sales.¹⁰⁸ Once the patent issued, however, use of the drug to treat baldness would infringe the patent, even though Upjohn still held the patent on the drug itself and its original use in treating high blood pressure. Therefore, a monetizer who bought the patent from MIT could sue Upjohn for contributory infringement, arguing that Upjohn was encouraging doctors and patients to infringe the patent.¹⁰⁹

A patent like this could be a "lottery-ticket" patent, if it were able to completely block the only or most important treatment indication for a drug.¹¹⁰ More frequently, the monetizer could also assert this patent against the doctors prescribing minodixil for baldness, or even patients using it. This type of plausible nuisance suit could quickly garner high returns, since tens of thousands of doctors would be potential targets for demand letters, and settlements or licensing fees in the low thousands of dollars would be

¹⁰⁶ U.S. Pat. No. 4,681,893 (filed May 30, 1986). Claims 1–7 claim various active pharmaceutical ingredient variants; Claim 8 claims a drug containing an active pharmaceutical ingredient (such as Lipitor), and Claim 9 claims "[a] method of inhibiting cholesterol biosynthesis in a patient in need of such treatment by administering [such a drug]."

¹⁰⁷ The initial patent on minoxidil, U.S. Pat. No. 3,461,461 (filed Aug. 12, 1969) covered the compound itself and a method of using it to treat high blood pressure. Using minoxidil to treat baldness was claimed in a later patent, U.S. Pat. No. 4,139,619 (filed Feb. 13, 1979).

¹⁰⁸ *United States v. Caronia*, 703 F.3d 149, 167–68 (2d Cir. 2012) (finding that a complete and criminal ban on off-label promotion by pharmaceutical manufacturers fails the commercial free speech inquiry and is unconstitutional).

¹⁰⁹ Inducing infringement of a patent creates liability for infringement under 35 U.S.C. § 271(b).

¹¹⁰ If a drug company is not directly advertising a new use covered by a patent, it would likely be more challenging to win a suit for induced infringement against the drug company itself. This lack of advertising would be quite likely if the company did not hold the new use patent; the company would be unlikely to seek FDA approval for the new use, and promoting unapproved uses is prohibited by the FDA. On the other side of this dynamic, it is challenging for companies to enforce new use patents even if they do hold them, since they do not have information about the purposes for which doctors prescribe drugs to any individual patient.

far less than the cost of defending against a patent suit.¹¹¹ These nuisance suits would be problematic and expensive for doctors and could create tremendous leverage against drug companies to license the relevant patents. While once the thought of monetizers targeting small-scale users was considered very unlikely,¹¹² such tactics have recently become much more common, as described above.¹¹³

One example of such a broad method of treatment patent we found could potentially implicate postmenopausal hormone replacement therapy (HRT).¹¹⁴ Patent no. 6,692,763, filed July 11, 2000 and assigned to the University of California system, disclosed “methods for treatment of postmenopausal women using ultra-low doses of estrogen.” The broad independent claim covers administration of estrogen to postmenopausal women in very low doses.¹¹⁵ Although HRT most frequently uses higher dosage levels,¹¹⁶ this patent could plausibly be asserted against industry and

¹¹¹ This cost disparity also decreases the challenge that patent-holders—whether drug companies or monetizers—cannot easily tell for what purpose a doctor is prescribing a drug; successfully defending against a nuisance suit is still far more expensive than a typical settlement or licensing fee for small targets.

¹¹² Executive Office of the President, Patent Assertion and U.S. Innovation (June 2013), available at http://www.whitehouse.gov/sites/default/files/docs/patent_report.pdf (indicating recent increase in targeting smaller entities, as compared to the past: “PAE activities hurt firms of all sizes. Although many significant settlements are from large companies, the majority of PAE suits target small and inventor-driven companies. In addition, PAEs are increasingly targeting end users of products, include many small businesses.”).

¹¹³ See *supra* pt. I at 8.

¹¹⁴ Although HRT has been the subject of some controversy regarding its preventative effects, it is still in wide use. See generally Debora Kotz, *Hormone replacement therapy supported for some*, Boston Globe (Oct. 2, 2013), available at <http://www.bostonglobe.com/news/nation/2013/10/01/hormone-replacement-therapy-less-risky-for-women-their-latest-data-suggest/pqdVCCO4i4EXP4shXBODsI/story.html> (last visited Nov. 22, 2013)

¹¹⁵ Claim 1 claims:

A method for treating a physical condition resulting from estrogen decline in a postmenopausal subject, said method comprising administering to said subject an amount of estrogen which is effective to produce a resulting serum level of said estrogen in said subject that is equivalent to a serum estradiol [sic] level not exceeding of between about 5 pg/ml and about 15 pg/ml [note – for postmenopausal women, the level typically ranges from 0 to 35 pg/ml], wherein:

the estrogen is administered orally, parenterally, or transdermally;
said physical condition is selected from the group consisting of osteoporosis, headaches, nausea, depression, hot flashes, decrease in bone mineral density, and increased risk or incidence of bone fracture;
and

the resulting serum level of the estrogen is responsive to the administering of the estrogen.

