

# Learning from Past Mistakes—The US Patent System and International Trade Agreements

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*To ensure that the TPP agreement works properly in practice with regard to patents and the governance of pharmaceuticals and semiconductors, strong mechanisms for enforcement and for rooting out system abuse are needed. To make this happen, regulators should learn from past mistakes of the U.S. patent system: the proliferation of non-practicing entities (NPEs), and strategic behavior that blocks or delays generic competition in the pharmaceutical industry. This Think Piece presents key findings of the author's research on the complexity of the U.S. litigation and regulatory frameworks that have provided fertile ground for strategic behavior that can have negative effects on innovation, and may distort the expected gains from trade for innovation.*

## Introduction

In the process of negotiating international trade agreements such as the Trans-Pacific Partnership, new regional standards will be set in areas ranging from textiles to intellectual property. These standards may serve as a baseline for greater global governance structures such as through the World Trade Organization. In the regional talks, IP discussions have focused on debates over patent term lengths and data exclusivity rights. For example, based on United States law, the U.S. sought a twelve-year period of data exclusivity for complex biologic drugs derived from living organisms, while other countries argued that a shorter period is necessary to curb climbing drug prices. The final length was a seven-year period. No matter what balances are chosen in international agreements, however, we need to ensure that these carefully calibrated choices function properly in practice and have both strong mechanisms for enforcement and for rooting out system abuse.

In particular, with patents and pharmaceuticals driving much of the IP debate in TPP negotiations, we should ensure that regulators learn from our past mistakes. Merely coming to a conclusion on issues such as patentability and term length is not enough—flexible yet firm enforcement initiatives are needed to ensure that the TPP becomes a strong instrument of trade, not another regulatory mechanism to be picked apart by those wishing to exploit it. And as pharmaceutical game playing hits the press with the Turing and Valeant cases, where companies dramatically increased drug prices and attempted to obstruct generic competition,<sup>1</sup> it is important to consider the complexities in the U.S. system that create opportunities for these activities.

With this concern in mind, the paper will focus on two areas of U.S. law, both of which are creating challenges within the U.S. system. These are 1) the rapid emergence of NPEs, entities that do not make products but whose focus centers on licensing and litigating patents, and 2) behaviors to block the emergence of generic competition in the pharmaceutical industry. In both of these areas, complexity breeds opportunity. The complexity of various litigation and regulatory schemes have created opportunities for strategic behaviors that are suboptimal. Many companies and patent lawyers in the United States, however, have become accustomed to these intricacies and to the accompanying strategic behaviors. And the solutions are not easy to identify. One has to choose carefully to avoid dampening the fires of innovation. The focus for all economies, however, should remain on the creation and production of products. Whatever type and stage of innovation industry may exist in an individual nation or in a region, policies that encourage the creation and production of innovative products will be more beneficial than policies that encourage intellectual property itself as a disembodied industry.

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<sup>1</sup> For a summary of the Turing and Valeant controversies, see Robin Feldman & Evan Frondorf, *Drug Wars: A New Generation of Generic Pharmaceutical Delay*, 53 Harv. J. on Legis. \_\_\_ (forthcoming 2016) (manuscript at 52-57), <http://ssrn.com/abstract=2659308>.

## Problems and Responses

The United States patent system has helped to drive innovation in a variety of fields, from computers to pharmaceuticals and other life science inventions to semiconductors. Although a system of patent rights could be based on an inventor's moral or natural right to the invention, the approach of the U.S. system is explicitly utilitarian, that is, the U.S. grants patent rights for the purpose of promoting the "useful arts,"<sup>2</sup> in other words, products.

In addition to the Constitutional language and history, the importance of the creation of new products to patent policy is evident in the Bayh-Dole Act, passed by the U.S. Congress in 1980. Bayh-Dole gave universities the power to file for patents on federally-funded inventions and also permitted them to license those inventions. The hope was that this licensing and commercialization power would spur the innovation of new products, furthering the societal benefit of spending federal dollars on research. Commentary at the time of the passage of the Act focused on the importance of the value proposition for taxpayers whose money is going to funding research at universities. In return, society should benefit in the form of the introduction of new products, and universities were judged to be better facilitators of that commercialization than allowing patent rights to remain with the federal government itself.<sup>3</sup>

New patents, however, have not always meant new products. Until the last decade, most patent holders never succeeded in commercializing their inventions, and most patents garnered no returns. At the same time, although many patents contain claims of questionable quality, the fact that most patents sat on the shelf meant that the courts could focus on the limited number of patents that would have an impact in the market. That happy circumstance—limited quality of

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<sup>2</sup> U.S. CONST. art. 1, § 8.

