The Rule of Reason and the Scope of the Patent

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The Rule of Reason and the Scope of the Patent

HERBERT HOVENKAMP*

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I. INTRODUCTION

For a century-and-a-half, the Supreme Court has described perceived abuses of patents as conduct that reaches “beyond the scope of the

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That phrase, which evokes an image of boundary lines in real property, was applied to both government and private activity and came to have many different meanings. Sometimes it was used offensively to conclude that certain patent uses were unlawful because they extended beyond the scope of the patent. Later it came to be used defensively as well, to characterize activities as lawful if they did not extend beyond the patent's scope. In the first half of the twentieth century, this doctrine was imported from patent law into antitrust law, where it has been widely used to assess license agreements or other contracts involving patents, as well as settlements of patent infringement lawsuits.

The "scope of the patent" metaphor might remain useful for assessing conduct thought to be inconsistent with patent law, which has a legitimate concern with patent breadth. It is not a helpful tool for antitrust analysis, however. Offensive antitrust use of the scope of the patent test often identified practices as anticompetitive when they were in fact competitively harmless. By contrast, defensive antitrust uses created an enclosure that protected collusion or anticompetitive exclusion from antitrust scrutiny. The result could be socially costly collusive arrangements that were more profitable for the parties than the litigated solution, precisely because they limited output or increased price excessively. The dissenters' position in the Supreme Court's 2013 Actavis decision represents such a situation and one where the majority rightfully rejected the scope of the patent test for legality.

II. ANTITRUST APPROACHES TO PATENT PRACTICES

Courts assess most antitrust practices under a "rule of reason," which requires them to estimate the defendant's market power and the impact of some practice that is claimed to be unreasonably collusive or exclusionary. Antitrust law also recognizes a "per se" rule that is applied only to naked restraints of trade—mainly price fixing, market division, and some boycotts, all of which are addressed under section 1 of the Sherman Act. A practice is "naked" if it is unrelated to any kind of collaborative activity with efficiency-enhancing potential, such as joint production, joint research or

1. See infra, note 42 and accompanying text.
technology sharing, or joint distribution. Whether some intermediate form of “quick look” analysis exists is controversial, but there is no need for a distinctive intermediate approach if proof burdens and presumptions under the rule of reason are properly assigned.

Some antitrust challenges to patent practices involve unilateral exclusionary conduct. Most are complaints about the competitive effects of various collaborations or licensing agreements. Many of these are simply contracts negotiated in the technology marketplace, while others are the outcome of patent infringement litigation.

The existence of a license plus the licensee’s actual production indicates that the firms are sharing technology. Absent other restraints, they are very likely increasing output above what would occur without licensing. This should indicate that a restraint is not naked but rather ancillary to joint provision of some kind. For example, cross licensing in a large patent pool is typically an effort to compete within a common technology, which is often essential for achieving both competition and interoperability. This is a common feature of markets for digital products. Other types of patent licenses, such as those given to several local producers to make the patentee’s product, are a form of vertical integration. They serve to establish a dealership network for a common product, give dealers incentives to promote the supplier’s product, eliminate double marginalization, or


7. See Hovenkamp, Antitrust and Information Technologies, supra note 6.

8. Double marginalization—sometimes-called royalty stacking in the case of intellectual property licenses—occurs when two firms supply complementary inputs to some good, each has some market power, and they do not coordinate their pricing. In that case, the sum of the prices charged by each will exceed their combined price if they were a single entity or could coordinate. See 3B PHILLIP E. AREEDA & HERBERT HOVENKAMP, ANTITRUST LAW ¶ 758 (4th ed. forthcoming 2015).
simply take advantage of complementarities that technologies often provide.\(^9\) Such practices are typically procompetitive and thus are properly treated under the rule of reason.\(^10\)

A few agreements, such as the one at issue in the Supreme Court’s 2013 *Actavis* decision,\(^11\) are not ancillary to any kind of joint-production activity or technology sharing. In *Actavis*, a firm with a patent essential to manufacturing a product paid a rival to stay out of that market for a specified period of time.\(^12\) There was no integration of production, sharing of technology, or licensing. Outside the patent law context, such an agreement would be unlawful per se and could even be a criminal violation. As a result, the Supreme Court’s decision to apply the rule of reason must have been driven exclusively by considerations of patent law.

Applying antitrust law to agreements involving patents raises several issues. One is whether the practice falls completely within an express authorization of the Patent Act. If so, then antitrust rarely has a place. The rather general language of the antitrust laws yields to specific provisions of the Patent Act. For example, the Patent Act authorizes a patentee, acting unilaterally, to refuse to license its patent to others.\(^13\) As a result, a simple refusal to license is not an antitrust violation.

