

## **COMMENT OF U.S. FEDERAL TRADE COMMISSIONER JOSHUA D. WRIGHT AND JUDGE DOUGLAS H. GINSBURG ON THE CANADIAN COMPETITION BUREAU'S DRAFT UPDATED INTELLECTUAL PROPERTY ENFORCEMENT GUIDELINES**

This comment is submitted in response to the Canadian Competition Bureau's (the Bureau's) draft stage 2 update of its Intellectual Property Enforcement Guidelines (Draft Updated Guidelines).<sup>1</sup> We appreciate the opportunity to comment and commend the Bureau for its transparency. We submit this comment based upon our extensive experience and expertise in antitrust law and economics generally, and specifically with respect to the intersection of intellectual property and antitrust.<sup>2</sup>

This comment addresses five issues in the Draft Updated Guidelines: (1) product switching in the context of pharmaceutical patents; (2) settlement of patent infringement litigation between competitors, commonly referred to as "reverse-payment settlements"; (3) deceptive failure to disclose patents essential to a standard, commonly referred to as "patent ambush"; (4) renegeing on a commitment to license a standard-essential patent (SEP) on fair, reasonable, and nondiscriminatory (FRAND) terms; and (5) seeking injunctive relief against infringement of a FRAND-encumbered SEP.

### **I. PRODUCT SWITCHING**

Example 9 of the Draft Updated Guidelines specifies that the Bureau will not view product switching—defined as a brand name manufacturer seeking to switch demand from a drug Product A, with expiring patent protection, to drug Product B, which has a longer term of patent protection by withdrawing Product A from the market—as a "mere exercise of its patent right and thereby exempt [from competition law scrutiny] under section 79(5)." Instead, the Bureau will apply a standard competition law analysis, considering market definition and market power, competitive effects, and proffered business justifications.

For the following reasons, we respectfully recommend against imposing a competition law sanction on product switching absent clear and convincing objective evidence that Product B represents a sham innovation with zero or negative consumer welfare benefits. We urge the Bureau to revise Example 9 to specify that absent such evidence it will, in its prosecutorial discretion, treat product substitution as falling within the exemption for "mere exercise" of a patent right under Section 79(5).

First, while it is plausible that product switching may under narrowly defined

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<sup>1</sup> The views reflected in this statement are our own and do not necessarily represent the views of the Commission or any other Commissioner. The Draft Updated Guidelines are available at <http://www.competitionbureau.gc.ca/eic/site/cb-bc.nsf/eng/03935.html>.

<sup>2</sup> Wright is a United States Federal Trade Commissioner, antitrust law professor, and Ph.D. economist. Ginsburg is a Senior Judge on the United States Court of Appeals for the District of Columbia and former head of the Antitrust Division of the United States Department of Justice. Both are professors at the George Mason University School of Law and have each written extensively on the law and economics of regulation, intellectual property rights, and antitrust.

circumstances constitute exclusionary conduct, applying a standard competition law analysis is likely to deter innovation that would have benefitted consumers. It is well-established that innovations, including even small changes in product design, can generate significant consumer benefits, and that such changes are consistent with the normal competitive process. For example, new drug formulations may involve changes that appear small but are of significant benefit to consumers or are critical stepping-stones to potentially life-saving inventions.<sup>3</sup> Therefore, potential competition law liability for introducing new formulations or introducing minor product design changes risks chilling future innovation that could yield significant consumer benefits.

Competition law is not a suitable instrument for micromanaging product design and innovation. Imposing competition law liability upon new product introductions requires competition agencies and courts to weigh the benefits to consumers from the innovation against any costs to consumers arising from the diminution of competition. Not only are agencies and courts ill-equipped to make such determinations, but it is also unclear whether the balancing contemplated by a rule prohibiting anticompetitive product switching can be done at all. Courts in the United States have recognized these difficulties. As a United States district court recently explained, “[t]he prospect of costly and uncertain litigation every time a company reformulates a brand-name drug would likely increase costs and discourage manufacturers from seeking to improve existing drugs.”<sup>4</sup> United States appellate courts have advised against applying an antitrust law sanction to product design decisions more generally. For example, the U.S. Court of Appeals for the Ninth Circuit recently cautioned that “[t]o weigh the benefits of an improved product design against the resulting injuries to competitors is not just unwise, it is unadministrable. There are no criteria that courts can use to calculate the ‘right’ amount of innovation, which would maximize social gains and minimize competitive injury.”<sup>5</sup> Similarly,

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<sup>3</sup> See, e.g., Jerry A. Hausman, *Valuation of New Goods Under Perfect and Imperfect Competition* in *THE ECONOMICS OF NEW GOODS* (Timothy F. Bresnahan & Robert J. Gordon eds., Univ. of Chicago Press, 1996); Ernst R. Berndt, Iain M. Cockburn & Karen A. Grépin, *The Impact of Incremental Innovation in Biopharmaceuticals: Drug Utilisation in Original and Supplemental Indications*, 24(2) *PHARMACOECONOMICS* 69-86 (2006) (studying data on drug utilization by diagnosis for the period 1999-2004 combined with data on the approval histories of three important classes of drugs, and finding that: (1) incremental innovation to existing pharmaceutical products in the form of new dosages, formulations, and indications account for a substantial share of drug utilization and associated economic and medical benefits; and (2) all three drug classes studied have been approved for numerous new indications, some targeting markedly distinct populations from that of the original indication, significantly increasing the economic and medical benefits of these drugs).

<sup>4</sup> Memorandum at 28, *Mylan Pharm., Inc. v. Warner Chilcott Public Ltd. Co.*, No. 12-3824, (E.D. Pa. Apr. 16, 2015) (rejecting a claim of anticompetitive product switching, finding, among other things, that the alleged product switch did not amount to exclusionary conduct), *available at* <http://www.paed.uscourts.gov/documents/opinions/15d0331p.pdf> [hereinafter *Mylan Memo*].

<sup>5</sup> *Allied Orthopedic Appliances, Inc. v. Tyco Health Care Group LP*, 592 F.3d 991, 1000 (9th Cir. 2010); see also *United States v. Microsoft Corp.*, 147 F.3d 935, 948 (1998) (“Antitrust scholars have long recognized the undesirability of having courts oversee product design, and any dampening of technological innovation would be at cross-purposes with antitrust law.”). On the difficulties associated with assessing the optimal amount of innovation from an antitrust perspective, see Douglas H. Ginsburg & Joshua D. Wright, *Dynamic Analysis and the Limits of Antitrust Institutions*, 78 *ANTITRUST L.J.* 1, 12 (2012) and Joshua D. Wright, *Antitrust, Multi-Dimensional Competition, and Innovation: Do We Have*

the U.S. Court of Appeals for the Second Circuit warned that “no one can determine with any reasonable assurance whether one product is ‘superior.’”<sup>6</sup>

In our experience, even the most economically sophisticated competition agencies are not equipped to make such determinations and to displace the judgment upon the value of product design changes levied by consumers in the market. The economic analysis upon which antitrust liability for product switching is premised requires the agency or court to assess the tradeoff between consumer benefits of new pharmaceutical formulations and the premium consumers pay for the new branded product relative to the hypothetical generic price for the old formulation. In this sense, the product-switching theory places the competition agency or court in the role of price regulator. This is a complex and difficult task rendered even more difficult by the fact that what appear to be a minor product improvement can generate a significant gain in consumer welfare. Relying upon a competition agency to engage in ex post valuation of a product design change and weigh it against the reduction in competition and the resulting anticompetitive effects can only reduce the incentive to innovate or distort those incentives towards blockbuster innovations rather than reformulations that may result in incremental but significant consumer benefits.

Second, in general, product switching does not amount to exclusionary conduct because the generic company is still free to compete and is “able to reach consumers through, *inter alia*, advertising, promotion, cost competition, or superior product development.”<sup>7</sup> Example 9 recognizes as much, yet states that because Product A is the reference product for (or bioequivalent of) Generic A, generic companies cannot take advantage of automatic substitute laws. But, as the court in *Mylan Pharmaceuticals v. Warner Chilcott* explained, brand companies “have no duty to facilitate” a generic company’s free-riding on the brands’ promotional efforts by keeping older versions of their product on the market, and competition law does not require that a generic company be permitted to distribute its product through

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*an Antitrust-Relevant Theory of Competition* in REGULATING INNOVATION: COMPETITION POLICY AND PATENT LAW UNDER UNCERTAINTY (Geoffrey A. Manne & Joshua D. Wright eds., Cambridge Univ. Press, 2009).

<sup>6</sup> *Berkey Photo, Inc. v. Eastman Kodak Co.*, 603 F.2d 263, 287 (2d Cir. 1979).

<sup>7</sup> *Mylan Memo*, *supra* note 4, at 25-29. *But see* *New York v. Actavis plc*, No. 14-4624, at 40-41 (2nd Cir. May 22, 2015), available at [www.ca2.uscourts.gov/decisions/isysquery/a48130f2-3d3d-4da4-b90b-70ca54de403b/1/doc/14-4624\\_redacted\\_opn.pdf#xml=http://www.ca2.uscourts.gov/decisions/isysquery/a48130f2-3d3d-4da4-b90b-70ca54de403b/1/hilite/](http://www.ca2.uscourts.gov/decisions/isysquery/a48130f2-3d3d-4da4-b90b-70ca54de403b/1/doc/14-4624_redacted_opn.pdf#xml=http://www.ca2.uscourts.gov/decisions/isysquery/a48130f2-3d3d-4da4-b90b-70ca54de403b/1/hilite/) [hereinafter *Actavis*]. The court of appeals in *Actavis* held the trial court did not abuse its discretion by issuing a preliminary injunction that barred a brand company from withdrawing its branded drug from the market. In so holding, the court credited the trial court’s finding that “competition through state drug substitution laws is the only cost-efficient means of competing available to generic manufacturers” (*Actavis* at 40-41) and then held that U.S. antitrust law “requires [brand companies] to allow generic competitors a fair opportunity to compete using state substitution laws” (*id.* at 47). The district court’s finding is not supported by empirical evidence and its statement of the law is contrary to the teaching of the United States Supreme Court, which has explicitly held that the antitrust laws do not impose a general duty to aid one’s rivals. *See Verizon Commc’ns Inc. v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398, 415 (2004).

automatic substitution laws.<sup>8</sup>

Third, a related problem is that an anticompetitive product-switching theory does not only involve agencies and courts performing their own complex analysis of the value of product design changes; it means substituting their judgment for the judgment made by consumers in the marketplace. An anticompetitive product-switching theory assumes consumers (here, both prescribing doctors and patients) are incapable of determining the value of a pharmaceutical product improvement and adequately responding in their own best interests. This most remarkably assumes that pharmaceutical markets are somehow so different from other product markets that producers are free to ignore consumer judgments about the value of product innovations and should be forced to defer to the judgment of a competition agency or court as to whether the premium charged for the innovative version of the drug is worth whatever benefit it confers. For these reasons, we respectfully urge the Bureau, in the exercise of its prosecutorial discretion, to refrain from imposing a competition law sanction for introducing a drug product innovation absent clear and convincing objective evidence that the new formulation resulted in no or negative consumer welfare benefits.

Lastly, we respectfully urge that Example 9 be further revised to distinguish between a “hard” switch (e.g., removing Product A from the market and the formulary list such that generic companies cannot take advantage of automatic substitution laws) and a “soft” switch (e.g., aggressively attempting to persuade patients and doctors to switch to Product B, by means such as offering rebates and other discounts, while allowing Product A to remain on the market and the formulary list). While it is plausible that the former may under certain narrowly defined circumstances constitute exclusionary conduct, the latter amounts to no more than competition on the merits. As the U.S. Court of Appeals for the Second Circuit recently explained, “[a]s long as [the brand] sought to persuade patients and their doctors to switch from [Product A] to [Product B] while both were on the market (the soft switch) and with generic . . . drugs on the horizon, patients and doctors could evaluate the products and their generics on the merits in furtherance of competitive objectives.”<sup>9</sup> In short, imposing a competition law sanction on soft switches would punish the very type of competition the Competition Act is intended to promote.

In sum, when regulators and courts encounter a sham innovation—when there is clear and convincing objective evidence that the reformulation has no or negative consumer welfare benefits—they do not need to weigh any increased costs consumers face against the consumer benefits typically associated with new products because the benefit is nil; but extending an anticompetitive product-switching theory beyond sham reformulations necessarily would require such comparisons and, as a result, would place the Bureau in the position of making economic value judgments that are methodologically questionable, fall outside the traditional scope of competition analysis, and are based upon the premise that consumers cannot be relied upon to

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<sup>8</sup> *Mylan Memo*, *supra* note 4, at 24-25.

