

## INTELLECTUAL PROPERTY RIGHTS: THE VIEW FROM COMPETITION POLICY

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Three propositions inform the debate over the relationship between intellectual property rights and competition policy. The first involves concerns over how the anticompetitive uses of intellectual property will increase as intellectual property rights become stronger. The second is that the uses of competition norms to loosen intellectual property rights will diminish the incentives for innovation. Finally, there is the belief that the tension between competition policy and intellectual property rights can be reconciled by recognizing how market competition is consistent with innovation and by acknowledging the competition norms that shape the scope of intellectual property rights. In this Essay, I examine these three propositions and their application to the preliminary report on the pharmaceutical industry released by the European Commission on November 28, 2008.<sup>1</sup>

### I. SCRUTINIZING THREE PROPOSITIONS

The first proposition—that anticompetitive uses of intellectual property will increase as intellectual property rights become stronger—should not be read as an anti intellectual property comment. The quantity of rhetoric that is critical of intellectual property rights is unfortunate, as is the view that competition law, particularly United States antitrust law, is antithetical to the goals of intellectual property. Nonetheless, as intellectual property rights grow stronger through legislative changes and judicial interpretations, the opportunity for abusing the right to exclude, through licensing and other practices, does increase. In addition, stronger intellectual property protections can lead to market concentration as firms become able to realize economies of scale and scope through the exercise of intellectual property rights. Increased market concentration invites increased scrutiny from competition policymakers.

The second proposition—that the uses of competition norms to loosen intellectual property rights will diminish the incentives for innovation—is a tautology that often follows from the arguments in favor of strong intellec-

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<sup>1</sup> EUROPEAN COMMISSION, PHARMACEUTICAL SECTOR INQUIRY: PRELIMINARY REPORT (2008), [hereinafter PRELIMINARY REPORT] available at [http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/preliminary\\_report.pdf](http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/preliminary_report.pdf) (link).

tual property rights. If one accepts the claim that intellectual property rights create incentives for innovation, then weaker intellectual property rights logically should reduce incentives to innovate. The problem, however, is that there is no simple linear relationship between intellectual property rights and innovation. Cumulative and serial innovation can be hampered by strong intellectual property rights.<sup>2</sup> Furthermore, strong rights can create entrenched business models that are often difficult to displace through business and technological innovation.<sup>3</sup>

Nonetheless, the second proposition is worth bearing in mind. First, it is an argument that needs to be confronted as competition policy more aggressively challenges intellectual property rights. Second, even without a simple linear relationship between the strength of intellectual property rights and innovation incentives, there is the concern that policymakers fixated on competition may be overly aggressive and lose sight of how competition policy affects innovation markets. The experience in the United States with IBM in the 1970s is an example of how competition policy can lose its focus in ensuring that markets remain dynamically competitive.<sup>4</sup>

The third proposition—the idea that the tension between competition policy and intellectual property rights can be reconciled by recognizing how market competition is consistent with innovation and by acknowledging the competition norms that shape the scope of intellectual property rights—synthesizes the tensions described in the first two. Reconciling intellectual property and competition policy requires recognizing that intellectual property law is a form of competition policy.<sup>5</sup> The arguments for recognizing intellectual property as a type of competition policy extend beyond market competition and include rivalries between competing artists or between nonprofit entities, such as universities.<sup>6</sup> However, if the focus is on the context of market competition, which is the primary concern of competition policy, then we see that intellectual property rights shape the structure of and conduct within markets based on exchange and price mechanisms in two ways.

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<sup>2</sup> See SUZANNE SCOTCHMER, *INNOVATION AND INCENTIVES* 156–57 (2004) (describing incentive structures for cumulative and serial innovation).

<sup>3</sup> See Michael J. Madison, *Intellectual Property and Americana, or Why IP Gets the Blues*, 18 *FORDHAM INTELL. PROP. MEDIA & ENT. L.J.* 677, 708–10 (2008) (discussing intellectual property and the protection of business models).