In one situation, the antitrust laws are more specific than the Patent Act. Section 3 of the Clayton Act forbids anticompetitive exclusive dealing or tying of goods, “whether patented or unpatented.”\(^14\) While section 261 of the Patent Act authorizes exclusive licenses,\(^15\) an exclusive license is not the same thing as exclusive dealing. An exclusive license operates in favor of the licensee, giving it the right to exclude other licensees of the same patent. For example, a licensee who has an exclusive license for the state of Nebraska can exclude others who attempt to practice that patent in Nebraska. By contrast, exclusive dealing operates against the licensee, forbidding it from purchasing and reselling competing goods. For example,

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\(^9\) On these and other advantages of organized networks of independent dealers, see 8 Phillip E. Areeda & Herbert Hovenkamp, *Antitrust Law* \(\S\) 1601, 1608, 1611–19 (3d ed. 2010).


\(^12\) Id. at 2229.

\(^13\) 35 U.S.C. § 271(d)(4) (2012) (“No patent owner . . . shall be denied relief or deemed guilty of misuse or illegal extension of the patent right by reason of his having . . . (4) refused to license or use any rights to the patent[.]”).


a dealer in Alpha’s patented product in Nebraska may be forbidden from selling the product of Beta, a rival supplier. Because the Patent Act is silent on exclusive dealing, the Clayton Act provision controls.

When a practice is not authorized by the Patent Act, general antitrust provisions such as those contained in the Sherman Act should have relatively free rein. This does not mean that practices that the Patent Act does not authorize are unlawful under the antitrust laws, but only that antitrust is free to impose the analysis it would ordinarily apply. There are good reasons for this presumptive rule. First, the Patent Act reflects a long history of producer control. When a statutory provision that reflects special interest capture is ambiguous, sound interpretation requires construing the statute against the interest group that has shown its ability to control the process. If the courts get it wrong, the interest groups involved are in a position to have it changed. If the statute is construed the other way, however, it will probably never be changed. Historically, whenever courts imposed either antitrust rules or rules about patent scope that were regarded by patenting entities as overly restrictive, Congress amended the Patent Act to counter them. For example, the 1952 Patent Act limited what had come to be regarded as overly aggressive claims of patent “misuse.” Then again, in 1988, Congress made clear that unilateral refusals to license were not unlawful misuse and that tying arrangements were unlawful only if the defendant had market power in the tying product.

Second, virtually all patent practices subject to antitrust analysis occur after a patent has been issued. This includes both restricted and unrestricted licensing, pooling, price fixing, and settlements of infringement suits. This fact is important because the patent process is characterized by intense government supervision during the patent application and prosecution process, but almost no supervision at all once a patent has been issued. Here, we can apply the same set of rules that generally govern antitrust

16. See infra text accompanying note 71.
analysis in regulated markets. When markets are intensely regulated and a government official has reviewed and supervised the practice under consideration, there is very little room for antitrust. As a result, antitrust has virtually no role to play in the patent issuance process, not even for the fraudulent or inequitable conduct of a patent applicant in obtaining a patent. The patent system has ample legal authority and resources for policing such conduct.

Even antitrust’s Walker Process doctrine, which recognizes antitrust liability for some improper infringement actions, pertains entirely too post-issuance conduct. The gravamen of a Walker Process violation is not obtaining a patent fraudulently. Rather, it lies in later enforcing or threatening to enforce a patent that had been obtained fraudulently, by inequitable conduct, or where a reasonable person in the patentee’s position should have known that the patent was not enforceable. Once a patent has issued, it is a personal property asset, and its use is largely in the discretion of the patent owner. This makes antitrust an important instrument for dealing with allegedly anticompetitive conduct involving issued patents.

Third, antitrust policy has a relatively robust, although certainly imperfect, tradition of examining the economic effects of practices in the industry where they occur. For example, in a challenge to exclusive dealing, a court may consider market structure, the height and nature of entry barriers, the duration of exclusive contracts, the availability of alternative distribution mechanisms, and the like. In sharp contrast, patent law is almost completely indifferent to market-specific factors that pertain to patent value and the effects of patent practices. As a general proposition, it treats all markets alike and has never developed useful tools for considering how or when a