<sup>9</sup> *Actavis*, *supra* note 7, at 37; *see also Walgreen Co. v. AstraZeneca Pharm.*, 534 F. Supp. 2d 146, 152 (D.D.C. 2008) (dismissing allegations that the brand company’s soft switch amounted to anticompetitive conduct, holding that “[t]he fact that a new product siphoned off some of the sales from the old product and, in turn, depressed sales of the generic substitutes for the old product, does not create an antitrust cause of action”).

make their own assessments of the value of new products and reformulations.

## II. REVERSE-PAYMENT SETTLEMENTS

### A. Criminal Liability

Section 7.2 of the Draft Updated Guidelines specifies that the Bureau may sanction a reverse-payment settlement criminally under Section 45 of the Competition Act when “there is evidence that the intent of the payment was to fix prices, allocate markets or restrict output.” We respectfully recommend against imposing criminal liability (and against the use of a *per se* approach) for reverse-payment settlements because such an approach threatens to over-deter procompetitive conduct. Furthermore, the Bureau’s reliance on intent evidence is misplaced. The proper focus of competition law is not upon the anticompetitive intent of the actor but rather upon the competitive effects of its conduct. As the United States Supreme Court has repeatedly explained, when considering whether to impose a *per se* approach, the relevant inquiry is whether the conduct is so likely to harm competition and to have no significant procompetitive benefits that it does not warrant the time and expense required for a particularized inquiry into its effects.<sup>10</sup> As the Supreme Court recently held in *Federal Trade Commission v. Actavis, Inc., et al.* the underlying economics of reverse-payment settlements do not meet this criterion and instead require a case-by-case effects-based analysis.<sup>11</sup> It is well understood in the economics literature that not all reverse-payment settlements harm competition and some result in increased consumer welfare, as discussed in the paper attached hereto as Appendix A.<sup>12</sup>

### B. Size of the Payment as a Proxy for Likely Anticompetitive Effects

Section 7.2.1 and Example 12 specify that in determining whether but-for the settlement, the brand and generic would have been likely to compete earlier than the generic entry date specified in the settlement, the Bureau “would examine the size of the payment to determine whether it was likely for the purpose of delaying GENERIC’s entry.” For the following reasons, we respectfully recommend that the Bureau revise Section 7.2.1 and Example 12 to specify that

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<sup>10</sup> See, e.g., *Federal Trade Commission v. Superior Court Trial Lawyers Ass’n*, 493 U.S. 411, 432-36 (1990); see also Joshua D. Wright, Comm’r, Fed. Trade Comm’n, Remarks at the Global Competition Review Live 2<sup>nd</sup> Annual IP & Antitrust Conference: Intellectual Property Rights, Truncation, and *Actavis*: Who’s Afraid of the Rule of Reason? at 3 (April 14, 2015) (explaining that “[t]runcated [or per se] analysis is appropriate when it, rather than the full blown or unstructured rule of reason, minimizes the sum of error costs and the administrative costs of adjudicating antitrust claims”), available at [https://www.ftc.gov/system/files/documents/public\\_statements/636901/150414gcr-ip-antitrust.pdf](https://www.ftc.gov/system/files/documents/public_statements/636901/150414gcr-ip-antitrust.pdf).

<sup>11</sup> 133 S. Ct. 2223, 2237-38 (2013) (rejecting a quick look approach and holding that reverse-payment settlement agreements must be analyzed under the rule of reason).

<sup>12</sup> See Bruce H. Kobayashi et al., *Actavis and Multiple ANDA Entrants: Beyond the Temporary Duopoly*, 29(2) ANTITRUST SOURCE 89 (Spring 2015) (attached hereto as Appendix A). The model set forth in this paper emphasizes that the generic entrant that successfully challenges the validity of the patent typically obtains duopoly profits for only the 180-day exclusivity period provided by the U.S. Hatch-Waxman Act. Taking account of the absence of a post-180-day exclusivity period in Canada does not change the conclusion that there are many settlements involving sizable reverse payments in which the brand and the generic entrant have legitimate incentives to settle the case other than to prevent the risk of competition.

it will focus directly upon the anticompetitive effects of a settlement instead of on the purpose of the agreement, and that it will not use the size of the payment as a proxy for the likelihood of anticompetitive effects or the strength of the patent.

First, an inference drawn from the size-of-the-payment is weak at best. For one thing, the economic analyses supporting the inference are based upon a monopoly-to-duopoly model that ignores the possibility of rapid entry by multiple firms that often follows the invalidation of a patent.<sup>13</sup> Once this institutional feature is incorporated into economic models of patent settlement—that is, the single new entrant is not assumed to obtain duopoly profits for the remaining life of the patent, but rather will receive only competitive profits after the invalidation of the patent—the logic supporting the inference from size of payment to anticompetitive effects no longer holds. Rather, economic models of patent settlement that allow for multiple entrants (see Appendix A) show the payoff for the generic entrant that seeks to invalidate the patent is smaller than the monopoly-to-duopoly litigation payoffs generated in the single entrant models. This reduced payoff decreases the incentive for the entrant to litigate and, likewise, the amount for which it will settle. Conversely, because of the collateral estoppel effect, litigating a patent imposes greater losses upon the patentee than is the case when there is a single entrant. This, in turn, increases the litigation risk the patentee faces and, likewise, the amount it will pay to settle. Compared to the single-entrant model, the result is a significantly broader range of settlements in which the brand and the generic entrant have incentives to settle the case other than avoiding the costs of competition, which is the relevant anticompetitive harm. (See Figure 4 at Appendix A.) This broad range of settlements renders ineffective attempts to infer a settlement is anticompetitive based solely upon its size. Incorporating multiple entrants also changes the direct relationship between the litigation-adjusted expected life of the patent and consumer welfare and, most important, weakens the relationship between the strength of the patent and the size of the settlement.

Second, relying upon the size of the payment as a proxy for anticompetitive effects limits the analysis to a static consumer-welfare-only standard that ignores the fact that settlement avoids the incremental private and social costs of litigation. A static consumer welfare standard is incomplete as it ignores direct costs and considers only some of the error costs. The full error costs include the cost of Type I (false positive) and Type II (false negative) errors, as well as dynamic Type I errors, i.e., the cost of forgone innovation due to the reduced incentives that result from the erroneous invalidation of patents and the *in terrorem* settlements paid to avoid that outcome.<sup>14</sup>

In short, as demonstrated by the model in the paper at Appendix A, relying upon the size of the payment as a proxy for anticompetitive harm will erroneously deem anticompetitive some

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<sup>13</sup> *See id.*

<sup>14</sup> The social costs of Type I errors include the forgone benefits of research deterred and of the drugs that would have been produced. The consideration of these costs is a critical component of any legal or normative economic analysis of the patent-antitrust interface. *See, e.g.,* United States v. Glaxo Grp., 410 U.S. 52, 58 (1973) (“It is as important to the public that competition should not be repressed by worthless patents, as that the patentee of a really valuable invention should be protected in his monopoly.”); *see also generally* HERBERT HOVENKAMP ET AL., IP AND ANTITRUST: AN ANALYSIS OF ANTITRUST PRINCIPLES APPLIED TO INTELLECTUAL PROPERTY LAW § 1.3 (Aspen Publishers 2d ed. 2014).

settlements that in fact increase both consumer and total welfare. It also encourages litigants to use other, potentially more inefficient means to settle, and increases the costs of dynamic Type I errors.

### III. PATENT AMBUSH

Section 7.3 and Example 15 of the Updated Draft Guidelines specify that the Bureau will “likely” review patent ambush under Section 79 of the Competition Act. We respectfully recommend that the Bureau revise Section 7.3 and Example 15 to specify that liability will be imposed only when there is proof of the following six elements: (1) the patent holder or applicant is an active voting participant in a standard-setting organization (SSO); (2) the patent holder knows or should know that its patent or pending patent (patent application) may be incorporated into the relevant standard; (3) the patent holder or applicant deliberately conceals information about that patent from the SSO in violation of the SSO’s policies on written disclosures; (4) after adoption of the standard, the patent holder or applicant asserts its standard-essential patents against implementers of mandatory portions of the standard; (5) but for the patent holder’s or applicant’s failure to disclose, a different technology would have been incorporated into the standard; and (6) the patent holder’s or applicant’s conduct causes or is likely to cause an adverse effect upon competition in the relevant market.<sup>15</sup>

The fifth requirement is particularly important. If the technology would have been adopted regardless whether the SEP holder had made the disclosure, then the SEP holder did not prevent or lessen competition in a market. As the U.S. Court of Appeals for the D.C. Circuit explained in *Rambus Inc. v. Federal Trade Commission*, if the SSO would have standardized the technology *even if* the SEP holder had disclosed its intellectual property, then the SSO would have lost

only an opportunity to secure a [F]RAND commitment from [the SEP holder]. But loss of such a commitment is not a harm to competition from alternative technologies in the relevant markets. . . . Indeed, had [the SSO] limited [the SEP holder] to reasonable royalties and required it to provide licenses on a nondiscriminatory basis, we would expect to see *less* competition from alternative technologies, not more; high prices and constrained output tend to attract competitors, not to repel them.<sup>16</sup>

### IV. RENEGING ON A COMMITMENT TO LICENSE A SEP ON FRAND TERMS

Examples 16 and 17 of the Draft Updated IP Guidelines specify that the Bureau is “likely” to analyze the breach of a FRAND commitment (whether committed by the original SEP holder or a successor in interest) under Section 79 of the Act. For the following reasons, we respectfully recommend against imposing a competition law sanction for the mere breach of a FRAND commitment, and urge that Examples 16 and 17 be deleted in their entirety. In the

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<sup>15</sup> See, e.g., *Rambus Inc. v. Federal Trade Commission*, 522 F.3d 456, 464-67 (D.C. Cir. 2008); see also Bruce H. Kobayashi & Joshua D. Wright, *The Limits of Antitrust and Patent Holdup: A Reply to Cary, et al.*, 78 ANTITRUST L.J. 505 (2012) [hereinafter Kobayashi & Wright].

<sup>16</sup> *Rambus Inc.*, 522 F.3d 456 at 466 (emphasis in original).

alternative, at the very least, we recommend that Examples 16 and 17 be revised to specify that liability will be imposed only when there is proof that: (1) the SEP holder engaged in deceptive conduct that resulted in the unlawful acquisition or enhancement of market power; and (2) but for the SEP holder's deception, a different technology would have been incorporated into the standard.

First, contrary to the Bureau's analysis in Examples 16 and 17, reneging on a FRAND commitment does not necessarily involve deception. Rather, the conduct described in Examples 16 and 17 could amount to no more than pure ex-post contractual opportunism when a SEP holder attempts to renegotiate or deviate from the original FRAND commitment made in good faith in to obtain higher royalty rates. That conduct is properly analyzed under contract, not antitrust, law.<sup>17</sup> As the United States Supreme Court explained in *NYNEX Corp. v. Discon, Inc.*, while the evasion of a pricing constraint may hurt consumers, it does not harm the competitive process.<sup>18</sup> The Court distinguished the mere breach of a pricing commitment from the unlawful acquisition or exercise of monopoly power by pointing out that, with the former, the "consumer injury flowed . . . from the exercise of market power that is lawfully in the hands of a monopolist."<sup>19</sup>

Second, as explained in Section III above, if the technology would have been adopted regardless whether the SEP holder had made the deceptive misrepresentation, then the SEP holder did not prevent or lessen competition in a market.

## **V. THE SEEKING OF INJUNCTIVE RELIEF AGAINST INFRINGEMENT OF A FRAND-ENCUMBERED SEP**

Section 7.3 and Example 18 of the Draft Updated Guidelines provide the Bureau will "likely" review seeking injunctive relief against infringement of a FRAND-encumbered SEP that results in anticompetitive patent holdup under Section 79 of the Competition Act. Section 7.3 further states that such potential liability is premised upon concerns that patent holdup may result in "increased prices to consumers of standard-compliant products" and "weaken incentives for firms to participate in procompetitive standard setting activity generally." For the following reasons, we respectfully recommend against imposing a competition law sanction for seeking injunctive relief, and urge that any suggestion to that effect be deleted in its entirety from the Updated Guidelines.

First, as explained below, there is no empirical evidence to support the concerns raised in Section 7.3. Second, imposing a competition law sanction is likely to reduce incentives to innovate and deter SEP holders from participating in standard setting, thereby depriving consumers of the substantial procompetitive benefits of standardized technologies. Indeed, any liability theory that would require a SEP holder to prove that an accused infringer is an unwilling licensee threatens to deter participation in standard setting, particularly if an accused infringer

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<sup>17</sup> See, e.g., Bruce H. Kobayashi & Joshua D. Wright, *Federalism, Substantive Preemption, and Limits on Antitrust: An Application to Patent Holdup*, 5(3) J. COMPETITION LAW & ECON. 469, 493-501 (2009).