<sup>3</sup> For more discussion of Bayh-Dole, see Robin Feldman & Mark A. Lemley, *Do Patent Licensing Demands Mean Innovation?*, 101 IOWA L. REV. 137, 174-75 (2015), [http://ilr.law.uiowa.edu/files/ilr.law.uiowa.edu/files/ILR\\_101-1\\_Lemley%26Feldman.pdf](http://ilr.law.uiowa.edu/files/ilr.law.uiowa.edu/files/ILR_101-1_Lemley%26Feldman.pdf).

patent claims combined with limited numbers of patents in play—meant that the system would not be overly burdened.

The status has changed in the last five to seven years, however, with the advent of the modern NPE business model. NPEs, or “non-practicing entities,” are those entities whose core activity involves licensing or litigating patents, rather than making products. Some NPEs have undertaken behavior such as indiscriminately suing or demanding payment from thousands of defendants, regardless of the merits of the claim, with the hopes that companies will choose to settle rather than face costly litigation. Such lawsuits originating from NPEs have risen significantly over the last decade. Patent lawsuits increased from about 2,500 in 2007 to over 5,000 in 2012, and NPEs have been responsible for the large majority of this growth.<sup>4</sup> Further, the number of defendants sued has climbed along with the number of lawsuits filed. Recent Supreme Court decisions led to a decline in the amount of patent litigation in 2014,<sup>5</sup> but activity has remained extremely high compared to pre-2007 levels. And levels appear to be rising once again—November 2015 was a all-time record month for lawsuit filings, with 790 filed.<sup>6</sup> New regulations have not stopped new NPEs and novel models of NPE activity from appearing, with one private study concluding that 143 new NPEs filed patent lawsuits in 2014.<sup>7</sup> While there are

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<sup>4</sup> See Robin Feldman, Tom Ewing & Sara Jeruss, *The AIA 500 Expanded: The Effects of Patent Monetization Entities*, 17 UCLA J.L. & TECH. 1, 42 (2013), available at <http://www.lawtechjournal.com/articles/2013/041024-Feldman.pdf>; see also Matthew Sag, *IP Litigation in United States District Courts: 1994 to 2014*, IOWA L. REV. (forthcoming) (manuscript at 17), available at [http://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=2570803](http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2570803) (finding that patent litigation volume doubled from 2010 to 2013).

<sup>5</sup> For a description of key Supreme Court decisions in 2014, see Robin Feldman, *Theme of Restraint in Term’s IP Cases*, DAILY JOURNAL (July 8, 2014).

<sup>6</sup> Joe Mullin, *Patent Trolls Filed Hundreds of Lawsuits to Beat Dec. 1 Deadline*, ARS TECHNICA (Dec. 2, 2015), <http://arstechnica.com/tech-policy/2015/12/patent-trolls-filed-hundreds-of-lawsuits-to-beat-dec-1-deadline/> (citing data from Lex Machina).

<sup>7</sup> RPX, 2014 NPE LITIGATION REPORT 6 (2015), <http://www.rpxcorp.com/2015/01/09/2014-npe-litigation-new-and-smaller-targets-2/>.

numerous definitional and methodological choices made in studies of NPE activity, conclusions across studies been remarkably consistent—patent litigation activity in the U.S. has exploded since 2007, and the large majority of this proliferation can be traced to NPEs.

Many of these cases are filed to exploit the cost and uncertainty of patent litigation in an effort to obtain a settlement, regardless of the merits of the patent claims. Patent litigation can easily cost \$1 million or more, while the price of a settlement is often a mere fraction of litigation costs.<sup>8</sup> For many rational companies, settling is the logical choice, even in the face of serious concerns about whether the patent being wielded is valid or whether the company is actually infringing. NPEs are aware of this incentive to settle, particularly for small companies. For example, one study suggested that more than half of unique defendants in NPE suits have less than \$10 million in annual revenue, and more than three-quarters have annual revenues less than \$100 million.<sup>9</sup>

The question remains, however, whether NPE activity actually hampering innovation. Few patent demands actually reach the litigation stage, with most early-stage threats and licensing negotiations taking place outside of the courtroom. Information about this widespread activity, perhaps 90% of all patent demand activity, is not captured by large-scale, generalizable data sets similar to those available for litigation. Instead, the interaction might be as simple as: “You are infringing my patents; if we take this to court, it will cost you millions in legal fees; many other companies have been agreeable and accepted a licensing deal, so there must be a way for us to work something out. To get more details, we also need you to sign a non-disclosure agreement.” The complexity and incentives of the U.S. legal system have helped create this

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<sup>8</sup> Colleen Chien, *Startups and Patent Trolls*, 17 STAN. TECH. L. REV. 461, 472-73 & 473 tbl.1 (2014), <http://journals.law.stanford.edu/sites/default/files/stanford-technology-law-review/online/startupsandpatenttrols.pdf>

<sup>9</sup> *Id.* at 471.

mostly unregulated market of demands and settlements, with little data collected to track the phenomenon.