21. See 1A PHILLIP E. AREEDA & HERBERT HOVENKAMP, ANTITRUST LAW ¶¶ 244b, 244c (4th ed. 2013).
22. See AREEDA & HOVENKAMP, supra note 5, ¶ 706a.
24. See AREEDA & HOVENKAMP, supra note 5, ¶ 706; see also FMC Corp. v. Manitowoc Co., 835 F.2d 1411, 1418 & n.16 (Fed. Cir. 1987) (distinguishing “mere procurement” of a patent from subsequent enforcement: the former cannot be an antitrust violation); Cygnus Therapeutics Sys. v. ALZA Corp., 92 F.3d 1153 (Fed. Cir. 1996) (noting that the procurement of a patent by fraud cannot establish an antitrust violation absent evidence of any action toward enforcement of a patent).
particular practice furthers or restrains competition or, for that matter, even when it furthers or restrains innovation.\textsuperscript{27}

To be sure, factors such as high fixed costs, restricted entry, nonrivalry, product differentiation, or information flow may play an important role in predicting how a patent practice might affect competition or innovation. The need for interconnectivity or product complementarity may also serve to explain the value of joint innovation or information sharing. But these are \textit{antitrust} tools, derived from industrial organization economics. Patent law has no equivalent tool set for assessing either the competitive or the innovation effects of specific post-issuance patent practices.

The discussion that follows evaluates practices that are not expressly authorized by the Patent Act and might be subjected to antitrust scrutiny. It considers: (1) the significance of adversity between the parties to patent settlements; (2) the scope of the patent test for patent and antitrust practices favored by the dissenters in the \textit{Actavis} pay-for-delay case, but rejected by the majority; (3) the relevance of pre- versus post-issuance patent conduct in determining antitrust immunity; and (4) proper application of the rule of reason, considering burdens of proof, the relevance of less restrictive alternatives, as well as why the antitrust analysis should usually proceed without considering patent validity or scope (infringement).

\section*{III. Patent Settlements and Adversity Between the Parties}

Most lawsuits settle when each party has some prospect of winning or losing. The settlement discounts these probabilities into a certain agreement immediately rather than an uncertain outcome later. The classic patent infringement lawsuit settled by a production license is a good example. Under the settlement agreement, the infringement defendant becomes a producing licensee. The relative strength of the infringement claim appears mainly in the size of the agreed upon royalty, although it can also show up in other provisions, such as the extent of geographical or other output limitations. In general, the more likely the patent was valid and infringed, the higher the royalty payment or the more restrictive the license terms will be.\textsuperscript{28}

\begin{footnotesize}
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\item \textsuperscript{27} See Hovenkamp, \textit{Antitrust and the Patent System}, supra note 2, at 496–504.
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One problem with pay-for-delay pharmaceutical patent infringement suits that originate under the Hatch-Waxman Act is the way the statutory structure limits adversity between the patentee and the generic infringer. Under the Act, a generic firm commits patent infringement when it files an abbreviated new drug application (ANDA) for a biological equivalent to a pioneer drug and the relevant patent has not yet expired. The significance of the abbreviated application is that, because the drug is bioequivalent to a drug that has already undergone comprehensive FDA testing, most of that testing need not be repeated. At the time the generic files its ANDA, the pioneer patent holder can either acquiesce and permit the generic to produce or else can file a patent infringement action. The Act provides that once the generic begins producing under this ANDA, it will have a 180-day period of exclusivity, during which time no other generics can enter the market.

The Hatch-Waxman statutory mechanism contemplated that the generic would begin production after pioneer acquiescence, or upon winning the infringement lawsuit, or settling with a production license. However, if the parties agree that the generic will delay entry for a specified period in exchange for a payment from the patentee, production may not begin for several years. The clock does not run on the generic exclusivity provision. The parties are in a position to share the full returns available on a patent that has now been placed beyond challenge by potential infringers.

When a payment-for-delay is possible, a settlement agreement on the delay period does not reflect adversity between the parties. Both profit from a longer delay. This is because prescription drug prices drop when generic entry occurs, often quickly and dramatically.

entry, the pioneer was setting its profit-maximizing output and price. The parties could attain similar profits after generic entry occurs only by colluding. The price and output set by a perfect cartel of an undifferentiated product—such as bioequivalent drugs—is the same as the monopoly price and output. But that would be unlawful per se. If the generic and competitor do not fix prices, output will increase and prices will drop. While development costs for drugs are high, manufacturing costs are relatively low, magnifying the extent of the price reduction. As a result, price–cost margins are typically very high just prior to generic entry, leaving a great deal of room for the parties operating under competitive constraints to cut the price. In many of these cases, two or more generic producers are waiting in the wings to compete. In such situations, the incentive for an anticompetitive settlement is even larger than for a single generic. 