<sup>18</sup> 525 U.S. 128, 135-37 (1998). See also Kobayashi & Wright at 519-20, *supra* note 15.

<sup>19</sup> *NYNEX Corp.*, 525 U.S. at 129.



can prove willingness simply by agreeing to be bound by terms determined by neutral adjudication. If the worst penalty an SEP infringer faces is not an injunction but merely paying, after neutral adjudication, the FRAND royalty that it should have agreed to pay upon demand, then reverse holdup and holdout<sup>20</sup> give implementers a profitable way to defer payment—or if they are judgment proof, to avoid payment altogether—and puts SEP holders at a disadvantage that reduces the rewards to, and therefore can only discourage, both innovation and participation in standard setting.<sup>21</sup>

In the alternative, should the Bureau decide to retain a competition law sanction for the seeking of injunctive relief—which we strongly urge not to do—at the very least, Section 7.3 and Example 18 should be amended to limit liability to situations when there is proof that a FRAND-encumbered SEP holder has engaged in patent holdup, i.e., that the patent holder used the threat of injunctive relief to demand supra-competitive royalties. This revision is necessary to avoid the presumption that an SEP holder who seeks injunctive relief will necessarily use that relief (or the threat of it) in an improper manner to demand supra-competitive royalties.<sup>22</sup> For one thing, market mechanisms impose a number of constraints that militate against acting on the opportunity for holdup. For example, reputational and business costs may deter repeat players from engaging in holdup and “patent holders that have broad cross-licensing agreements with the SEP-owner may be protected from hold-up.”<sup>23</sup> In addition, patent holders often enjoy a first-mover advantage if their technology is adopted as the standard. “As a result, patent holders who manufacture products using the standardized technology ‘may find it more profitable to offer attractive licensing terms in order to promote the adoption of the product using the standard, increasing demand for its product rather than extracting high royalties.’”<sup>24</sup>

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<sup>20</sup> Holdup requires lock-in, and standard-implementing companies with asset-specific investments can be locked in to the technologies defining the standard. On the other hand, innovators that are contributing to an SSO can also be locked-in if their technologies have a market only within the standard. Thus, incentives to engage in holdup run in both directions. There is also the possibility of holdout. While reverse holdup refers to the situation when licensees use their leverage to obtain rates and terms below FRAND, holdout refers to licensees either refusing to take a FRAND license or delaying doing so.

<sup>21</sup> Such delay tactics are magnified when the patent owner has a large worldwide portfolio of SEPs requiring it to file lawsuits around the world to adjudicate a FRAND royalty on a patent-by-patent basis. In such cases, international arbitration on a portfolio basis would appear to be the most efficient and realistic means of resolving FRAND disputes.

<sup>22</sup> See Anne Layne-Farrar & Koren W. Wong-Ervin, *Methodologies For Calculating FRAND Damages*, LAW360 at 3-4 (Oct. 8-10, 2014) (explaining that “the actual practice of hold-up requires two elements: opportunity and action,” listing a number of market mechanisms that militate against the opportunity for holdup), available at <https://www.ftc.gov/system/files/attachments/key-speeches-presentations/wong-ervin-methodologies-for-calculating-frand-damages.pdf>.

<sup>23</sup> See, e.g., Prepared Statement of the Federal Trade Commission Before the U.S. Senate Committee on the Judiciary Subcommittee on Antitrust, Competition Policy and Consumer Rights Concerning “Standard Essential Patent Disputes and Antitrust Law” at 6 (July 30, 2013), available at [https://www.ftc.gov/sites/default/files/documents/public\\_statements/prepared-statement-federal-trade-commission-concerning-standard-essential-patent-disputes-and/130730standardessentialpatents.pdf](https://www.ftc.gov/sites/default/files/documents/public_statements/prepared-statement-federal-trade-commission-concerning-standard-essential-patent-disputes-and/130730standardessentialpatents.pdf).

<sup>24</sup> *Id.*

## A. Empirical Evidence Suggests No Systemic Problem with Holdup

While serious and important scholarly work exists exploring the theoretical conditions under which patent holdup might occur, this literature merely demonstrates the *possibility* that an injunction (or the threat of an injunction) against infringement of a patent *can* be profitable and *potentially* harmful to consumers. This same literature has long recognized, in both the intellectual property rights and real property context, the threat of reverse holdup and holdout.

It is important to distinguish the hypotheses generated in the theoretical literature on patent holdup from empirical evidence that would substantiate those hypotheses. Our own assessment and that of other close students of the subject is that the existing empirical evidence is not consistent with the view that holdup is a prevalent or systemic problem that is causing harm to consumers.<sup>25</sup> The evidence required to support the Bureau’s proposed approach—which is likely to deter procompetitive conduct including participation in standard setting—requires that there be a probability, not a mere possibility, of higher prices, reduced output, and lower rates of innovation.

In fact, evidence from the smartphone market, which is both patent and standard intensive, is to the contrary. Output has grown exponentially, while market concentration has fallen, and wireless service prices have dropped relative to the overall consumer price index (CPI).<sup>26</sup> A recent study by the Boston Consulting Group found that globally the cost per megabyte of data declined 99% from 2005 to 2013 (demonstrating both innovation to make data transmission more cost efficient as well as the healthy state of competition); the dollar per megabyte fell 95% in the transition from 2G to 3G, and 67% in the transition from 3G to 4G; and the global average selling prices for smartphones decreased 23% from 2007 through 2014, while prices for the lowest-end phones fell 63% over the same period.<sup>27</sup> A recent study found that

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<sup>25</sup> See, e.g., J. Gregory Sidak, *The Antitrust Division’s Devaluation of Standard-Essential Patents*, 104 GEORGETOWN L.J. ONLINE 48, 61 (2015) (collecting studies at n.49) (“By early 2015, more than two dozen economists and lawyers had disapproved or disputed the numerous assumptions and predictions of the patent holdup and royalty stacking conjectures.”), available at <https://www.criterioneconomics.com/docs/antitrust-divisions-devaluation-of-standard-essential-patents.pdf>; ANNE LAYNE-FARRAR, PATENT HOLDUP AND ROYALTY STACKING THEORY AND EVIDENCE: WHERE DO WE STAND AFTER 15 YEARS OF HISTORY? (Dec. 2014), available at <http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=DAF/COMP/WD%282014%2984&doclanguage=en> (surveying the economic literature and concluding that the empirical studies conducted thus far have not shown that holdup is a common problem).

<sup>26</sup> According to data from Gartner, worldwide smartphone sales to end-users have increased over 900% between 2007 to 2014, and 320% between 2010 to 2014. Market concentration in smartphones, as measured by HHIs, went from “highly concentrated” in 2007, as defined by the U.S. Antitrust Agencies’ Horizontal Merger Guidelines, to “unconcentrated” by the end of 2012. See Keith Mallinson, *Theories of harm with SEP licensing do not stack up*, IP FINANCE BLOG (May 24, 2013), available at <http://ipfinance.blogspot.com/2013/05/theories-of-harm-with-sep-licensing-do.html>. According to the U.S. Bureau of Labor Statistics, the ratio of the CPI for wireless telephone services to the overall CPI has dropped 34% from 2007 to 2014.

<sup>27</sup> JULIO BEZERRA ET AL., THE MOBILE REVOLUTION: HOW MOBILE TECHNOLOGIES DRIVE A TRILLION DOLLAR IMPACT 3, 9 (The Boston Consulting Group Jan. 15, 2015), available at

prices in SEP-reliant industries in the United States have declined faster than prices in non-SEP intensive industries.<sup>28</sup>

Economic analysis provides the basis upon which to understand the apparent disconnect between holdup theory and the existing evidence. As economic theory would predict, patent holders and those seeking to license and implement patented technologies write their contract so as to minimize the probability of holdup. As explained above, several market mechanisms are available to transactors to mitigate the incidence and likelihood of patent holdup. This is not surprising. The original economic literature upon which the patent holdup theories are based was focused upon the various ways that market actors use reputation, contracts, and other institutions to mitigate the inefficiencies associated with opportunism in the real property setting.<sup>29</sup>

Recognizing the theoretical nature of holdup concerns, the United States Court of Appeals for the Federal Circuit (which has nationwide jurisdiction over patent disputes) has held that claims of holdup must be substantiated with “actual evidence” of holdup, and that the burden is on accused infringers to show that the patent holder used injunctive relief to gain undue leverage and demand supra-FRAND royalties.<sup>30</sup>

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[https://www.bcgperspectives.com/content/articles/telecommunications\\_technology\\_business\\_transformati\\_on\\_mobile\\_revolution/#chapter1](https://www.bcgperspectives.com/content/articles/telecommunications_technology_business_transformati_on_mobile_revolution/#chapter1).

<sup>28</sup> Alexander Galetovic, Stephen Haber, & Ross Levine, *An Empirical Examination of Patent Hold-Up* (Nat'l Bureau of Econ. Research, Working Paper No. 21090, Apr. 2015), available at <http://www.nber.org/papers/w21090.pdf>.

<sup>29</sup> Benjamin Klein, *Why Hold-Ups Occur: The Self-Enforcing Range of Contractual Relationships*, 34 ECON. INQUIRY 444, 449-50 (1996); Benjamin Klein, Robert G. Crawford & Armen A. Alchian, *Vertical Integration, Appropriate Rents, and Competitive Contracting Process*, 21 J.L. & ECON. 297, 303-07 (1978); OLIVER E. WILLIAMSON, *MARKETS AND HIERARCHIES: ANALYSIS AND ANTITRUST IMPLICATIONS* 26-30 (New York: Free Press 1975); see also Joshua D. Wright, Comm'r, Fed. Trade Comm'n, remarks before George Mason University of Law: SSOs, FRAND, and Antitrust: Lessons Learned from the Economics of Incomplete Contracts at 2-3 (Sept. 12, 2013) (explaining that “the economics of hold-up began not as an effort to explain contract failure, but as an effort to explain real world contract terms, performance, and the enforcement decisions starting with the fundamental premise that contracts are necessarily incomplete”), available at [https://www.ftc.gov/sites/default/files/documents/public\\_statements/ssos-frand-and-antitrust-lessons-economics-incomplete-contracts/130912cpip.pdf](https://www.ftc.gov/sites/default/files/documents/public_statements/ssos-frand-and-antitrust-lessons-economics-incomplete-contracts/130912cpip.pdf). There is empirical evidence that SSO contract terms vary both across organizations and over time in response to changes in perceived risk of patent holdup and other factors. See Joanna Tsai & Joshua D. Wright, *Standard Setting, Intellectual Property Rights, and the Role of Antitrust in Regulating Incomplete Contracts*, forthcoming 80(1) ANTITRUST L.J. (2015), available at [http://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=2467939](http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2467939).

<sup>30</sup> See, e.g., *Ericsson v. D-Link Sys.*, 773 F.3d 1201, 1234 (Fed. Cir. 2014) (“In deciding whether to instruct the jury on patent hold-up and royalty stacking, again, we emphasize that the district court must consider the evidence on the record before it. The district court need not instruct the jury on hold-up or stacking unless the accused infringer presents actual evidence of hold-up or stacking. Certainly something more than a general argument that these phenomena are possibilities is necessary.”); see also Anne Layne-Farrar & Koren W. Wong-Ervin, *An Analysis of the Federal Circuit’s Decision in Ericsson v. D-Link*, CPI ANTITRUST CHRONICLE at 5-7 (Mar. 2015), available at

## B. A Competition Law Sanction is Likely to Reduce Incentives to Innovate and Deter Participation in Standard Setting

A FRAND commitment is, of course, a contractual commitment.<sup>31</sup> Economists have long understood that contractual relationships involving asset-specific investments between transactors generate the potential for opportunism. Similarly, a patentee participating in the standard-setting process can, once the standard is adopted by an SSO, “holdup” potential licensees by exploiting asset-specific investments to demand a higher royalty rate than would have prevailed in a competitive process. The view that contractual opportunism alone gives rise to an antitrust problem rather than a contract problem is in tension with substantial economic literature on the subject.<sup>32</sup> Consistent with this view, no United States court has held that seeking injunctive relief on a FRAND-encumbered SEP violates the antitrust laws. Instead, United States courts that have addressed the issue have done so under contract law principles.

Specifically, in analyzing the contractual nature of the FRAND commitment, courts have held that: (1) a commitment to an SSO to license on FRAND terms constitutes a binding contract between the SEP holder, the SSO, and its members<sup>33</sup>; (2) potential users of the standard are third-party beneficiaries of the agreements with standing to sue<sup>34</sup>; (3) seeking injunctive relief on a FRAND-encumbered SEP may violate the universal duty of good faith and fair dealing when a SEP holder has made a contractual commitment to license on FRAND terms<sup>35</sup>; and (4) FRAND

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<http://www.crai.com/sites/default/files/publications/An-Analysis-of-the-Federal-Circuits-Decision-in-Ericsson-v-D-Link.pdf>.