The data that are available, often from small-sample surveys, are not encouraging. These studies observe a disproportionate effect of NPEs on startups, little evidence of innovation transfer through NPE licensing, substantial legal costs, and additional harms to business and product development, including minimal “trickle down” of NPE revenue to original patentees. Moreover, other studies have reported the use of pressure sales tactics and opportunistic behavior by NPEs.<sup>10</sup>

Despite evidence that NPEs are hampering, and at times downright abusing, a system meant to spur innovation, patent rights in general are essential to innovation. These rights would be useless if they cannot be enforced. Efforts to curb strategic behavior have been met with resistance, as universities, NPEs, and pharmaceutical companies have argued that such reform efforts would diminish the ability of patent holders to legitimately assert their rights. Of particular note, the U.S. semiconductor industry has been a vocal and active opponent of patent reform. Key semiconductor companies do not actually manufacture products but instead invent and create prototypes that the companies then license to others to manufacture. Thus, semiconductor companies occupy an unusual space, one not purely like large patent holding companies nor like traditional product producing companies—although some have complained that semiconductor company behavior at times strays across the line toward classic NPE tactics.

Given the state of the global semiconductor industry, entities across the world have a significant stake in the result of U.S. patent reform. The U.S. and China, for example, are

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<sup>10</sup> For more detail about these studies, see Robin Feldman, *Federalism, First Amendment, & Patents*, COLUM. SCI. & TECH. L. REV. (forthcoming 2016) (manuscript at 11-13), <http://ssrn.com/abstract=2616519>.

particularly interdependent in the electronics space: semiconductor firms such as Intel and Qualcomm are dependent on China for one-fifth to a full half of their revenue, while China currently imports 80% of the semiconductors it uses in electronics manufacturing.<sup>11</sup> As the world's largest electronics exporter, China then exports a large proportion of the finished goods back to the countries where the semiconductor components were first created. China is trying to grow its own domestic semiconductor industry; U.S. and other international companies are clamoring to maintain Chinese market share through joint ventures and technology transfer with Chinese firms that may well become competitors. To the extent that U.S. semiconductor companies, Chinese firms, and government entities establish partnerships, these nations are likely to face challenges and pressure to skirt legal rules that might hamper the semiconductor approach to patent licensing and enforcement.

In addition to the proliferation of the NPE business model, and the resulting fallout, the U.S. patent system has struggled with another problem in the pharmaceutical industry: manipulations that block or delay the introduction of generic drugs.<sup>12</sup> Competition from generic drugs is immensely powerful in lowering the price of prescription medications in the U.S. When a generic enters a monopoly market, the drug is normally priced at 80% of the cost of the brand-name drug within six months of launch.<sup>13</sup> Over time, the price of generics generally falls to just

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<sup>11</sup> Dieter Ernst, *Xi's Visit Highlights U.S. and Chinese Expectations in the Semiconductor Industry*, EAST-WEST CENTER (Sept. 2015), <http://www.eastwestcenter.org/news-center/east-west-wire/xi's-visit-highlights-us-and-chinese-expectations-in-the-semiconductor>

<sup>12</sup> For a full discussion of original and new tactics for blocking or delaying generic competition, see Feldman & Frondorf, *Drug Wars*, *supra* note 1.

<sup>13</sup> Ernst R. Berndt & Murray L. Aitken, Brand Loyalty, Generic Entry and Price Competition in Pharmaceuticals in the Quarter Century After the 1984 Waxman-Hatch Legislation 4, 9-10 & 10 fig.2 (NBER Working Paper No. 16431, October 2010), <http://www.nber.org/papers/w16431.pdf>.

15% to the 20% of the name-brand cost,<sup>14</sup> and as low as 10% of the original price when many generic entrants are present. In 2012 alone, the FDA estimated that generics saved consumers over \$217 billion.<sup>15</sup>

On the other side of the coin, generic introduction is devastating to the revenues of the brand-name drug maker. In the year after generic entry, the brand-name drug can lose between 80% and 90% of its market share.<sup>16</sup> With many popular brand-name drugs bringing in over \$1 billion in U.S. revenue a year for drug manufacturers, the loss of a monopoly market—often known as the “patent cliff” when it coincides with patent expiration—can lead to the near-instantaneous loss of a company’s largest revenue streams. This balance, however, is written into the U.S. patent system itself: in return for publicly disclosing its invention, a pharmaceutical company receives a *limited-time* grant of exclusivity to help recoup the costs of research and development and (hopefully) incentivize further innovation. For pharmaceutical companies, all good things must come to an end.