Congress did not foresee that this situation creates an opportunity that is well known in the history of collusion: sharing the monopoly profit is a better outcome for the cartel players, no matter how little or how much each of them produces. The only trick is to make the cartel legal. For example, suppose that under the pioneer’s original monopoly its profits are 100, while under generic entry the price will drop and the aggregate profits of the two firms will go down to 60—say, 40 to the pioneer and 20 to the generic. Any output allocation that tends to preserve the 100 in


34. Sometimes the price of the pioneer alone actually increases after generic entry, but this is generally accompanied by a significant loss of market share by the pioneer. That is, generic entry sometimes creates segmented markets in which a relatively small group of people continue to pay a high price for the pioneer version, while the larger balance of the market moves to the generic at a much lower price. See Henry Grabowski et al., Recent Trends in Brand-name and Generic Drug Competition, 17 J. Med. Econ. 207, 212 (2013), http://fds.duke.edu/db/attachment/2575 [http://perma.cc/9LFY-UVAK] (finding that for drugs in the studied sample, the pioneer retained only 16% of the market one year after generic entry).

profits can be profitable for both parties, including one in which the generic firm produces nothing at all. For example, the pioneer might pay the generic 30 to stay out of the market, retaining 70 to itself. The payment that the generic receives is more profitable than anything it could reasonably expect to earn by producing, and the pioneer is better off as well. This outcome is no different than what would happen if a dominant firm bought out its only rival and shut it down, except that in this case the duration of the shutdown is limited. The history of cartels has seen instances when cartel members have compensated one of those among them for a complete shutdown.

The cartel is especially profitable in the Hatch-Waxman pay-for-delay situation because government regulation provides the entry barrier that virtually guarantees its success. Under the Hatch-Waxman Act, no one else can challenge the patent in question until 180 days after the generic begins producing, which under the settlement agreement could be several years in the future—right up to the expiration date of the patent. If market power is present, the parties will have achieved a cartel protected from entry for the term set by the settlement agreement.

One reason adversity is missing in this setting is that the parties can trade the size of the payment and the generic’s entry date against each other—a larger payment to the generic in exchange for a later entry date. As noted below, under the Actavis’ dissenters’ scope of the patent test, if any date prior to patent expiration is within the scope of the patent, the

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36. See Ruben Jacobo-Rubio et al., Generic Entry, Pay-for-Delay Settlements, and the Distribution of Surplus in the US Pharmaceutical Industry (Oct. 7, 2014), http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2481908 http://perma.cc/8TLM-APX9] (measuring high value of pay-for-delay settlements). One important finding is that pioneer drug makers value entry deterrence by roughly $4.6 billion, while generics value the right to enter at about $236.8 million. Id. at 3. This provides enormous bargaining room for an exclusion payment once the parties have come fairly close to an understanding about patent value.

37. This is true because the cartel needs to reduce output, and the most profitable output reduction gets rid of the highest cost output. As a result, it may be more profitable to compensate a high cost member for shutting down than to retain part of its production. For examples, see JEFFREY R. FEAR, ORGANIZING CONTROL: AUGUST THYSSEN AND THE CONSTRUCTION OF GERMAN CORPORATE MANAGEMENT 255 (2005) (describing such shutdowns within German steel cartels); Henry C. Adams, Relation of the State to Industrial Action, 1 PUBLICATIONS AM. ECON. ASS’N 465, 482–83 (1887) (describing one such incident in a grain elevator cartel); see also HOVENKAMP, FEDERAL ANTITRUST POLICY, supra note 33, § 4.1c (discussing the internal efficiencies of cartels).
equilibrium entry point for the generic will be just at the patent’s expiration.\textsuperscript{38} That will maximize the value of the monopoly period and give the participants the largest amount to share. By contrast, fixing the entry date without any payments to the generic is more likely to preserve adversity and creates a “less restrictive alternative” that can serve to validate the license agreement under the antitrust laws.\textsuperscript{39}

IV. THE SCOPE OF THE PATENT TEST—OFFENSIVE AND DEFENSIVE

Historically, the courts used the scope of the patent formulation as a limiting device to restrict activities thought to reach beyond the statutory authorization granted to the patentee. For example, nineteenth-century decisions used such formulations when limiting retroactive statutory term extensions as creating rights beyond the monopoly granted by an issued patent.\textsuperscript{40} Patent law’s “first sale,” or exhaustion, doctrine used the same concept. Adams v. Burke described a patentee’s attempt to control the use of a patented good after it had been sold as asserting rights “no longer within the limits of the monopoly.”\textsuperscript{41} The concept was later used to refer to overly broad patent claim constructions as attempts to “enlarge a patent beyond the scope of its claim.”\textsuperscript{42} In the first half of the twentieth century, the Supreme Court used similar language repeatedly when discussing patent tying arrangements or similar practices that were thought to extend the patentee’s rights beyond the patent’s intended scope.\textsuperscript{43} The Court wrote


\textsuperscript{39} See infra text accompanying note 106.