<sup>31</sup> See, e.g., *In re Innovatio IP Ventures, LLC Patent Litig.*, 2013 WL 5593609 at \*4 (N.D. Ill. Oct. 3, 2013); *Microsoft Corp. v. Motorola, Inc.*, 2013 WL 2111217 at \*1 (W.D. Wash. Apr. 25, 2013), *aff'd* 2015 WL 4568613 (9th Cir. July 30, 2015); *Apple, Inc. v. Motorola Mobility, Inc.*, 886 F. Supp. 2d 1061, 1083-84 (W.D. Wis. 2012); *Microsoft Corp. v. Motorola, Inc.*, 854 F. Supp. 2d 993, 999-1001 (W.D. Wash. 2012), *reaffirmed*, 864 F. Supp. 2d 1023, 1030-33 (W.D. Wash. 2012), *aff'd in relevant part*, 696 F.3d 872, 884 (9th Cir. 2012).

<sup>32</sup> Joshua D. Wright & Douglas H. Ginsburg, *Patent Assertion Entities and Antitrust: A Competition Cure for a Litigation Disease*, 79 ANTITRUST L.J. 501, 509 (2014); see also Benjamin Klein, *Market Power in Antitrust: Economic Analysis After Kodak*, 3 SUP. CT. ECON. REV. 43, 62-63 (1993) (“Antitrust law should not be used to prevent transactors from voluntarily making specific investments and writing contracts by which they knowingly put themselves in a position where they may face a ‘hold-up’ in the future . . . . [C]ontract law inherently recognizes the pervasiveness of transactor-specific investments and generally deals with ‘hold-up’ problems in a subtle way, not by attempting to eliminate every perceived ‘hold-up’ that may arise.”).

<sup>33</sup> See, e.g., *Innovatio*, 2013 WL 5593609 at \*4 (citing *In re Innovatio IP Ventures Patent Litig.*, 2013 WL 427167 at \*17 (N.D. Ill. 2013)); *Microsoft Corp.*, 854 F. Supp. 2d at 999; *Apple, Inc.*, 886 F.Supp.2d at 1083-85.

<sup>34</sup> See, e.g., *Innovatio*, 2013 WL 5593609 at \*17; *Microsoft Corp.*, 854 F. Supp. 2d at 999; *Apple, Inc.*, 886 F.Supp.2d at 1083-84; *Research In Motion Ltd. v. Motorola, Inc.*, 644 F.Supp.2d 788, 797 (N.D. Tex. 2008); *ESS Technology, Inc. v. PC-Tel., Inc.*, 1999 WL 33520483, \*4 (N.D. Cal. Nov. 4, 1999).

<sup>35</sup> See, e.g., *Realtek Semiconductor Corp. v. LSI Corp.*, 2013 WL 2181717, at \*7 (N.D. Cal. May 20, 2013) (holding that it was a breach of the RAND commitment to seek injunctive relief in another forum (there, the U.S. International Trade Commission) before offering a license to an implementer of a standard willing to accept a RAND license); Verdict Form at 3, *Microsoft v. Motorola*, Case No. C10-

licensing “includes an obligation to negotiate in good faith,” and that obligation is “a two-way street.”<sup>36</sup>

Competition law remedies prohibiting or limiting the ability of a FRAND-encumbered SEP holder to seek injunctive relief are not likely in the public interest for the following three reasons.

First, a competition law remedy is not only unnecessary to protect consumer welfare given that the law of contracts is sufficient to provide optimal deterrence, but is likely to be harmful.<sup>37</sup> Significant monetary sanctions are likely to over-deter procompetitive participation in SSOs. Significant monetary fines are also likely to over deter FRAND-encumbered SEP holders that need the credible threat of an injunction to recoup the value added by their patents and have no other adequate remedy against an infringing user. Indeed, excessive deterrence is particularly likely because, with liability turning upon whether the infringing user was truly a “willing licensee—a factual determination that may be far from clear in many cases—the outcome of a competition law case would necessarily be uncertain. The prospect of penalizing a FRAND-encumbered SEP holder for seeking injunctive relief diminishes the value of its patents and hence reduces its incentive to innovate.<sup>38</sup>

Second, the prospect of competition law liability for a patentee seeking injunctive relief would enable an infringing user to negotiate in bad faith, knowing that its exposure is capped at the FRAND licensing rate, and requires a SEP holder to take a below-FRAND rate from an unscrupulous or judgment-proof infringing user.<sup>39</sup>

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1823JLR (Sept. 4, 2013) (the jury found that Motorola’s conduct in seeking injunctive relief violated its duty of good faith and fair dealing with respect to its contractual commitments to the IEEE and the ITU); *Apple v. Motorola, Inc.*, 869 F. Supp. 2d 901, 913-14 (N.D. Ill. 2012); *see also* *Microsoft Corp. v. Motorola, Inc.*, 696 F.3d 872, 884-85 (9th Cir. 2012).

<sup>36</sup> *Ericsson Inc. v. D-Link Systems, Inc.*, 2013 WL 4046225 at \*25 (E.D. Tex. Aug. 2013), *aff’d-in-part, reversed-in-part, and vacated-in-part on other grds* by *Ericsson v. D-Link Sys.*, 773 F.3d 1201 (Fed. Cir. 2014).

<sup>37</sup> Douglas H. Ginsburg, Taylor M. Owings, & Joshua D. Wright, *Enjoining Injunctions: The Case Against Antitrust Liability for Standard Essential Patent Holders Who Seek Injunctions*, THE ANTITRUST SOURCE 1, 5-6 (Oct. 2014); *see also* Kobayashi & Wright, *supra* note 15.

<sup>38</sup> *See, e.g.*, Luke Froeb & Mikhael Shor, *Innovators, Implementers, and Two-sided Hold-up*, THE ANTITRUST SOURCE (Aug. 2015) (explaining that the curtailing of injunctive relief serves “to shift bargaining power and profits from innovators to implementers,” which “weakens the value of patents and can significantly reduce the incentive to innovate”), *available at* [http://www.americanbar.org/content/dam/aba/publishing/antitrust\\_source/aug15\\_froeb\\_7\\_21f.authcheckdam.pdf](http://www.americanbar.org/content/dam/aba/publishing/antitrust_source/aug15_froeb_7_21f.authcheckdam.pdf); Bernhard Ganglmair, Luke M. Froeb & Gregory J. Werden, *Patent Hold Up and Antitrust: How a Well-Intentioned Rule Could Retard Innovation*, 60 J. INDUS. ECON. 249 (2012) (finding that “enforcement of a FRAND commitment, with damages awarded for excessive license fees, solves the holdup problem, but can retard innovation, and it is even possible that this solution is worse than the problem”) [hereinafter Ganglmair et al.].

<sup>39</sup> *See generally* Ganglmair et al., *supra* note 38 (finding that the innovator’s and the implementer’s holdup problems are not directly comparable as it is possible for negotiations to occur prior to the

Third, the prospect of competition law liability is likely to deter patent holders from contributing their technology to an SSO under FRAND terms if doing so will require them to forfeit their right to protect their intellectual property by seeking an injunction against infringing users. These possibilities, far from protecting the public interest in competition and innovation, actually threaten the gains from innovation and standardization.

## **VI. CONCLUSION**

For the foregoing reasons, we respectfully recommend that the Draft Updated Guidelines be amended as described above. We appreciate the opportunity to comment and would be happy to respond to any questions the Bureau may have regarding this comment.

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implementer's investment in the standard, but negotiations always occur after the innovator's investment in research and development is sunk).

# **Appendix A**

# Actavis and Multiple ANDA Entrants: Beyond the Temporary Duopoly

BY BRUCE H. KOBAYASHI, JOSHUA D. WRIGHT,  
DOUGLAS H. GINSBURG, AND JOANNA TSAI

IN *FTC V. ACTAVIS, INC.*,<sup>1</sup> THE COURT, in a 5-3 decision, resolved a Circuit split over the antitrust treatment of “reverse payments” included in agreements to settle the litigation generated by the Hatch-Waxman regulatory scheme.<sup>2</sup> The Court held that reverse payments would be analyzed under the rule of reason, leaving “to the lower courts the structuring of the present rule-of-reason antitrust litigation.”<sup>3</sup> In adopting the rule of reason approach, the Court rejected the use of more administrable per se rules used by some lower courts to evaluate reverse payments.

Specifically, the Court declined to adopt the “scope of the patent test” used by the Eleventh Circuit.<sup>4</sup> This test recognizes the brand firm’s legal ability to use a valid and unexpired patent to prevent entry until the expiration of the patent. In contrast, the Court found there is “reason for concern that settlements taking this form tend to have significant adverse effects on competition.”<sup>5</sup> In particular, the Court suggested that an otherwise unexplained large reverse payment “likely seeks to prevent the risk of competition. And . . . that consequence constitutes the relevant anticompetitive harm.”<sup>6</sup> The Court also declined the FTC’s invitation to apply to settlements involving such payments a rule of per se illegality or, alternatively, to subject them to a “quick look” analysis in which such settlements would be presumptively unlawful.<sup>7</sup>

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This article examines the economics of litigation and settlement of patent disputes arising from Paragraph IV Abbreviated New Drug Application (ANDA) filings under the Drug Price Competition and Patent Term Restoration Act (Hatch-Waxman Act) within the framework set out in *Actavis*.<sup>8</sup> Recent economic analyses of reverse payment settlements demonstrate how agreements to settle patent litigation that delay the date of generic entry beyond the litigation-adjusted expected life of the patent reduce consumer welfare. An important implication of these models is that settlements must reduce consumer welfare if the size of the reverse payment exceeds the patentee’s litigation costs.<sup>9</sup> These analyses have been used to support antitrust rules that would prohibit reverse payments that exceed the cost of litigation.<sup>10</sup>

This article builds upon these analyses by taking into account important institutional features of the Hatch-Waxman Act’s regulatory regime and of procedural law. Our analysis incorporates the rapid entry by multiple firms that often follows the invalidation of a patent and the expiration of the marketing exclusivity period.<sup>11</sup> Instead of a single entrant obtaining duopoly profits for the remaining life of the patent, as is assumed in prior analyses,<sup>12</sup> the generic entrant that successfully challenges the validity of the patent typically obtains duopoly profits only for the 180-day exclusivity period provided by the Act. After this period, both the brand firm with the invalidated patent and the generic entrant that invalidated the patent face additional generic entrants and, consequently, earn lower profits than they earned during the duopoly period. This typical pattern is the joint product of the Hatch-Waxman Act and the doctrine of collateral estoppel under *Blonder-Tongue Laboratories, Inc. v. University of Illinois Foundation*,<sup>13</sup> which prevents the brand firm with an invalidated patent from relitigating the validity of the patent.

Accounting for this critical institutional detail has important and different implications for patent settlements, welfare, and application of the rule of reason pursuant to *Actavis*. Our analysis of the multi-entrant model implies the payoff for the generic entrant that files the first Paragraph IV ANDA and invalidates the patent is smaller than the monopoly-to-duopoly litigation payoffs generated in the single-entrant models. This reduced payoff decreases the incentive for the entrant to litigate and, likewise, the amount for which it will settle. Litigating a patent under a rule of defensive non-party non-mutual collateral estoppel imposes greater losses upon the patentee than is the case when there is a single entrant. This, in turn, increases the litigation risk the patentee faces and, likewise, the amount it will pay to settle. Compared to the single-entrant model, the result is a significantly broader range of settlements in which the brand and generic entrant have legitimate incentives to settle the case other than “to prevent the risk of competition,” which is “the relevant anticompetitive harm.”<sup>14</sup>

This broad settlement range renders ineffective attempts to regulate the size of patent settlements or to infer a settlement is anticompetitive based solely upon its size. Incorporation



rating multiple entrants also changes the direct relationship between the litigation-adjusted expected life of the patent and consumer welfare and, most important, weakens the relationship between the strength of the patent and the size of the settlement, which relationship has underlain calls to deem presumptively unlawful all payments greater than anticipated litigation costs. Thus, using litigation cost as an indicator of an anticompetitive settlement would neither induce litigation that would invalidate “bad” patents nor encourage settlements that would increase consumer welfare.

In addition to the positive analysis of litigation, the article examines the alternatives to the static consumer-welfare-only standard used in some analyses to evaluate reverse payment settlements. In this context, a welfare standard that includes more than static consumer surplus should be considered. Settlement avoids the incremental private and social costs of litigation. In addition, the design of the Hatch-Waxman Act, which includes provisions that encourage generic entry and patent term restoration, embodies the tradeoff between producers’ incentive to innovate and consumers’ need for access that is a central focus of the economic analysis of intellectual property rights.

**The Single-Entrant Model and the Litigation Cost Benchmark**

The single-entrant models provide analytical support for the Court’s inference that reverse payments greater than anticipated litigation costs are likely to harm competition.