However, complexities in the U.S. regulatory pathway for generic entry, known as Hatch-Waxman, have changed the calculus for many pharmaceutical companies. It appears that some companies are no longer solely competing on the basis of innovation but also on their ability to manipulate existing regulation. Rather than placing bets on risky, expensive drug development pipelines, companies are driven to block generic entry by any means possible, reclaiming

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<sup>14</sup> *Facts About Generic Drugs*, U.S. FOOD AND DRUG ADMINISTRATION, <http://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/UnderstandingGenericDrugs/ucm167991.htm> (last visited Dec. 9, 2015).

<sup>15</sup> GENERIC PHARMACEUTICAL ASS'N., *GENERIC DRUG SAVINGS IN THE U.S.* (2013), [http://www.gphaonline.org/media/cms/2013\\_Savings\\_Study\\_12.19.2013\\_FINAL.pdf](http://www.gphaonline.org/media/cms/2013_Savings_Study_12.19.2013_FINAL.pdf) (data supplied by IMS Health).

<sup>16</sup> See Berndt & Aitken, *Brand Loyalty, Generic Entry and Price Competition in Pharmaceuticals*, at 9 & 10 fig. 2; Henry G. Grabowski *et al.*, *Evolving Brand-Name and Generic Drug Competition May Warrant a Revision of the Hatch-Waxman Act*, 30 HEALTH AFF. 2157, 2163 (2011).



enormous profits and expending far less money and effort than is required to develop new drugs. Even a few months of delay—and thus a few additional months of monopoly profits—can be worth hundreds of millions of dollars, so the temptation is clear.

To block generic entry, companies are using ever more clever and complicated strategies to extend periods of monopoly and duopoly sales. Not all generic entry disputes are concerning or even malicious in nature. Hatch-Waxman provides a system by which prospective generic manufacturers can challenge brand-name patents even before patent expiration, and when companies preserve their existing exclusivity by reasserting the validity of their patents, that behavior is appropriate and fully in line with the goals of intellectual property. After all, if patent rights were found to have no actual enforcement power in practice—and generics could enter at any point—no one would see patents as providing a legitimate incentive for innovation. However, when pharmaceutical firms use tactics to unlawfully prevent generic entry—or block generics from even challenging brand-name companies—the behavior undermines the patent system by imposing costs on society. The public loses billions of dollars in savings, patients are unable to afford prescriptions that would otherwise have generic equivalents, and resources are diverted away from actual innovation activities such as drug development.

At first, strategies to prevent generic entry took the form of “pay-for-delay” settlements: brand-name pharmaceutical companies would pay generic competitors to *stay out* of the market, essentially providing the generic a share of the monopoly profits greater than the generic would earn in a duopoly or competitive market. While pure cash pay-for-delay deals have begun to lose prominence, especially as they face suspicion from government agencies, pharmaceutical companies have made settlements involving generic delay by using more opaque forms of payment. These deals can involve settling multiple cases at once to mask the value being

transferred or deals where a generic company is overpaid to promote, manufacture, or supply materials for drugs sold by the brand-name company in exchange for generic delay.

New tactics no longer focus on making deals with would-be generics; instead, the goal is to obstruct generics by using trivial or minor drug modifications, U.S. Food and Drug Administration processes, and regulatory abuse to extend monopoly franchises and prevent generic access. In many instances, the timing and deployment of these tactics seem clearly geared toward generic delay, hidden behind ulterior motives of safety concerns or improved drug efficiency. Strategies include filing “citizen petitions” with the FDA cautioning against on generic approval with the knowledge that even a baseless petition will take months to review and deny. Other strategies include “REMS”-based delay where a pharmaceutical company cites FDA-imposed safety restrictions as a reason for not providing samples to generic manufacturers. Others involve “product hopping” schemes where a company switches consumers to a slightly different form of an existing drug (*e.g.* extended-release, a new tablet formulation) just before generic entry to severely constrain the market for the generic. And finally, companies engage in “multiplicity tactics,” whereby a number of these strategies are deployed at once. These mechanisms, and the complex legislative and regulatory framework that allow for their development, help to maintain pharmaceutical pricing and avoid competitive entry. Further, Hatch-Waxman does not have the proper enforcement safeguards against abuse. Rather, most changes to the pathway have been “hole-plugging” measures that patch over long-standing problems, rather than forward-looking measures that prevent further exploitation.

## **Conclusion**

As described above, the complexity of U.S. litigation and regulatory frameworks have provided fertile ground for strategic behavior that can have negative innovative effects. These types of complexity tend to reward large players and repeat players, at the expense of smaller—and sometimes more innovative—entities. Regardless of the level of innovative industry for any nation, creation of new products is the optimal developmental approach. As we develop regional and global intellectual property frameworks, the focus should be on streamlining complexity and the creation of new products, rather than the creation of new intellectual property games and stripped markets. In this era of mega-regionalism, we want to export the strengths of the U.S. intellectual property system and not its flaws to the world.