\textsuperscript{40} E.g., Bloomer v. McQuewan, 55 U.S. 539, 548 (1852) (Taney, C.J.) (“[W]hen the machine passes to the hands of the purchaser, it is no longer within the limits of the monopoly.”).


\textsuperscript{42} Coupe v. Royer, 155 U.S. 565, 576 (1895).

\textsuperscript{43} Motion Pictures Patents Co. v. Universal Film Mfg. Co., 243 U.S. 502, 517 (1917) (determining that the tying of a patented projector to unpatented films was an attempt to extend power “wholly without the scope of the patent monopoly.”); Carbice Corp. of Am. v. Am. Patents Dev. Corp., 283 U.S. 27, 33 (1931) (discussing tying of patented ice box to unpatentable dry ice: “Control over the supply of such unpatented material is beyond the scope of the patentee’s monopoly[.]”); Mercoid Corp. v. Mid-Continent Inv. Co., 320 U.S. 661, 665–66 (1944) (denying ability to “acquire a monopoly which is not plainly within the terms of the grant”); see also Henry v. A.B. Dick Co., 224
at some length on the beyond the scope formulation in its 1940 Ethyl
decision, holding that the patentee of a gasoline antiknock additive could
not use its sales agreements to specify the price at which the gasoline was
to be sold.44 Finally, in its 1964 Brulotte decision, the Supreme Court
condemned a patentee’s agreement requiring royalty payments after the
patent expired as an “effort to enlarge the monopoly of the patent.”45

A. Defensive Uses

Beginning in the early twentieth century the scope of the patent doctrine
found a different, defensive use—mainly, that a patent settlement or other
licensing provision is lawful, even if facially anticompetitive, provided
that the agreement did not extend the patent monopoly beyond its lawful
scope. For example, in its 1902 Bement decision, the Supreme Court held
that product price fixing contained in a license agreement is lawful if it
does no more than “keep up the monopoly” granted by the patent.46 In
approving a product price fix in the controversial 1926 General Electric
case, the Court concluded that a patent licensee acts unlawfully only when
“he steps out of the scope of his patent rights.”47 The Court divided on the
issue in Line Material. The majority condemned a product price fixing
scheme contained in patent cross licenses and sublicenses. Three dissenting
Justices objected that the scheme did not reach “beyond the scope of the
statutory patent rights,” because a single patentee would have been legally
able to set the product price in any event.48

44. Ethyl Gasoline Corp. v. United States, 309 U.S. 436, 455–59 (1940) (A price setting
clause expanded the defendant’s power beyond the “scope of the patent monopoly.”).
45. Brulotte v. Thys Co., 379 U.S. 29, 33 (1964). The decision has been widely
criticized. See Herbert Hovenkamp et al., IP AND ANTITRUST: AN ANALYSIS OF
ANTITRUST PRINCIPLES APPLIED TO INTELLECTUAL PROPERTY LAW § 23.2 (2d ed. 2010 &
2014 Supp). Nevertheless, in 2015 the Supreme Court adhered to Brulotte on grounds of
very little attention to the merits. Rather, it cited long-standing reliance by private parties,
in addition to the fact that Congress had many opportunities to overrule Brulotte statutorily
but had never done so. Id. at 2409–10. For further analysis, see Herbert Hovenkamp,
What the Line Material majority realized but the dissenters did not was that a patentee always has the power to set the price of its own output, no matter the strength or value of its patent. Stipulating the product price of licensees, however, cartelizes any market that they might collectively control. Further, the lawful cartel that results is more profitable to the parties than competitive alternatives, thus limiting adversity among them. As we shall see below, the scope of the patent test should never be used to immunize behavior contractually imposed on someone else simply because a patent owner could lawfully engage in that same business itself.

The defensive scope of the patent test regards the patent as a walled garden whose contents are free from antitrust scrutiny, provided that the challenged conduct stays inside the wall. A practice that reaches outside is beyond the scope of the patent, but that does not necessarily mean that it is an antitrust violation. Rather, the practice can then be subjected to antitrust analysis. In Actavis, the dissenters would have applied the scope of the patent test in this defensive way. Chief Justice Roberts concluded that when a patent holder does anything, including entering a settlement agreement, the “key” is that it “must act within the scope of the patent. If its actions go beyond the monopoly powers conferred by the patent, we have held that such actions are subject to antitrust scrutiny.”