<sup>4</sup> See WILLIAM H. PAGE & JOHN E. LOPATKA, *THE MICROSOFT CASE: ANTITRUST, HIGH TECHNOLOGY, AND CONSUMER WELFARE* 243–44 (2007).

<sup>5</sup> See e.g., Shubha Ghosh, *Competitive Baselines for Intellectual Property Systems*, in *INTERNATIONAL PUBLIC GOODS AND TRANSFER OF TECHNOLOGY UNDER A GLOBALIZED INTELLECTUAL PROPERTY* 793, 795–802 (Keith E. Maskus & Jerome Reichman eds., 2004) (arguing that intellectual property rights and competition policy are inseparable).

<sup>6</sup> *Id.* at 795 (discussing the role of competition in intellectual property systems).

First, intellectual property rights resolve market failures that arise in information-based transactions.<sup>7</sup> In any market transaction requiring the transfer of information, either by itself or in addition to an exchange of a product or service, parties to the transaction face two types of potential market failures. The first type of failure is the appropriation problem, created by positive externalities that arise from the actual information itself. The second is the revelation problem, generated by the lack of incentives to reveal the information unless the party receiving the information will pay consideration for it. Intellectual property rights solve both of these problems by creating a right to exclude others from using or distributing the information. This right to exclude enables the owner of the intellectual property to appropriate enough return to develop and distribute the information. The exclusion right also allows the owner to reveal the information, with protections of legal recourse, should the information be misappropriated. By resolving these market failures, intellectual property rights protect owners in the context of competitive markets, which in turn promotes the dissemination of socially valuable information.

The second effect intellectual property rights have on market competition is also a by-product of the right to exclude. The right to exclude, in the context of a competitive market, can serve as a legal barrier to entry for new products, technologies, and business methods. Too broad a construction of intellectual property rights can hinder the very markets that are made possible by the rights.<sup>8</sup> Therefore, it is important to construe intellectual property rights narrowly so that they do not interfere with either dynamic entry into, or required exit from, the markets. This requires defining intellectual property rights in a way that is consistent with a dynamic market environment and necessary for healthy innovation.

Scrutinizing the three propositions closely yields an important conclusion: intellectual property is about competition policy. Innovation occurs through competition, and intellectual property rights ensure effective, dynamic competition. This is why intellectual property rights must be defined in a way that is consistent with dynamic market competition. If constructed too strongly, intellectual property rights can interfere with competition. If constructed too weakly, intellectual property rights may not adequately resolve the market failures that bedevil markets for information. The challenge is to design rules both within intellectual property law (the substantive law of patents, copyrights, trademarks, and trade secrets) and outside intellectual property law (substantive competition law) that promote

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<sup>7</sup> See Kenneth Arrow, *Economic Welfare and the Allocation of Resources for Invention*, in THE RATE AND DIRECTION OF INVENTIVE ACTIVITY: ECONOMIC AND SOCIAL FACTORS 609, 616–19 (Nat'l Bureau of Econ. Research ed. 1962) (explaining how the property rights system can address market failure for information).

<sup>8</sup> See *id.* (arguing that property rights in information can also have anticompetitive effects).

dynamic competitive markets. To this end, the recent preliminary report on pharmaceuticals from the European Commission provides a useful lesson.<sup>9</sup>

## II. LESSONS FROM PHARMACEUTICAL MARKET POLICY

At the outset, reconciliation of intellectual property and competition law may seem facile. If the answer were so simple, why is the controversy often so heated? The answer lies in the conflicting visions of competition that underlie competition law on the one hand and intellectual property law on the other. Competition law, particularly United States antitrust law, understands market competition as competition based on price and among small sized firms.<sup>10</sup> Intellectual property law, by contrast, often involves competition among large or mid-sized firms and operates on variables other than price, such as quality.<sup>11</sup> The tension between these two bodies of law does not rest on a commitment to norms of competition but on how competition operates in practice. Debates over pharmaceutical markets demonstrate this conflict.