**Market Structure and Profits under the Single-Entrant Model.** Litigation under the Hatch-Waxman Act begins when a generic entrant files an ANDA with a Paragraph IV Certification that the brand firm’s unexpired patent is either invalid or would not be infringed. The filing of a Paragraph IV ANDA creates an act of infringement that allows the patentee to file an infringement suit.

The single-entrant model is a special case of the more general model we discuss below. In particular, the single-entrant model makes the simplifying assumption that the first ANDA entrant that invalidates the brand patent obtains duopoly profits until the patent expires. The undiscounted profits in this model are illustrated in Figure 1. The vertical axis measures profits and the horizontal axis measures time, in years. The top panel shows the post-litigation profits for the Brand and the Generic if the Brand wins, which occurs

with probability  $p$ . Specifically, the Brand obtains monopoly profits  $\pi^M$  until the patent expires at time  $T$ . The middle panel shows the post-litigation profits if the Generic wins, which occurs with probability  $1-p$ . The middle panel in particular shows the effect of the single-entrant assumption. Instead of a short period of duopoly followed by free entry when the patent is invalidated, the single-entrant model generates duopoly profits  $\pi^D$  from the time the patent is invalidated until the time at which the patent would have expired.

Instead of litigating to judgment, the Brand and the generic entrant can settle the case. The terms of the settlement include a reverse payment  $X$  and an agreed upon early entry date  $E$  that is on or before the patent expiration date  $T$ . The bottom panel shows the profits from settlement: the Brand enjoys monopoly profits  $\pi^M$  until the Generic enters at time  $E$ . The Brand and the Generic obtain duopoly profits  $\pi^D$  from  $E$  until the patent expires, after which they obtain only free entry profits  $\pi^C$ .

**Feasible Settlements in the Single-Entrant Model.**

Figure 2 illustrates the set of feasible settlements generated by the single-entrant model when both the Brand and the generic entrant estimate the probability the patent will be upheld ( $p$ ) is relatively high, here 0.9.<sup>15</sup> The vertical axis measures the size of the reverse payment  $X$  in dollars, and the horizontal axis measures the date of early entry  $E$  in years. The set of feasible settlements are those both the Brand and the Generic prefer to litigation. They lie in the shaded area between the Brand’s minimum acceptable entry date line and the Generic’s maximum acceptable entry date line.<sup>16</sup> As shown in other papers, absent antitrust constraints on set-

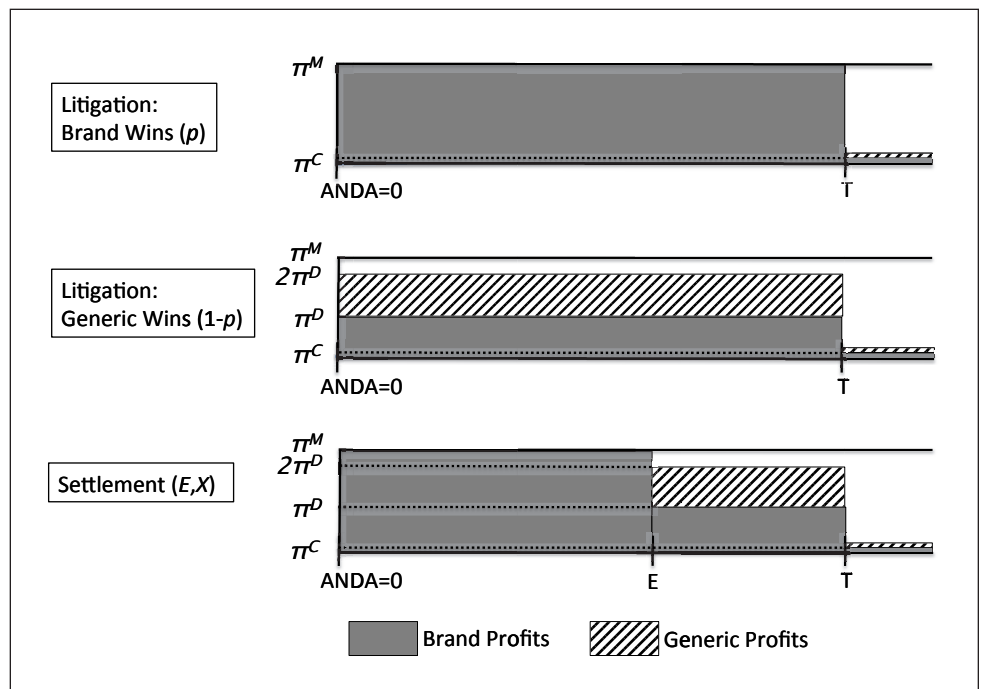


Figure 1: Litigation and Settlement Profits for the Brand and Generic Firm (Single-Entrant Model)

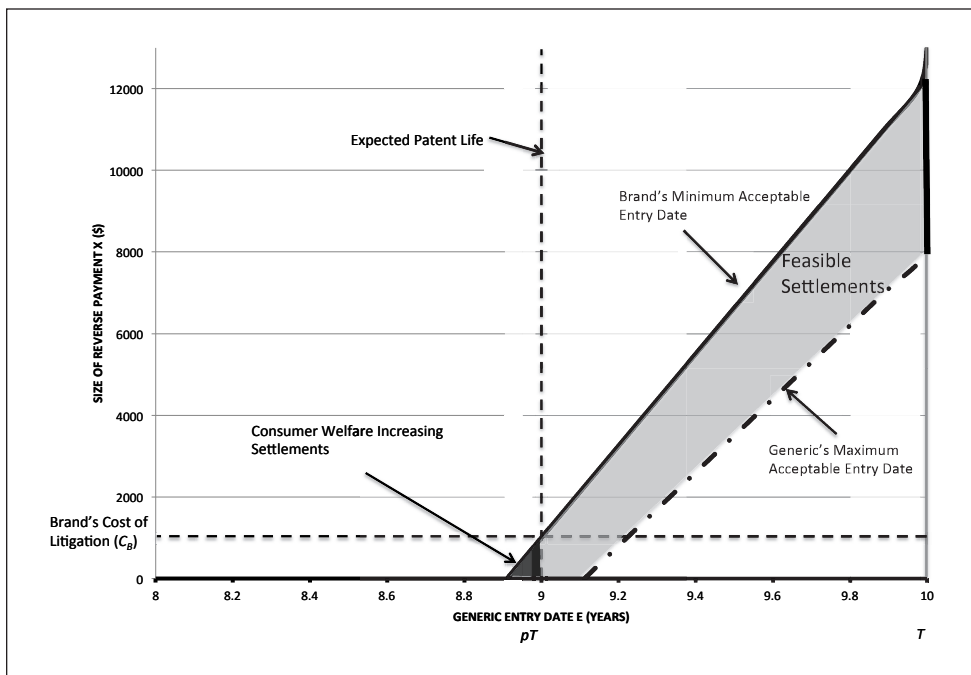


Figure 2: Feasible Settlements in the Single-Entrant Model

tlement, the set of equilibrium settlements, which maximize the joint benefit to the parties, are those that allow entry only at patent expiration ( $T$ ) and hence can have feasible reverse payments that are between 8 and 12 times the Brand's litigation costs, as indicated by the range of payments on the right edge of Figure 2.<sup>17</sup>

**Equilibrium Settlement and Welfare in the Single-Entrant Model.** In considering how settlements affect static consumer welfare, an important benchmark for consumer welfare comparisons is the litigation-adjusted expected patent life, which equals the life of the patent multiplied by the probability the patent will be held valid if litigated ( $pT = 9$  years in the example in Figure 2). Settlements that set the early entry date equal to the expected patent life generate consumer welfare equal to the expected consumer welfare generated by litigation. Settlements with entry dates sooner (or later) than the litigation-adjusted patent life generate consumer welfare that is larger (or smaller) than is expected under litigation.<sup>18</sup>

The dark shaded triangle in Figure 2 shows the set of feasible settlements that also increase consumer welfare. In theory, an antitrust rule that required settlements to allow entry on or before the expected patent life could be used to promote consumer welfare increasing settlements.<sup>19</sup> As the Court recognized in *Actavis*, the problem with such a rule is that assessing the strength of a patent would ordinarily require a costly inquiry into the validity of the patent.<sup>20</sup>

The Court and economic analysts have focused upon the size of the Brand's avoided litigation costs as a more observable proxy for strength of its patent.<sup>21</sup> Under the assumptions of the single-entrant model, the Brand's minimum acceptable

entry date equals the litigation-adjusted life of the patent when the size of the reverse payment equals the Brand's litigation costs. Moreover, any feasible settlement in which the reverse payment exceeds the Brand's litigation costs must reduce consumer welfare. In that analysis, therefore, a necessary but not sufficient condition for a feasible settlement to increase consumer welfare is that the size of the reverse payment be less than the Brand's litigation costs.

A rule that limits the size of reverse payments to no more than the Brand's litigation costs, however, will not necessarily generate settlements that increase consumer welfare relative to the expected welfare generated through litigation. Equilibrium settlements under such a rule, which result in reverse payments equal to the Brand's litigation

costs, will necessarily result in entry dates that are later than the litigation-adjusted life of the patent.

In addition, limiting the size of reverse payments to the Brand's litigation costs can prevent a settlement that would result in litigation costs savings greater than any loss in consumer welfare.<sup>22</sup> For example, under the parameters in Figure 2, the breakeven entry date that increases the sum of consumer welfare plus avoided litigation costs ( $E^*$ ) is 9.254 years.<sup>23</sup>

Although litigation will force the parties to incur higher costs and can lower consumer welfare net of litigation costs, it is important to note that the absence of a settlement is not necessarily a "failure."<sup>24</sup> In patent litigation, whenever a judgment correctly invalidates or correctly upholds a patent, it produces benefits that generally inure to non-parties, including other generic entrants and consumers. It follows that the welfare associated with a judgment can be greater than the welfare associated with a settlement. The benefits to non-parties, however, are not taken into account in the single-entrant model, which is another reason to move the analysis beyond the temporary duopoly assumption in such models.

### A Model of Litigation and Settlement Under Hatch-Waxman and *Blonder-Tongue*: Accounting for Multiple Generic Entrants

The single-entrant model does not account for key institutional features of the Hatch-Waxman Act and of *Blonder-Tongue* that render the post-invalidation duopoly assumption unrealistic when there are multiple entrants. In this section, we set out a more general model of litigation and settlement under the Hatch-Waxman Act that explicitly accounts for the effect of these institutional features.

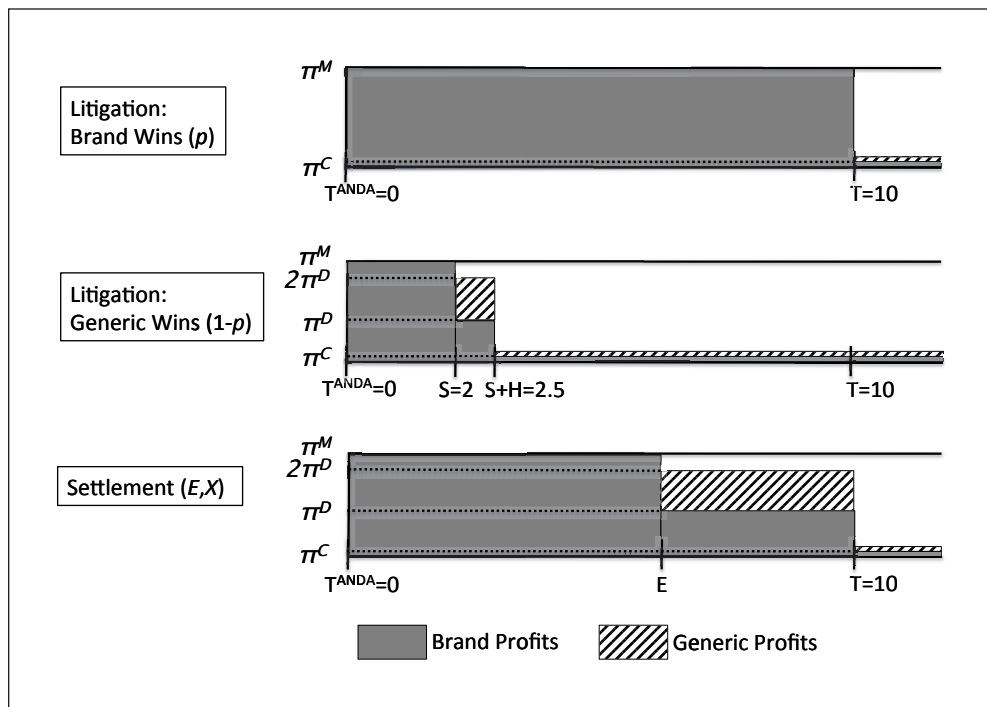


Figure 3: Litigation and Settlement Profits for the Brand and Generic Firm

**Market Structure and Profits Under Hatch-Waxman and Blonder-Tongue.** Figure 3 modifies Figure 1 to show the effects of multiple generic entrants. Assuming that the patent will not be challenged if the first ANDA entrant fails to invalidate the patent, the settlement profits of the Brand and of the Generic, depicted in the bottom panel of Figure 3, are identical to those depicted in Figure 1.<sup>25</sup> The profits depicted in the top panel of Figure 2, which show the profits when the Brand plaintiff successfully defends the patent, are also identical to those depicted in Figure 1. As a result, the Brand makes monopoly profits  $\pi^M$  during the remaining life of the patent (from time 0 to time  $T$ ).