¹¹⁶ See Rice VM, *Optimizing the Dose of Hormone Replacement Therapy*, 47(5) INT’L

practitioner targets.

3. Manufacturing methods

In addition to central patents covering active pharmaceutical ingredients and methods of treatment, other patents cover more peripheral activities. For instance, patents can cover methods used to manufacture drugs. Such a patent could block the manufacture of a drug if it covered a central process, or could less powerfully force a firm to shift its methods, which is itself costly.¹¹⁷

We found several potentially assertable patents covering manufacturing methods. As one of us has previously noted, determining actual infringement of manufacturing methods patents is challenging due to the secrecy of pharmaceutical manufacturing.¹¹⁸ This makes assertion of such patents less likely to successfully support a “lottery-ticket” strategy. However, that would not prevent the assertion of these patents in a “peddler’s bag” or “assault rifle” strategy, especially for manufacturing method patents which are relatively common or which form a small but useful part of typical manufacturing procedures.

For instance, Patent no. 6,890,740, filed February 12, 2001 and assigned to the University of California, claims a method of separating different-sized biological materials.¹¹⁹ The patent broadly covers separating

J. OF FERTILITY AND WOMEN’S MED. 205–10 (2002) (“[M]ore commonly prescribed doses” ranges include 0.625 mg of CEE or 0.5 mg 17beta-estradiol.).

¹¹⁷ See W. Nicholson Price II, *Making Do in Making Drugs: Innovation Policy and Pharmaceutical Manufacturing*, B.C. L. REV. (forthcoming 2014), available at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2311682, 25–31. Although determining potential infringement is challenging because manufacturing processes are typically kept secret, *see id.* at 35–35, once an infringement suit is brought demonstrating infringement is made somewhat easier by a statutory presumption of infringement on a showing “(1) that a substantial likelihood exists that the product was made by the patented process, and (2) that the plaintiff has made a reasonable effort to determine the process actually used in the production of the product and was unable to so determine.” *Id.* (citing 35 U.S.C. § 295). This presumption exists to counter the typical secrecy accorded manufacturing methods. *Id.* While the initial stage of identifying potential infringement may deter most suits by pharmaceutical companies, who have incentives to avoid bringing frivolous or losing suits against repeat-player competitors, monetizers may lack those incentives and are demonstrably much more willing to bring “fishing expedition” suits.

¹¹⁸ *See id.* at 34–36.

¹¹⁹ Claim 1 claims:

A method for separating different sized biological materials to increase throughput of sampling, comprising the following steps in the order named:

- a. centrifuging said biological materials in a container;
- b. inserting a separation barrier into said container to separate biological materials with a size small enough to pass through said

biological materials of different sizes by centrifuging the materials in a container with a size-specific sieve so smaller materials pass through and larger materials do not.¹²⁰ Such a method is broadly useful in the manufacture of biologics,¹²¹ and might plausibly be alleged to be infringed in many manufacturing processes, even if the monetizer has little or no direct knowledge.

4. Dosage forms

Patents can also cover the specific dosage form of a drug. Dosage form describes the physical form of the drug taken by a patient—that is, a tablet, capsule, solution, or some other format. A patent which could be used to block a particular dosage form could provide a significant weapon to monetizers; while it would not block all uses of a drug, it could block the dominant format of a single drug and could also potentially impact multiple drugs made by a single firm.

While many traditional dosage forms, such as a basic coated tablet, a capsule, or a solution, are unlikely to be patentable, other more recent forms may be. For example, Patent no. 7,300,668, filed October 29, 2002 and assigned to MIT, covers a three-dimensionally printed controlled-release dosage form.¹²² The patent claims a printed dosage form made up of

separation barrier from biological materials with a size too large to pass through said separation barrier;

c. withdrawing a portion of said biological materials from only one side of said separation barrier.

¹²⁰ Claim 1 covers:

A method for separating different sized biological materials to increase throughput of sampling, comprising the following steps in the order named:

a. centrifuging said biological materials in a container;

b. inserting a separation barrier into said container to separate biological materials with a size small enough to pass through said separation barrier from biological materials with a size too large to pass through said separation barrier;

c. withdrawing a portion of said biological materials from only one side of said separation barrier.