By contrast, the majority conceded that the competitor-exclusion agreement at issue, which terminated prior to the patent’s expiration date, did not go beyond the scope of the patent. Nevertheless, this fact did not “immunize the agreement from antitrust attack.”

As the tying, resale price maintenance, and product price fixing cases indicate, the idea of scope of the patent can refer to things other than patent duration. Patent ties were condemned, not because their duration extended beyond patent expiration but rather because they were thought to represent patentee overreaching, extending the patent to things or rights that the

49. This formulation owes a great deal to Ward S. Bowman, Jr., who posed the antitrust question as, “Is more being monopolized than what the patent grants, or is the practice merely maximizing the reward attributable to the . . . patent?” WARD S. BOWMAN, JR., PATENT AND ANTITRUST LAW: A LEGAL AND ECONOMIC APPRAISAL 9 (1973).


52. Id. at 2230.
patent did not properly include. For example, the Edison projector patent monopoly did not extend to the unpatented films that were shown in it. Likewise, an agreement that purported to be a patent settlement but that excluded a firm from some market not even arguably covered by the patent would be an attempt to extend the patent beyond its scope. Some pharmaceutical settlements have involved such claims.

B. Scope of the Patent Under Vertical Integration

The scope of the patent rule is not nearly as unambiguous as the Actavis dissenters believed. For example, when resale price maintenance (RPM) was unlawful per se, the Supreme Court consistently condemned RPM agreements contained in patent licenses. RPM agreements seem to fall within the scope of the patent, however, because if the patentee sold the goods directly to consumers itself, it could charge any price it pleased. That outcome would be no different if it sold to a reseller but stipulated the resale price. That was precisely the reasoning the Courts used to uphold horizontal product price fixing in the Bement and GE cases mentioned above.

The scope of the patent rule becomes quite arbitrary when we compare patent use by vertically integrated versus unintegrated firms. For example, a vertically integrated patentee might engage in tying internally and stay completely within the scope of the patent. Suppose that Edison Films made movies and then invented and patented a superior projector for showing them. It could lawfully refuse to license the projector to anyone else, using it exclusively to show its own films. In that case, the projector would be an upstream component in Edison’s process, and using it to show

55. RPM was made unlawful per se by Dr. Miles Med. Co. v. John D. Park & Sons Co., 220 U.S. 373, (1911), but was placed under the rule of reason in Leegin Creative Leather Prods., Inc. v. PSKS, Inc., 551 U.S. 877 (2007) (overruling Dr. Miles).
57. See supra notes 46, 47 and accompanying text.
its own films would clearly be within the scope of the patent. Section 3 of the Clayton Act tracks this outcome, condemning anticompetitive patent ties imposed on another firm by agreement, but not internal production that uses two inputs together.60

By the same token, both Ethyl and Line Material, mentioned above,61 involved a practice—RPM of the product price—that a patentee could lawfully have done had it made the entire product itself, using the patent internally but refusing to license it to anyone else. They ran afoul of the antitrust laws only because they licensed their product to others and then stipulated the price that the licensees must charge. In Ethyl, the defendant made an antiknock additive that was used in very small amounts in gasoline, but when it sold the additive to refiners, it stipulated the price of the gasoline itself.62 The Court found that this extension from the patented additive to the gasoline went beyond the scope of the patent.63 If Ethyl had purchased gasoline, added the additive, and then resold the gasoline itself at any price it chose, it is difficult to find any basis for an antitrust violation. That is, antitrust liability turned on which direction the product moved in the marketplace.

The scope of the patent test, as the courts have interpreted it, apparently means that a patentee may lawfully do something internally, such as using two products together or setting a retail price, but that this same activity steps outside of the scope of the patent as soon as the patentee attempts to transfer part of the activity to someone else, even though the end result is precisely the same. Under that reasoning, it is hardly clear that the pay-for-delay settlement is within the scope of the patent. The patentee was not merely manufacturing under its patent, but also paying a rival to stay out of the market. There was no integration of distribution between the parties, as there is in most tying or RPM cases, but that would cut against rather than in favor of the practice.

To summarize: if a patentee refuses to license to others, then it is free to practice its patent internally, set the product price on its own sales, produce

60. 15 U.S.C. § 14 (2012). The doctrine of patent “misuse” was invented in tying cases where the premise was that the patent was otherwise in force. See 10 PHILLIP E. AREEDA & HERBERT HOVENKAMP, ANTITRUST LAW ¶¶ 1781–82 (3d ed. 2011); Christina Bohannan, IP Misuse as Foreclosure, 96 IOWA L. REV. 475, 501 (2011).
61. See supra notes 44, 48.
63. Id. at 456–58.
wherever and as much as it wants, use only its own complementary products, and so on. Patent validity is not even an issue as long as the patentee does not try to enforce the patent against others, and all of these activities fall within the scope of the patent.