Relaxing the assumption of the single-entrant model changes the middle panel in Figure 3, which shows the payoffs when the first generic entrant invalidates the Brand's patent.<sup>26</sup> Our model accounts for two additional features of the process: the litigation stay and the limited period of exclusivity. If the Brand files an infringement suit within 45 days of the ANDA filing, then FDA action on the ANDA is stayed for 30 months, during which the Brand will continue to make monopoly profits (from time 0 to time  $S$ ).<sup>27</sup> The first generic to file a Paragraph IV certification is entitled to 180-day marketing exclusivity under some circumstances, including when the patent is invalidated in litigation.<sup>28</sup> Thus, when the first generic entrant to file a paragraph IV ANDA invalidates the Brand's patent through litigation, the Hatch-Waxman regulatory regime produces a six-month period of duopoly competition between them. Both the Brand and the first generic earn duopoly profits  $\pi^D$  during the period of marketing exclusivity from time  $S$  to time  $S + H$  in Figure 3.

With subsequent generic entrants, this short period of duopoly is followed by free-entry competition. At the end of the six-month exclusivity period, other firms that file Paragraph IV certifications can enter the market, and firms in the market, including the Brand and the first generic entrant, earn free-entry profits  $\pi^C$  from the end of the marketing exclusivity period (at time  $S + H$ ) to the expiration of the patent at time  $T$  (and, of course, beyond).<sup>29</sup> By invalidating a Brand's patent, the first Paragraph IV generic entrant provides a benefit to other generic entrants, which can enter after the expiration of the 180-day period of marketing exclusivity, and to consumers, who pay the lower prices brought on by increased competition.

**Feasible Settlements Under Hatch-Waxman and Blonder-Tongue.** For simplicity and for a more direct comparison to the single-entrant model, we assume, as that model does, that the discount rate is zero, and we abstract away from the litigation stay.<sup>30</sup> The examples in this section, however, explicitly take into account the effect of the limited 180-day marketing exclusivity period  $H$  and the potential for additional generic entry once a patent has been invalidated and this exclusivity period has ended.

Figure 4 depicts the greater range of feasible settlements in the case where both parties estimate that  $p = .9$  and where both expect three additional entrants will enter if the patent is invalidated or expires.<sup>31</sup> Taking into account the effect of collateral estoppel and free entry after the invalidation of a patent expands the set of feasible settlements. Collateral estoppel imposes additional litigation losses on the Brand and shifts its earliest acceptable entry date to the left. The litigation payoff for the first generic entrant to file a Paragraph IV ANDA is lowered because it obtains duopoly profits only for the duration of the 180-day period of market exclusivity and lower free entry profits afterwards. This shifts the first generic's maximum acceptable entry date to the right.

**Equilibrium Settlement and Welfare with the Multiple-Entrant Model.** Figure 4 shows the conditions under which a settlement increases consumer welfare compared to the expected consumer welfare net of litigation costs that would be generated through litigation. Such settlements would have to specify an early entry date  $E$  that is earlier than  $E^*$ .<sup>32</sup> The breakeven entry date  $E^*$  with multiple entrants is earlier than the breakeven entry date generated by the single-entrant model, and earlier than the expected patent life ( $pT$ ).

The challenge that remains for the lower courts is to fashion a relatively accurate and administrable procedure under the rule of reason that minimizes the sum of error costs and direct costs.

Under the conditions depicted in Figure 4,  $E^* = 8.16$ .<sup>33</sup> Intuitively, the breakeven date for early entry ( $E^*$ ) is earlier than under the single-entrant model because litigation that results in the invalidation of the patent will produce a greater static expected welfare gain with multiple entrants; instead of resulting in a duopoly for the remainder of the patent life, invalidation of the patent produces six months of duopoly followed by the higher static welfare produced under free-entry competition. Therefore, if settlements are to increase consumer welfare, they must allow entry at a time earlier than the litigation-adjusted life of the patent in order to offset the long period of free entry welfare gains generated by the generic's successful litigation.

As illustrated in Figure 4, the breakeven early settlement date is earlier than the Brand's minimum acceptable entry

date (where the Brand's minimum acceptable entry date line intersects with the horizontal axis). Therefore, all feasible settlements, including those in which there is no reverse payment, generate consumer welfare that is lower than the expected welfare net of litigation costs that would be produced through litigation. Moreover, the model predicts that absent bargaining failure or antitrust restrictions on settlement, litigation is unlikely. For example, litigant optimism that would generate litigation in the single-entrant model generates a broad settlement range when the effect of anticipated multiple entry after patent invalidation is taken into account.<sup>34</sup>

### Patent Settlements, Antitrust Rules, and Welfare Standards

We turn now to the normative question of antitrust policy and welfare. Under the standard error cost approach, the optimal antitrust policy minimizes the sum of error costs and direct costs of enforcement.<sup>35</sup> A bright line rule can be optimal if it results in cost savings and benefits from increased certainty that outweigh the associated increase in error costs.<sup>36</sup>

Of the two bright line rules examined by the Court in *Actavis*, the scope of the patent test would yield a correct outcome for valid patents and protect against the costs associated with the erroneous invalidation of valid patents (Type I error costs). That test, however, produces the error costs associated with erroneously allowing invalid patents to remain in force (Type II error costs). The *Actavis* Court rejected this approach, expressly out of concern over the possibility of Type II errors. In particular, the Court noted that an important "patent-related policy" is to "eliminat[e] unwarranted patent grants so the public will not 'continually be required to pay tribute to would-be monopolists without need or justification.'"<sup>37</sup>

The bright line rule advocated by some<sup>38</sup>—per se condemnation of reverse payments—would have protected against Type II errors and increased the costs of Type I errors when valid patents were challenged. The Court, recognizing the legitimate value of settling litigation, as well as the complexities involved in the antitrust evaluation of reverse payment settlements, also rejected the bright line rule of per se illegality and the somewhat less error-prone quick-look rule with a presumption of illegality.<sup>39</sup>

The challenge that remains for the lower courts is to fashion a relatively accurate and administrable procedure

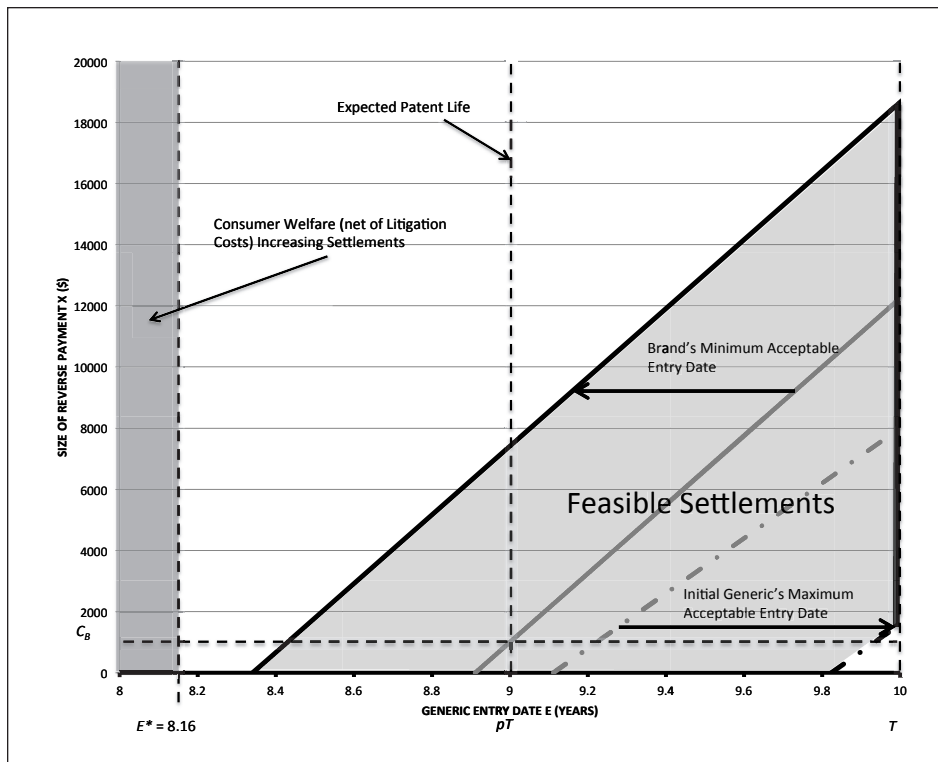


Figure 4: Feasible Settlements and Welfare in the Multiple-Entrant Model

under the rule of reason that minimizes the sum of error costs and direct costs.<sup>40</sup> One possibility would be to embed an inquiry into the validity of the patent as part of the antitrust case.<sup>41</sup> In theory, if this inquiry enabled courts accurately to determine the validity of the patent at a low cost, the scope of the patent test could be applied to cases where the inquiry concludes that the patent is valid, while allowing antitrust claims to proceed in cases where the inquiry concludes the patent is not valid.

The uncertainty and cost of “deciding a patent case within an antitrust case about the settlement of the patent case, a turducken task,” led the Eleventh Circuit to adopt the bright line scope of the patent test.<sup>42</sup> The rule of reason analysis adopted by the Supreme Court in *Actavis* likewise avoids an inquiry into the validity of the patent: It is “normally not necessary to litigate patent validity to answer the antitrust question” as such litigation would “prove time consuming, complex, and expensive,” and likely “not be worth that litigation candle.”<sup>43</sup>

Rather than a full-blown inquiry into the merits of the patent, the Court suggested that the portion of the reverse payment that is not explained by traditional settlement considerations or other procompetitive justifications “can provide a workable surrogate for a patent’s weakness, all without forcing a court to conduct a detailed exploration of the validity of the patent itself.”<sup>44</sup> Focusing upon this surrogate, “a court, by examining the size of the payment, may well be able to assess its likely anticompetitive effects along with its potential justifications without litigating the validity of the patent; and parties may well find ways to settle patent disputes without the use of reverse payments.”<sup>45</sup>

As we demonstrated above, however, even under the assumptions of the single-entrant model, equilibrium settlements can involve very large payments. Even when both parties in the example estimate that the patent will be upheld 90 percent of the time, the range of equilibrium reverse payment settlements is 8 to 12 times each party’s litigation costs. If, perhaps more realistically, both parties estimate the probability of the patent being upheld at only 50 percent, then the range of equilibrium reverse payment settlements is from 7 to 53 times each party’s litigation costs.<sup>46</sup> If the patent is valid, the reverse payment is the cost to the Brand of avoiding a Type I error.<sup>47</sup> Unconstrained equilibrium settlements allow the Brand to minimize the costs of Type I error. That is, there is always some settlement without early entry that

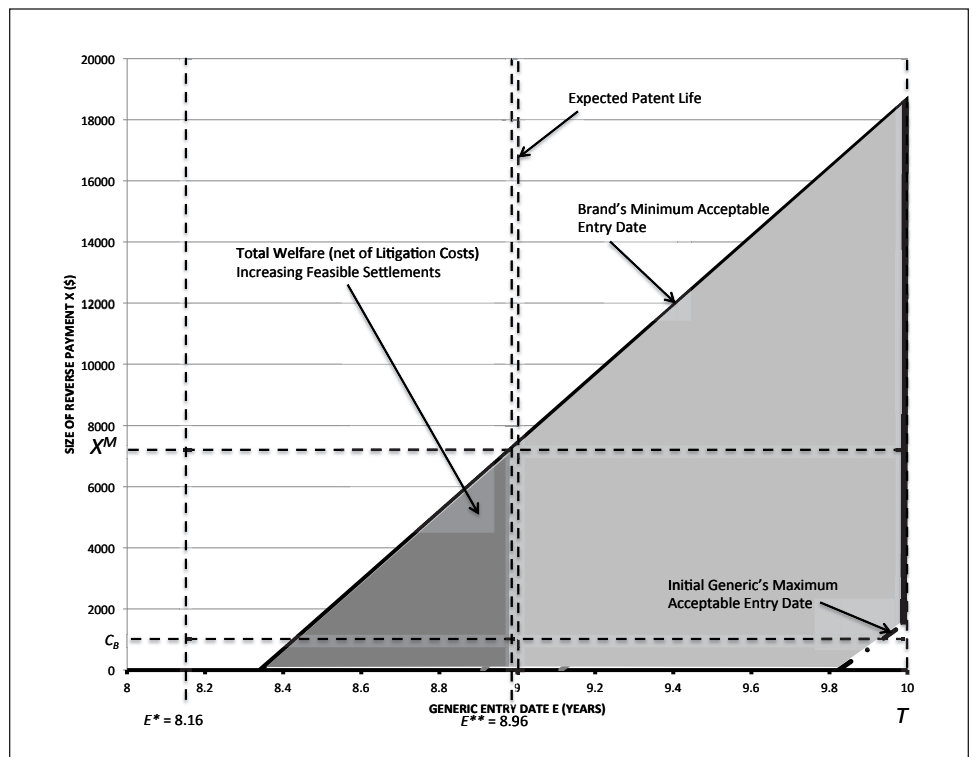


Figure 5: Total Welfare Net Litigation Costs Standard

allows the Brand to reduce its costs relative to litigating and an alternative settlement that allows generic entry prior to the expiration of the patent.