¹²¹ Biologics are large-molecule drugs made by living systems rather than chemical synthesis. They include proteins, vaccines, and antibodies, and make up a large and growing fraction of blockbuster drugs. See Jordan Paradise, *Follow-On Biologics: Implementation Challenges and Opportunities: Foreword*, 41 SETON HALL L. REV. 501, 502 (2011).

¹²² Claim 1 covers:

A dosage form comprising:

a three-dimensionally printed innermost region comprising a first regional concentration of at least one Active Pharmaceutical Ingredient; and

multiple layers, each layer with a different concentration of the active ingredient. Without the three-dimensional printing limitation, that format describes many current extended-release dosage forms, and a broad construction of the term “three-dimensionally printed” is at least plausible.

5. Screening methods

Patents can also cover the processes that companies use to find new drugs, particularly ways to screen large sets of possible drugs to find the ones which are likely to be medically useful. We found several such patents in our search. While monetizers asserting these patents are less likely able to exploit the leverage provided by regulatory hurdles described above,¹²³ it may still challenge significant research and development activity by drug companies. Such patents would be particularly amenable to “peddler’s bag” or “assault rifle” approaches.

One example is Patent no. 6,274,321, filed December 3, 1999 and assigned to the University of California system, covering a very general method of screening nucleic acids (including DNA, cDNA, and RNA) to find which nucleic acids express products of medical interest.¹²⁴ Such

plural three-dimensionally printed non-innermost regions in nested arrangement and comprising:

a) one or more nested internal regions each comprising a respective regional concentration of at least one Active Pharmaceutical Ingredient, wherein an internal region completely surrounds and is in contact with the innermost regions, and any other internal region present completely surrounds another internal region located to the interior thereof; and

b) an outermost region completely surrounding an internal region and comprising a respective regional concentration of at least one Active Pharmaceutical Ingredient,

wherein the internal and outermost regions are in nested arrangement, the regional concentration of Active Pharmaceutical Ingredient in a region is different from the regional concentration of Active Pharmaceutical Ingredient in another region adjacent to it, the regional concentration of Active Pharmaceutical Ingredient in an internal region is non-zero, the regional concentration of Active Pharmaceutical Ingredient in plural regions is non-zero, and the respective regional concentrations are selected so that the at least one Active Pharmaceutical Ingredient is released in approximately a zero-order release.

¹²³ See *supra* at 22.

¹²⁴ Claim 1 of the patent claims:

A method of identifying a nucleic acid in a pool of interest, comprising the steps of:

(1) obtaining a plurality of nucleic acids, wherein the nucleic acids are individually identifiable;

screening is a basic research step in many forms of pharmaceutical research, especially in developing new biologics.¹²⁵ Thus, such a patent could potentially be asserted against the research activities of many different firms.

6. Plausibly related patents

Finally, among the significant number of patents we found in the preceding categories which appear to have at least the possibility of meritorious assertion, we found many patents which would at least pass the risibility test—at least potentially enforced by the possibility of Rule 11 sanctions for frivolous suits—and which could therefore be useful to add bulk to a “peddler’s bag” approach or in any approach relying primarily on the high costs of patent litigation to extract relatively small settlements. For instance, we found patents on isotopically labeled DNA,¹²⁶ a method for treatment of retinal diseases,¹²⁷ fluorescent protein sensors for detection of analytes,¹²⁸ combinatorial synthesis of inorganic composite materials,¹²⁹ and catalytic reactions involving alkenes.¹³⁰ While it is possible that any of these might more accurately be placed in one of the prior categories, they did not appear to our initial examination as likely to form the basis for a stronger patent suit. However, each could potentially be used as part of a broader set of asserted patents to increase potential litigation costs and

(2) pooling the nucleic acids in step (1) into at least two pools of at least one nucleic acid each;

(3) expressing the nucleic acid pools in step (2) to obtain corresponding protein expression product pools;

(4) assaying the expression product pools in step (3) for products having an interaction with a target molecule;

(5) selecting a nucleic acid pool corresponding to an expression product pool identified in step (4); and

(6) identifying at least one individual nucleic acid in the nucleic acid pool identified in step (5).

¹²⁵ Paul H. Johnson, et al., *Multiplex Gene Expression Analysis for High-Throughput Drug Discovery: Screening and Analysis of Compounds Affecting Genes Overexpressed in Cancer Cells*, 1 MOLECULAR CANCER THERAPEUTICS 1293 (2002).

¹²⁶ U.S. Pat. No. 7,022,834 (filed September 16, 2004) (assigned to The Regents of the University of California).