Further, a patentee who is currently charging $5.00 each for its patented widgets might license another manufacturer only on the condition that this manufacturer also charge $5.00 for the finished product. The Supreme Court permitted this outcome when the restraint was horizontal, as in Bement and GE, but not when it was vertical, as in Univis and Ethyl. That result is perverse as a matter of antitrust policy, because it deals with a vertical restraint more harshly than a horizontal one. It also exposes the scope of the patent test as little more than easily manipulated rhetoric.

C. Scope of the Patent and Pay-for-Delay Equilibrium

In Actavis, the defendant was accused of violating the antitrust laws by paying the patent infringement defendant to stay out of the market for a period that was shorter than the remaining duration of the patent. Two things are noteworthy about this agreement. First, if the patent were both valid and infringed, then the pay-for-delay agreement would be no more exclusionary than a judicial decision upholding the patent for its full term. In this sense, the restraint was within the scope of the patent. Second, however, paying a rival to stay out of one’s market without any kind of license involving production or joint integration is a naked restraint on trade, and a practice that is not authorized by any provision in the Patent Act.

For the Actavis dissenters, the “precise terms of the grant define the limits of a patentee’s monopoly and the area in which the patentee is freed from competition.” Following other circuit courts, the Eleventh Circuit had defined “scope” strictly in reference to patent duration, indicating that a pay-for-delay settlement that kept the generic out indefinitely or for some period beyond the patent’s expiration would be beyond the scope of the patent. Justice Breyer’s opinion for the Court also interpreted scope

64. Compare supra notes 46, 47 and accompanying text, with supra notes 56, 62–63 and accompanying text.

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of the patent to refer to the patent’s duration. That is apparently what Chief Justice Roberts meant as well, although his dissenting opinion was not as explicit. Of course, the patentee in Actavis was not simply practicing the patent for its duration and refusing to license; it was also paying someone else not to challenge it in a legal environment that made it impossible for anyone else to challenge the patent either.

Without a reverse payment, the litigating parties’ selection of settlement options depends entirely on their assessment of the patent’s validity and infringement. They should have complete adversity on this question. A rock-solid patent would lead to a generic entry date close to the patent’s expiration date, while a very weak patent would lead to a much earlier expected entry date. If this expected entry date could be computed by a third party, it could provide a tool for evaluating patent settlements that include pay for delay: a settlement that permits generic entry at or prior to the expected entry date would be procompetitive because it would be no worse than the predicted, risk-adjusted outcome under litigation when no payment is available.

patent settlements in which the generic firm agrees to delay entry into the market in exchange for payment fall within the scope of the patent holder’s property rights . . . .); In re Ciprofloxacin Hydrochloride Antitrust Litig., 544 F.3d 1323, 1332–33 (Fed. Cir. 2008), abrogated by Actavis, 133 S. Ct. at 2238. But see In re K-Dur Antitrust Litig., 686 F.3d 197, 214 (3d Cir. 2012), cert. granted and judgment vacated sub nom. Upsher-Smith Labs., Inc. v. La. Wholesale Drug Co., 133 S. Ct. 2849 (2013) (rejecting scope of the patent test). 67. See Actavis, 133 S. Ct. at 2227 (“[S]ince the alleged infringer’s promise not to enter the patentee’s market expired before the patent’s term ended, the Circuit found the agreement legal and dismissed the FTC complaint.” (citing FTC v. Watson Pharm., Inc., 677 F.3d 1298, 1315 (2012)).

68. See id. at 2240 (Roberts, C.J., dissenting). The European Commission recently fined Lundbeck, Inc. for a pay-for-delay settlement that extended beyond the expiration date of the patent. The public version of the decision is available at http://ec.europa.eu/competition/antitrust/cases/doc_docs/39226/39226_831011.pdf.