Arguments in favor of strong pharmaceutical patents echo natural monopoly arguments for regulation.<sup>12</sup> The high fixed costs of pharmaceutical research and development and the low marginal cost of producing a pharmaceutical compound, once discovered, combine to create a firm level cost structure that requires developing pharmaceutical companies to recoup costs of production through some form of regulation.<sup>13</sup> The exclusivity of strong patent rights allows a firm to recoup its costs through above marginal cost pricing for a pharmaceutical compound. The economic rents that are realized through this pricing strategy permit the firm to recoup the fixed cost of its research and development investment and to stave off the effects of destructive competition that would drive price to the negligible marginal cost of production.

Critics of strong pharmaceutical patents also typically invoke principles of natural monopoly theory. Often, distributional or equity arguments are used to advocate a weakening of patent rights. In addition, the moral hazard of gold plating, or raising costs of production, is asserted in response to the arguments in favor of strong patents. Advocates for weaker rights contend that patent rights will become perhaps too strong, as patent

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<sup>9</sup> See PAGE & LOPATKA, *supra* note 4, at 5 (identifying strategies by pharmaceutical companies that are potentially anticompetitive).

<sup>10</sup> See, e.g., Donald F. Turner, *The Definition of Agreement Under the Sherman Act: Conscious Parallelism and Refusals To Deal*, 75 HARV. L. REV. 655, 663–73 (1962) (arguing that structural failures in certain markets require antitrust laws to break up large firms).

<sup>11</sup> See, e.g., Christopher Yoo, *Copyright and Product Differentiation*, 79 N.Y.U. L. REV. 212, 236 (2004) (showing how monopolistic competition model fits market for copyrighted works).

<sup>12</sup> See Shubha Ghosh, *Decoding and Recoding Natural Monopoly, Regulation, and Intellectual Property*, 2008 U. ILL. L. REV. 1125, 1138–42 (discussing a natural monopoly metaphor in patent law) (link).

<sup>13</sup> See *id.* at 1171–72.

owners have incentive to ratchet up patent protection at the expense of access and competition in the marketplace.<sup>14</sup> Put another way: if patents in the pharmaceutical industry represent a type of natural monopoly regulation, then patent law needs to be deregulated through various political and market mechanisms.

The problem with these well-worn arguments is that the positions are irreconcilable. Patents are either too weak or too strong. If the goal is one of moderation, the natural monopoly-based debate does not provide much guidance on how to effectively design patent rights. The focus should be on creating an innovative and dynamic market for pharmaceuticals while recognizing that rules are necessary for this marketplace. When the problem is understood in this way, the Preliminary Report from the European Commission offers much hope for how competition policy can inform intellectual property law.

The Report, extending over 400 pages, begins with a simple and noteworthy observation: from 2000–2007, aggregate expenditure on pharmaceuticals among the 17 member countries would have been €14 billion higher without generic competition; without the impediments to generic entry, the report estimates that the savings could have been €3 billion more.<sup>15</sup>

Four impediments affect the market for pharmaceutical products. Three of them affect the market for generics, and the fourth, the market for the originating pharmaceutical. The first impediment involves originating pharmaceutical companies allegedly pursuing patent clusters, or multiple patenting over variations of the pharmaceutical compound.<sup>16</sup> This patent cluster (or patent thicket, as it is also called) makes it difficult for generic companies to enter the market for the pharmaceutical. The cluster creates a minefield of legal rights that the potential entrant must negotiate.<sup>17</sup> These legal rights bring about the second impediment: patent litigation started by the originating company, leading to settlements which delay the market entry of generic firms.<sup>18</sup> In addition to potential and actual litigation, the third barrier for generic drugs consists of regulatory hurdles, such as drug approval and the approval process for reimbursements from nation state health plans.<sup>19</sup> Finally, the report finds that originating drug companies engage in a pervasive practice of defensive patenting, that is, obtaining patents solely to block a competitor from being able to market a potentially competing compound.<sup>20</sup> Pharmaceutical companies, the report concludes, engage in a

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<sup>14</sup> See *id.* at 1172.