If the patent is not valid, then reverse payment settlements impose the highest Type II error costs. Under the assumption that invalid patents do not promote innovation, a settlement that does not allow early entry imposes the deadweight loss from monopoly for the maximum amount of time—the life of the patent—and reduces consumer welfare relative to settlements that allow generic entry before the expiration of the patent.

The positive analysis based upon the multiple-entrant model shows that the competitive setting generated by the Hatch-Waxman regulatory regime and the Court’s collateral estoppel rules work to generate strong incentives for settlement. These incentives are much stronger than the incentives to settle in single-entrant models. Indeed, the multiple-entrant model predicts that litigation of the validity of the patent to judgment is unlikely, and so too, therefore, is the the invalidation of bad patents, a “public good” forgone.

Moving to the normative implications of our positive analysis, the multiple-entrant scenario implies that an antitrust rule based upon the size of reverse payments will not produce settlements that increase consumer welfare net of litigation costs. As shown in the example, all feasible settlements, including those with no reverse payments, reduce static consumer welfare as compared to litigation. Indeed, the multiple-entrant model shows the static welfare gains from invalidating a patent are much greater than those generated

in the monopoly-to-duopoly model. This has led many to advocate a policy that would not only ban reverse payments, but also have courts scrutinize closely all settlements of Hatch-Waxman patent litigation.<sup>48</sup>

Those more strict limitations upon settlements of Hatch-Waxman patent litigation do not reflect a full error cost analysis, which minimizes the sum of error costs and direct costs. A static consumer welfare standard is incomplete as it ignores direct costs and considers only some of the error costs. More specifically, this standard, at best, provides a proxy for the consumer welfare costs associated with Type II error.

Setting aside for the moment differences of opinion about the purpose of antitrust law<sup>49</sup> and applying standard price theory, a more direct measure of the welfare costs of Type II error would be the deadweight loss rather than the loss of consumer surplus. A welfare standard that attempted to minimize the sum of the deadweight losses plus litigation costs is equivalent to using a total welfare standard net of litigation costs, including costs imposed on third parties.<sup>50</sup> Figure 5 modifies Figure 4 to include that standard. Under a total welfare net litigation costs standard, the breakeven early entry date for a settlement  $E^{**} = 8.96$  in the multiple-entrant model. Using this standard, a large range of the feasible settlements would raise total welfare net of litigation costs.<sup>51</sup> Indeed, reverse payments as high as  $X^M$  can generate total welfare that is greater than the expected total welfare that would be generated through litigation net of litigation costs. In the example depicted in Figure 5, this amount is seven times the Brand's litigation costs.<sup>52</sup>

The standard of total welfare net of litigation costs shown in Figure 5, which only re-weights the relative importance of litigation costs and of static welfare reducing Type II errors,<sup>53</sup>

still fails to address the costs of “dynamic” Type I errors, i.e., the costs of forgone innovation due to the reduced incentives that result from the erroneous invalidation of patents and the *in terrorem* settlements paid to avoid that outcome.<sup>54</sup> Considering the full error cost analysis, including the costs of dynamic Type I error, the breakeven early entry date  $E^*$  may be even farther to the right of the breakeven point shown in Figure 5. Indeed, because patent terms are not set optimally, but are based upon the arbitrary statutory rule of 20 years from filing, it is possible that a full error cost analysis, taking dynamic Type I errors into account, would find that settlement agreements where generic entry is not allowed before the expiration of the patent in fact increase dynamic welfare, which would support the scope of the patent test. Inasmuch as the regulatory structure of the Hatch-Waxman Act includes patent term restoration, it is odd not to consider the costs of dynamic Type I error in any analysis of the patent/antitrust interface under the statute.

## Conclusion

In *FTC v. Actavis*, the Court rejected bright line rules of legality and illegality in favor of a standard to be fleshed out by the lower courts applying the rule of reason. At the same time, the Court recognized the costs of an unconstrained rule of reason analysis and suggested a simpler rule—one based upon the size of the brand patentee's litigation costs—in order to set an antitrust limit on the size of reverse payments. The analysis in this article, which incorporates a model that allows for multiple entrants under Hatch-Waxman, shows such a rule will deem some welfare increasing settlements anticompetitive, encourage litigants to use other, potentially more inefficient means to settle, and increase the costs of dynamic Type I errors. ■

<sup>1</sup> 133 S. Ct. 2223 (2013).

<sup>2</sup> For a history of antitrust enforcement activity and litigation over Hatch-Waxman settlements, see generally Sumanth Addanki & Henry N. Butler, *Activating Actavis: Economic Issues in Applying the Rule of Reason to Reverse Payment Settlements*, 15 MINN. J.L. SCI. & TECH. 77 (2013); Henry N. Butler & Jeffrey Paul Jarosch, *Policy Reversal on Reverse Payments: Why Courts Should Not Follow the New DOJ Position on Reverse-Payment Settlements of Pharmaceutical Patent Litigation*, 96 IOWA L. REV. 57 (2010). For earlier analyses of reverse payment settlements that focus upon the merits of per se rules, see generally David A. Balto, *Pharmaceutical Patent Settlements: The Antitrust Risks*, 55 FOOD & DRUG L.J. 321 (2000); Roger D. Blair & Thomas F. Cotter, *Are Settlements of Patent Disputes Illegal Per Se?*, 47 ANTITRUST BULL. 491 (2002); Michael A. Carrier, *Unsettling Drug Patent Settlements: A Framework for Presumptive Illegality*, 108 MICH. L. REV. 37 (2009); Herbert Hovenkamp, Mark Janis & Mark A. Lemley, *Anticompetitive Settlements of Intellectual Property Disputes*, 87 MINN. L. REV. 1719 (2003); Robert D. Willig & John P. Bigelow, *Antitrust Policy Toward Agreements that Settle Patent Litigation*, 49 ANTITRUST BULL. 655 (2004).

<sup>3</sup> *Actavis*, 133 S. Ct. at 2238.

<sup>4</sup> *FTC v. Watson Pharms. Inc.*, 677 F.3d 1298, 1313 (11th Cir. 2012). See also *Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1066 (11th Cir. 2005) (citing *Valley Drug Co. v. Geneva Pharm., Inc.*, 344 F.3d 1294, 1312 (11th Cir. 2003) (finding that the appropriate analysis of “antitrust liability requires

an examination of: (1) the scope of the exclusionary potential of the patent; (2) the extent to which the agreements exceed that scope; and (3) the resulting anticompetitive effects”). This test was also applied by the Second and Federal Circuits. See *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323, 1333 (Fed. Cir. 2008) (finding no error in the district court's analysis applying the 11th Circuit's scope of patent test); *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 207 (2d Cir. 2006) (“[W]e see no sound basis for categorically condemning reverse payments employed to lift the uncertainty surrounding the validity and scope of the holder's patent.”).

<sup>5</sup> *Actavis*, 133 S. Ct. at 2231.

<sup>6</sup> *Id.* at 2236.

<sup>7</sup> *Id.* at 2237 (citing *Cal. Dental Ass'n v. FTC*, 526 U.S. 756, 775 & n.12 (1999)).

<sup>8</sup> Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585, amended by Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066.

<sup>9</sup> Aaron Edlin, Scott Hemphill, Herbert Hovenkamp & Carl Shapiro, *Activating Actavis*, ANTITRUST, Fall 2013, at 16, 16 [hereinafter Edlin et al., *Activating Actavis*]; Aaron Edlin, Scott Hemphill, Herbert Hovenkamp & Carl Shapiro, *Actavis and Error Costs: A Reply to Critics*, ANTITRUST SOURCE, Oct. 2014, at 1, 4, [http://www.americanbar.org/content/dam/aba/publishing/antitrust\\_](http://www.americanbar.org/content/dam/aba/publishing/antitrust_)