¹²⁷ U.S. Pat. No. 6,066,675 (filed September 8, 1997) (assigned to The Regents of the University of California).

¹²⁸ U.S. Pat. No. 6,197,928 (filed March 14, 1997) (assigned to The Regents of the University of California).

¹²⁹ U.S. Pat. No. 7,767,627 (April 22, 1997) (assigned to The Regents of the University of California).

¹³⁰ U.S. Pat. No. 8,314,246 (filed August 30, 2006) (assigned to Massachusetts Institute of Technology).

consequently provide additional leverage in settlement negotiations.

7. Overall search conclusions

Our search confirmed our initial suspicions that university patent holdings are likely to provide fertile hunting grounds for monetizers. In a relatively short period of time, two researchers with only basic expertise were able to find dozens of potentially monetizable patents within the holdings of just five major universities. Undoubtedly the holdings of those universities include many more patents potentially assertable against players in the biopharmaceutical industry. And, of course, those are only five universities—there are many more schools with extensive holdings potentially available.

The ease with which we found potentially relevant patents inevitably raises the question: if these patents are around and threatening, why hasn't the biopharmaceutical industry found and dealt with them? One possibility, of course, is that the industry has found most or all commercially relevant patents, and that such patents have been evaluated by the relevant potential targets and either found unproblematic or licensed. Given the lack of discussion of ancillary patents or monetizers in the pharmaceutical industry generally, and the challenges of conducting a comprehensive search as opposed to our quick look, we think this outcome unlikely. It seems more likely that the conventional wisdom above—few relevant patents, a limited set of monetizer targets, and higher barriers to commercial entry—has helped to keep these potential patent threats off the radar of the industry.

A second possibility is simply that up until now, the patent holdings of major universities has posed little threat, particularly those peripheral patents that could be used for the type of bargaining leverage popularized in modern patent trolling, and have thus been too remote to consider. Universities traditionally have not engaged in widespread patent litigation. For example, an extensive academic study of all 13,000 patent lawsuits filed in 4 recent years showed that universities have served as the first named plaintiff in less than one-half of one percent of the lawsuits filed.¹³¹ Given that universities have not engaged in extensive litigation themselves, and have had a stated policy of not transferring to patent assertion entities, the threat of university holdings may have been too low to justify the costs of searching out and licensing every patent that could potentially be launched against a product. This would be particularly true, given the trolling tactics of extracting settlements related to the economics of litigation, rather than the value of the patent itself. Without a clear threat of that kind, the costs of

¹³¹ See Feldman, Ewing & Jeruss, *supra* note 16.

clearing the field of anything that could be waved at a biopharmaceutical company would be wasteful, if not prohibitive.

In short, modern patent trolling in the technology industry did not require the invention of new inputs. The basic raw materials existed, including broadly worded patents, a large inventory of unused patents and patent claims, and an imbalance of litigation costs. The catalyst for modern patent trolling in the technology industry was simply brilliant minds calculating how to take advantage of these elements on a large-scale and sophisticated manner, with many others following suit.

Although early anecdotal evidence suggests that patent trolling is moving into biopharmaceuticals, conventional wisdom has always held that the raw materials do not exist in that space. This study, however, demonstrates that the conventional wisdom is wrong. Where behavior is structurally predictable, opportunities exist to allow planning for and protecting against abuses in that behavior.

CONCLUSION

In the ongoing policy and scholarly debates about patent trolls, by far the most prominent focus has been on the software and high technology industries. Conventional wisdom has assumed that the biotechnology and pharmaceutical industries have little to fear from trolls, and at least partly because of that assumption, those industries have either opposed or skirted many reform efforts in both the past and present.

In this piece, we have argued that, on both theoretical and empirical levels, patent monetizers are able and likely to spread beyond their traditional targets and that the bio and pharmaceutical industries are vulnerable to monetization tactics. Theoretically, the newly diverse strategies of monetizers broaden potential targets, and in the drug industry, regulatory constraints may make patent holdups particularly costly. Empirically, our deliberately brief and cursory survey of university patent holdings reveals that many patents are potentially available for licensing to monetizers, and universities are becoming more amenable to such licensing.¹³² More broadly, potentially assertable patents are likely to be found not only in the holdings of universities, but in the portfolios of biotech and pharmaceutical companies, large and small, which may well be willing to license patents to the detriment of their competitors as has happened in the high tech sector. It is not inevitable that monetizers will descend on the bio and pharmaceutical industries, but in our opinion it is a serious threat. Potentially policy solutions to the problems raised by

¹³² See Basken, *supra* note 88.

monetizers should take this possibility into account.