<sup>15</sup> See PRELIMINARY REPORT, *supra* note 1, at 6.

<sup>16</sup> See *id.* at 5.

<sup>17</sup> See *id.*

<sup>18</sup> See *id.* (noting nearly 700 reported cases of patent litigation from 2000 to 2007).

<sup>19</sup> See *id.* (discussing originator company intervention in the national processes for approval as a tool used to delay market entry by companies producing generic pharmaceuticals).

<sup>20</sup> *Id.* at 6.

strategy of patenting designed to extend the revenue stream of existing compounds.<sup>21</sup>

The comparison with the market for generics in the United States is striking. According to the report, drug prices in Europe drop by about 25% below the price of a branded drug as generics begin to enter, and by about 40% within a year of entry.<sup>22</sup> By contrast, prices in the United States often drop by about 80% within a year of entry.<sup>23</sup> This difference suggests more aggressive competition in the United States, made possible by the structure of regulation and intellectual property rights to promote competition. The contrast in pricing suggests that there may be anticompetitive behavior among generic firms. In addition to addressing the four impediments noted in the report, aggressive investigation of generic firms is required.<sup>24</sup>

Policy recommendations addressing impediments to generic competition illustrate how competition policy norms inform the structure of intellectual property rights. The report focuses on three institutional changes, one addressing bottlenecks to pharmaceutical regulation, and two dealing with patent reform. The patent-related reforms are relevant to this Essay. Addressing the complexity created by multiple patent laws among the member states of the European Union, the report recommends creating a single European-wide patent system and a single unified judiciary specializing in patent law,<sup>25</sup> presumably modeled on the U.S. Court of Appeals for the Federal Circuit. Both originating and generic pharmaceutical companies support these measures as means of simplifying and streamlining the patent process,<sup>26</sup> but perhaps also as a way to preempt more aggressive competition law remedies. These structural changes are important considerations and may address the complexity created by patent clusters. There are, however, two important caveats to these proposals and one critical reform that the report does not fully address.

While a unified patent office and patent judiciary for the European Union have immediate appeal, they are insufficient unless accompanied by substantive reforms that introduce competition norms into the patent system. First, the proposed unified patent system needs to provide a fairly thorough and aggressive means of policing patent applications to ensure that patents are granted to truly novel and inventive pharmaceutical compounds. Achieving this goal would require strong funding to provide a thorough compilation and review of the prior art, along with fairly aggressive scrutiny of patent applications, to avoid the creation of patent clusters. The work of examiners may need to be complemented by input from various consti-

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<sup>21</sup> *Id.* at 5.

<sup>22</sup> *Id.* at 8.

<sup>23</sup> *Patently Absurd*, ECONOMIST, Dec. 6, 2008, at 92 (link).

<sup>24</sup> *See id.*

<sup>25</sup> *See id.* at 15.

<sup>26</sup> *Id.*

tencies affected by the grant of a patent. The use of post-grant, or even pre-grant, opposition would be desirable to provide additional scrutiny of patents and patent applications before they become the basis for anti-competitive litigation.

Second, a unified patent judiciary is a mixed-blessing. Streamlining patent law development and enforcement has obvious benefits, but these benefits may come at the expense of creating an entrenched court that has its own infighting and agenda. The United States experience with the Federal Circuit is demonstrative. Its success is in part due to the caliber of many of the judges on the bench and the fact that the United States Supreme Court provides some oversight (the importance of which was demonstrated by the *Festo*<sup>27</sup> decision in 2002 and the *eBay*<sup>28</sup> and *Independent Ink*<sup>29</sup> decisions in 2006). The concerns with the Federal Circuit arise from the inability of expertise to resolve fundamental questions about patent law, such as claim construction and the nonobviousness doctrine.<sup>30</sup> The last two matters may remain unresolved through expertise, and may require more aggressive legislative action. Finally, the Federal Circuit has not been supportive of competition policy norms in patent law, as its 2000 decision in the *Xerox* litigation illustrates.<sup>31</sup> The court's position may be the result of creating a specialized court whose ostensible job is to protect patents. A specialized court may be the institutional basis for strengthening patent rights, rather than using patent rights as an instrument for creating dynamic, innovative, and competitive markets.