- source/oct14\_full\_source.authcheckdam.pdf [hereinafter Edlin et al., *Actavis and Error Costs*]. But see Barry C. Harris, Kevin M. Murphy, Robert D. Willig & Matthew B. Wright, *Activating Actavis: A More Complete Story*, ANTITRUST, Spring 2014, at 83, 83–84 (using a single-entrant model, but criticizing antitrust limits on reverse payment settlements).
- <sup>10</sup> See *Actavis*, 133 S. Ct. at 2236–37 (explaining that the size of the unexplained reverse payment can provide “a workable surrogate for a patent’s weakness” and that a large reverse payment creates an inference that the settlement is anticompetitive).
- <sup>11</sup> See generally Joseph Farrell & Carl Shapiro, *How Strong Are Weak Patents?*, 98 AM. ECON. REV. 1347 (2008) (examining the effect of multiple entrants on the incentive to litigate patents generally); Mark R. Patterson, *Leveraging Information About Patents: Settlements, Portfolios and Holdups*, 50 Hous. L. REV. 483 (2012) (analyzing the informational effect of patent challenges and estoppel rules); see also C. Scott Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem*, 81 N.Y.U. L. REV. 1553, 1588–94 (2006) (using a model with zero profit competition occurring 180 days after the invalidation of the patent or after entry resulting from settlement of the patent litigation).
- <sup>12</sup> See Edlin et al., *Actavis and Error Costs*, *supra* note 9, at 1; Harris et al. *supra* note 9, at 84; see generally Einer Elhauge & Alex Krueger, *Solving the Patent Settlement Puzzle*, 91 TEX. L. REV. 283 (2012); Murat Mungan, *Reverse Payments, Perverse Incentives*, 27 HARV. J.L. & TECH. 1 (2013); Carl Shapiro, *Antitrust Limits to Patent Settlements*, 34 RAND J. ECON. 391 (2003).
- <sup>13</sup> 402 U.S. 313 (1971).
- <sup>14</sup> *Actavis*, 133 S. Ct. at 2236.
- <sup>15</sup> Figure 2 is based on a figure used by Harris et al., *supra* note 9, at 87 fig. 3. The example in Figure 2 assumes the demand for the drug is given by  $P = A - BQ$ , with  $A = 100$  and  $B = .1$ . The example also assumes that the costs of litigation over settlement for each party equals \$1,000, and  $T = 10$  years. Monopoly profits for the drug are \$20,250. If this is scaled up to be a \$200 million per year drug, then Paragraph IV litigation costs in the example would equal just over \$1 million. The limits of the bargaining range illustrated in the Figure are explicitly derived in Bruce H. Kobayashi, Joshua D. Wright, Douglas H. Ginsburg & Joanna Tsai, *Actavis and Multiple ANDA Entrants: Beyond the Temporary Duopoly* (GMU Law & Econ. Research Paper Series 14-62, 2014), available at [http://www.law.gmu.edu/assets/files/publications/working\\_papers/1462.pdf](http://www.law.gmu.edu/assets/files/publications/working_papers/1462.pdf).
- <sup>16</sup> The Brand’s minimum (Generic’s maximum) acceptable entry date line contains settlements specifying an entry date and reverse payment ( $E, X$ ) that make the Brand (Generic) indifferent between litigating and settling. The set of feasible settlements are those that both parties prefer to litigation. *Id.*
- <sup>17</sup> See *id.* at 7 n.14; Edlin et al., *Actavis and Error Costs*, *supra* note 9, at 5.
- <sup>18</sup> Edlin et al., *Actavis and Error Costs*, *supra* note 9, at 5.
- <sup>19</sup> See *id.*; Shapiro, *supra* note 12, at 407–08; Mark A. Lemley & Carl Shapiro, *Probabilistic Patents*, J. ECON. PERSP., Spring 2005, at 75, 94–95.
- <sup>20</sup> See *Actavis*, 133 S. Ct. at 2237.
- <sup>21</sup> See *id.* at 2236 (“Where a reverse payment reflects traditional settlement considerations, such as avoided litigation costs or fair value for services, there is not the same concern that a patentee is using its monopoly profits to avoid the risk of patent invalidation or a finding of noninfringement.”).
- <sup>22</sup> This point is made by Harris et al., *supra* note 9. See also Kobayashi et al., *supra* note 15, at 8–10 (showing how feasible settlements in the presence of mutual optimism by the parties require reverse payments in excess of litigation costs).
- <sup>23</sup> Settlement allows the parties and society to avoid the additional costs of litigating a case to judgment. See generally Robert D. Cooter & Daniel L. Rubinfeld, *Economic Analysis of Legal Disputes and Their Resolution*, 27 J. ECON. LITERATURE 1067 (1989). These costs are social costs that would be taken into account in a complete error cost analysis. This issue, as well as the problem of measuring welfare appropriately is discussed in more detail below.
- <sup>24</sup> See generally Ezra Friedman & Abraham L. Wickelgren, *Chilling, Settlement, and the Accuracy of the Legal Process*, 26 J.L. ECON. & ORG. 144 (2010) (finding that settlements are not always the best options and that prohibiting settlements in some cases can increase social welfare more than allowing it); Owen M. Fiss, *Against Settlement*, 93 YALE L.J. 1073 (1984) (arguing that imbalances in resources of the parties can negatively affect the benefits settlements can provide, and that adjudication might sometimes prove to be a better option).
- <sup>25</sup> A patent that was upheld in litigation against a generic would-be entrant may be challenged anew by a subsequent generic that files a Paragraph IV ANDA. We assume subsequent ANDA filers will be deterred from filing Paragraph IV ANDAs and entering if the first generic fails to invalidate the patent in litigation. The expected benefits of such a filing for a subsequent potential challenger are reduced for two reasons. First, under Hatch-Waxman a subsequent Paragraph IV ANDA filer does not get a period of market exclusivity. In addition, the persuasive effect of the first case may increase the perceived probability the patent will be upheld in any subsequent case. For a more complete analysis of these issues, see Bruce H. Kobayashi, *An Economic Analysis of Relitigation Rules in Intellectual Property Litigation* (Working paper, George Mason Law School, May 2014) (on file with author).
- <sup>26</sup> The example assumes that  $S = 2$ , not 2.5 years (30 months). This assumes that the parties execute the settlement agreement prior to the expiration of the stay. This might occur, for example, if the parties wanted to avoid the costs of continuing litigation.
- <sup>27</sup> If no infringement suit is filed, the FDA can approve the ANDA. The branded firm, however, can then sue the entrant for infringement and, if successful, collect damages based upon the generic entrant’s infringing sales. If the would-be generic entrant does not want to enter without first having invalidated the patent then, following *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118 (2007), the generic entrant can file a declaratory judgment action challenging the validity of the patent. See *Caraco Pharm. Labs. Ltd. v. Forest Labs., Inc.*, 527 F.3d 1278, 1291–92, 1297 (Fed. Cir. 2008) (citing *MedImmune, Inc.*, 549 U.S. at 126).
- <sup>28</sup> 21 U.S.C. § 355(j)(5)(B)(iv).
- <sup>29</sup> Free-entry profits are not zero. The extent of entry will be limited by the costs of entry, which are assumed to be positive. Thus, the model assumes that all firms, including the Brand, make symmetric Cournot profits given  $N$  firms, where  $N$  is determined by the free entry condition.
- <sup>30</sup> For an explicit analysis of these factors, including the effect of positive discount rates, the effect of the stay, and differential estimates of  $p$ , see Kobayashi et al., *supra* note 15.
- <sup>31</sup> That is, if the patent is invalidated, market competition after the expiration of the Hatch-Waxman 180-day marketing exclusivity period will include 5 firms, viz., the Brand firm (perhaps competing through an authorized generic), the first Paragraph IV generic entrant, and three subsequent ANDA generic entrants.
- <sup>32</sup> If litigation costs are not taken into account, the required early entry date would have to be earlier still than  $E^*$ .
- <sup>33</sup> For a derivation of this threshold and the basis for the numerical example, see Kobayashi et al., *supra* note 15, 24–26.
- <sup>34</sup> *Id.* at 15–16. (providing an example showing the effects of litigant optimism in the multiple-entrant setting).
- <sup>35</sup> See Daniel A. Crane, *Exit Payments in Settlement of Patent Infringement Lawsuits: Antitrust Rules and Economic Implications*, 54 FLA. L. REV. 747, 751–52 (2002); Butler & Jarosch, *supra* note 2, at 107–12; see generally Isaac Erlich & Richard A. Posner, *An Economic Analysis of Legal Rule-making*, 3 J. LEGAL STUD. 257 (1974) (setting out the general error cost approach); Richard A. Posner, *An Economic Approach to Legal Procedure and Judicial Administration*, 2 J. LEGAL STUD. 399 (1973) (same); Frank H. Easterbrook, *The Limits of Antitrust*, 63 TEX. L. REV. 1, 9–17 (1984) (applying the error cost framework to antitrust law); Geoffrey A. Manne & Joshua D. Wright, *Innovation and the Limits of Antitrust*, 6 J. COMPETITION L. & ECON. 153 (2010) (applying error cost analysis of antitrust law to innovation).
- <sup>36</sup> See, e.g., *Barry Wright Corp. v. ITT Grinnell Corp.*, 724 F.2d 227, 234 (1st Cir. 1983) (“[U]nlike economics, law is an administrative system the effects of which depend upon the content of rules and precedents only as they are applied by judges and juries in courts and by lawyers advising their clients.

- Rules that seek to embody every economic complexity and qualification may well, through the vagaries of administration, prove counterproductive, undercutting the very economic ends they seek to serve.”)
- <sup>37</sup> *Actavis*, 133 S. Ct. at 2233 (quoting *Lear, Inc. v. Adkins*, 395 U.S. 653, 670 (1969)).
- <sup>38</sup> See, e.g., *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896, 908 (6th Cir. 2003) (holding a reverse payment per se unlawful because the agreement “was, at its core, a horizontal agreement to eliminate competition in the market for [the pharmaceutical] throughout the entire United States, a classic example of a per se illegal restraint of trade”); Joshua P. Davis, *Applying Litigation Economics to Patent Settlements: Why Reverse Payments Should Be Per Se Illegal*, 41 RUTGERS L.J. 255, 306 (2009) (arguing reverse payments should be per se unlawful because the “general tendency will be to delay generic entry beyond the expected value entry date, resulting in unnecessary error costs . . .” and “judicial attempts to scrutinize reverse payments will be unlikely to succeed and will entail substantial transaction costs”).
- <sup>39</sup> *Actavis*, 133 S. Ct. at 2237.
- <sup>40</sup> See Joshua D. Wright, Comm’r, Fed. Trade Comm’n, *FTC v. Actavis and the Future of Reverse Payment Cases—Remarks at Concurrences Journal Annual Dinner* (Sept. 26, 2013), available at [http://www.ftc.gov/sites/default/files/documents/public\\_statements/ftc-v.actavis-future-reverse-payment-cases/130926actavis.pdf](http://www.ftc.gov/sites/default/files/documents/public_statements/ftc-v.actavis-future-reverse-payment-cases/130926actavis.pdf).
- <sup>41</sup> See Crane, *supra* note 35, at 785–88.
- <sup>42</sup> *FTC v. Watson Pharms., Inc.*, 677 F.3d 1298, 1315 (11th Cir. 2012). Turducken refers to a complex culinary dish consisting of a chicken stuffed inside a duck that is stuffed inside a turkey. See Amanda P. Reeves, *Muddying the Settlement Waters: Open Questions and Unintended Consequences Following FTC v. Actavis*, ANTITRUST, Fall 2013, at 9, 14 n.40.
- <sup>43</sup> *Actavis*, 133 S. Ct. at 2236.
- <sup>44</sup> *Id.* at 2236–37. The Court noted that the FTC acknowledged reverse payments can have redeeming virtues: “The reverse payment, for example, may amount to no more than a rough approximation of the litigation expenses saved through the settlement. That payment may reflect compensation for other services that the generic has promised to perform—such as distributing the patented item or helping to develop a market for that item. There may be other justifications. Where a reverse payment reflects traditional settlement considerations, such as avoided litigation costs or fair value for services, there is not the same concern that a patentee is using its monopoly profits to avoid the risk of patent invalidation or a finding of noninfringement.” *Id.* at 2236.
- <sup>45</sup> *Id.* at 2237.
- <sup>46</sup> See Kobayashi et al., *supra* note 15, at 17 (setting out alternative example where  $p = .5$ ).
- <sup>47</sup> In addition, as discussed below, the social costs of Type I error can be larger, and include the forgone benefits of research deterred and of the drugs that would have been produced. In a working paper posted to SSRN as this article goes to press, Edlin et al. suggest that considering costs associated with the erroneous invalidation of valid patents as a Type I error is “erroneous and confusing.” See Aaron Edlin, Scott Hemphill, Herbert Hovenkamp & Carl Shapiro, *The Actavis Inference: Theory and Practice*, available at <http://ssrn.com/abstract=2560107> or <http://dx.doi.org/10.2139/ssrn.2560107>. In contrast, our view is that consideration of these costs is a critical component of any legal or normative economic analysis of the patent/antitrust interface. As the Court noted: “It is as important to the public that competition should not be repressed by worthless patents, as that the patentee of a really valuable invention should be protected in his monopoly.” *United States v. Glaxo Group*, 410 U.S. 52, 58 (1973). See generally HERBERT HOVENKAMP, MARK D. JANIS, MARK A. LEMLEY & CHRISTOPHER R. LESLIE, *IP AND ANTITRUST, AN ANALYSIS OF ANTITRUST PRINCIPLES APPLIED TO INTELLECTUAL PROPERTY LAW*, SECOND EDITION, SECTION 1.3 (2014).
- <sup>48</sup> See Joshua D. Wright, Comm’r, Fed. Trade Comm’n, *Antitrust Analysis of Reverse Payment Settlements After Actavis: Three Questions and Proposed Answers—Remarks at the Antitrust Masters Course VII* (Oct. 10, 2014) (citing sources), available at [http://www.ftc.gov/system/files/documents/public\\_statements/591131/141010actavisspeech.pdf](http://www.ftc.gov/system/files/documents/public_statements/591131/141010actavisspeech.pdf).
- <sup>49</sup> See, e.g., Ken Heyer, *Welfare Standards and Merger Analysis: Why Not the Best?*, 2 COMPETITION POL’Y INT’L 29, 29 n.2 (2006); Steven C. Salop, *Question: What Is the Real and Proper Antitrust Welfare Standard? Answer: The True Consumer Welfare Standard*, 22 LOY. CONSUMER L. REV. 336, 336 (2010).
- <sup>50</sup> These would include the costs imposed upon the court system that are not borne by the parties. In the example, these are assumed to equal the brand’s litigation costs.
- <sup>51</sup> See Richard S. Higgins & Donald L. Martin, *The Economics of “Pay-For-Delay” Under Rule of Reason Generic Competition and Hybrid Settlements 6* (Working paper, Mar. 4, 2014), available at <http://ssrn.com/abstract=2404563> (using total welfare standard).
- <sup>52</sup> With linear demand and constant costs, this result does not depend upon  $p$ , the probability that the patent will be upheld in litigation. Under these conditions, changes in  $p$  will shift  $E^*$  and the Brand’s minimum acceptable entry date line to the left by the same amount, leaving  $X^M$  unchanged.
- <sup>53</sup> The consumer welfare minus litigation costs standard places greater weight on the reduction of surplus (a cardinal measure) relative to litigation costs than does the total welfare (also a cardinal measure) minus litigation costs standard, which is equivalent to minimizing deadweight loss plus litigation costs.
- <sup>54</sup> Indeed, it is interesting that the Court’s opinion in *Actavis* suggests payment of the Brand’s avoided litigation costs is a legitimate aim of settlement. In other contexts, the extraction of the other parties’ litigation costs has been one of the primary reasons for adopting rules that truncate litigation at an early stage. For example, in moving to a plausibility standard at the pleading stage in *Twombly*, the Court expressed concern over a plaintiff with “a largely groundless claim” being allowed to “take up the time of a number of other people, with the right to do so representing an *in terrorem* increment to settlement value.” *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 558 (2007) (quoting *Dura Pharms., Inc. v. Broudo*, 544 U.S. 336, 347 (2005)). See also Bruce H. Kobayashi, *Law’s Information Revolution as Procedural Reform: Predictive Search as a Solution to the In Terrorem Effect of Externalized Discovery Costs*, 2014 U. ILL. L. REV. 1473, 1516 (2014); David Rosenberg & Steven Shavell, *A Model in Which Suits Are Brought for Their Nuisance Value*, 5 INT’L REV. L. & ECON. 3, 4–6 (1985).