One important substantive change for any unified patent judiciary is greater scrutiny of injunctive relief. In 2006, the United States Supreme Court ruled in *eBay Inc. v. MercExchange, L.L.C.*<sup>32</sup> that a patent injunction is a discretionary, and not a mandatory, remedy.<sup>33</sup> This ruling put the United States at odds with all other patent jurisdictions. The Preliminary Report indicates that over the 2000–2007 period, injunctive relief was granted in just under half the litigated cases. While this result is consistent with civil litigation models showing a fifty-fifty split in the success rate for plaintiffs, if the Commission is correct about patent litigation being a serious impediment to the entry of generic competition, then there is a strong argument

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<sup>27</sup> *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722 (2002) (link).

<sup>28</sup> *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388 (2006) (link).

<sup>29</sup> *Ill. Tool Works Inc. v. Indep. Ink, Inc.*, 547 U.S. 28 (2006) (link).

<sup>30</sup> See David L. Schwartz, *Practice Makes Perfect?: An Empirical Study of Claim Construction Reversal Rates in Patent Cases*, 107 MICH. L. REV. 223, 259–60 (2008) (discussing claim construction indeterminacy despite Federal Circuit expertise); Gregory Mandel, *The Non-Obvious Problem: How The Indeterminate Nonobviousness Standard Produces Excessive Patent Grants*, 42 U.C. DAVIS L. REV. 57, 100–01 (2008) (discussing indeterminacy of nonobviousness standard despite Federal Circuit expertise).

<sup>31</sup> *In re Indep. Service Orgs. Antitrust Litig. CSU, L.L.C.*, 203 F.3d 1322 (Fed. Cir. 2000).

<sup>32</sup> 547 U.S. 388 (2006) (link).

<sup>33</sup> *Id.* at 394.

that injunctive relief should be discretionary, particularly in the area of pharmaceuticals.

The debate in the United States, over the exercise of judicial discretion in the context of patent injunctions, is revealing. The Federal Circuit's decision in *eBay* held that patent injunctions should be granted in all but extraordinary circumstances. The health concerns raised by pharmaceuticals would satisfy the narrow exception proposed by the Federal Circuit. The Supreme Court, in expanding judicial discretion, split three ways over how that discretion should be exercised when granting injunctive relief for patent infringement. The majority opinion urged courts to follow the traditional four-factor approach (irreparable injury, adequacy of legal remedies, balancing of hardships, and public interest),<sup>34</sup> while the concurrence by Chief Justice Roberts cautioned that the traditional four-factor test should be applied in light of judicial precedent on patent injunctions.<sup>35</sup> The concurrence by Justice Kennedy, citing the 2004 Federal Trade Commission report on anticompetitive uses of patents, emphasized that judicial discretion should consider the potential anticompetitive uses of the patent injunction.<sup>36</sup> As the Commission builds on its Preliminary Report in fashioning patent reform policy, the U.S. experience with injunctive relief offers an important model for how to address the anticompetitive uses of patent litigation. Denying patent injunctions in the context of anticompetitive litigation would be a linchpin of broader policies dealing with anticompetitive settlements.

#### CONCLUSION

The Preliminary Report is an important document that signals further enforcement activity in the pharmaceutical industry. As the Report is developed and implemented, the authors should remain mindful that competition policy informs not only formal competition law, but also the doctrine and practice of intellectual property law. Although this Essay touches only on a few salient points, it clearly shows the case for designing patent rights specifically—and intellectual property rights generally—as tools to foster a dynamic competitive market. Whether competition is fostered through competition law or the design of intellectual property rights, it is the promise of entry—not the promotion of rights—that is the engine for innovation.

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<sup>34</sup> *Id.* at 391.

<sup>35</sup> *See id.* at 394–95.

<sup>36</sup> *See id.* at 396–97.