69. Carl Shapiro, Antitrust Limits to Patent Settlements, 34 RAND J. ECON. 391, 407–08 (2003) (on computing the expected entry date); see also Aaron Edlin, Scott Hemphill, Herbert Hovenkamp, & Carl Shapiro, Activating Actavis, 28 ANTITRUST 16, 16 (Fall 2013) (discussing large reverse payments as a key source of the inference); Herbert Hovenkamp, Mark Janis, & Mark A. Lemley, Anticompetitive Settlement of Intellectual Property Disputes, 87 MINN. L. REV. 1719, 1762 (2003) (“[A]n agreement to delay entry likely reflects the parties’ joint assessment of the likely outcome of the litigation.”). Einer Elhauge and Alex Kreuger speak of the “expected litigation exclusion period.” See Einer Elhauge & Alex Kreuger, Solving the Patent Settlement Puzzle, 91 TEX. L. REV. 283, 284–85 (2012). They conclude that the period runs around 27%–52% of the remaining patent
Of course, courts do not compute expected entry dates based on variable predictions of patent strength. Even in fully litigated patent infringement lawsuits, their approach is binary, declaring a patent either valid or invalid. Under the first, expected entry cannot occur until after the full patent term ends; under the second, it can occur immediately. In responding to a settlement, a court might set aside a patent settlement based on an obviously deficient patent. Most of the time, however, it defers to the parties’ judgment, presumably assuming that adversity between them will resolve most issues. A realistic approach to anticompetitive patent settlements must take these limitations on judicial power into account.

In the Hatch-Waxman context, the availability of reverse payments plus third-party exclusion until 180 days after generic production seriously diminishes adversity between the parties by giving them a common goal, which is to maximize the overall size of the patent pie. Adversity remains on the size of the reverse payment, which determines how the pie will be divided.

This fact explains why the scope of the patent test advocated by the Actavis dissenter can be so harmful to competition. That rule effectively decides the size of the patent pie by presuming a 100% chance of patent validity. A durational scope of the patent test for pay-for-delay settlements creates a bargaining equilibrium equating the term of delay with the remaining duration of the patent. The figure below illustrates:

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term, by taking the inverse of statistics to show that patentees lose 48%–73% of Hatch-Waxman ANDA-generated patent litigation cases that are prosecuted to a judgment. As the authors observe, the patents that yield high pay-for-delay settlements would be closer to the 27% number. Id. at 287–88. Note, however, that the patents that are actually litigated are very likely stronger than the ones that settle. On patentee success in such cases, see ADAM GREENE & D. DEWEY STEADMAN, RBC CAPITAL MKTS., PHARMACEUTICALS: ANALYZING LITIGATION SUCCESS RATES 1 (2010); Paul M. Janicke & Lilan Ren, Who Wins Patent Infringement Cases?, 34 AIPLA Q.J. 1, 20 (2006).
Bracket A denotes the available margins, or the vertical distance between production and distribution cost and price, during the period that the patent is unchallenged. The horizontal lines extend from left to right to measure time. Point B marks the date that the patent expires or is declared invalid. The falling line to the right of B represents returns after entry by a single generic begins. For the first 180 days, the market contains only one generic and prices fall gradually to point C. After that, other generics can enter, and prices are likely to fall much further, depending on the extent of generic competition—often to 20% of pre-entry prices. This is so because these drugs are by definition bioequivalent, meaning that they are undifferentiated. In that case, competition drives prices toward marginal cost.

The pioneer’s unilateral maximizing position is to assert its patent rights all the way to point B, the date that the patent is no longer enforceable. However, this is also the joint maximizing position of the patentee plus the first generic. Further, maintaining monopoly markups all the way to point B is typically worth significantly more to the pioneer than early entry is to the generic, who will earn only its share of the post entry duopoly returns. The joint maximizing arrangement for the two parties is to delay the generic’s entry until point B. Any settlement that permitted generic entry to occur earlier than that would not be joint maximizing. For any arrangement that terminated prior to point B, the parties could obtain more by extending the agreement further, all the way to the scope of the patent trigger. This is simply an application of the Coase Theorem.


71. A perfect cartel has the same price and output as a monopolist. See HOVENKAMP, *FEDERAL ANTITRUST POLICY*, supra note 33, §§ 4.1–4.2.

72. On this point, see Jacobo-Rubio, et al., supra note 36, at 3, which finds that the value to the pioneer of maintaining its exclusion over the life of the patent runs about sixteen to twenty times higher than the value to the generic of being able to enter.
under which the firms will reach a settlement that maximizes joint profits, although the size of the transfer payment between them is indeterminate.\footnote{Ronald H. Coase, \textit{The Problem of Social Cost}, 3 J. L. & ECON. 1, 2–8 (1960).}

In sum, if the Court had adopted a scope of the patent rule that exonerated all pay-for-delay agreements that did not extend beyond the patent’s term, a robust equilibrium for future agreements would extend them right up to the expiration date of the patent. The only indeterminate question would be the size of the payment, which would be a function of the parties’ collective evaluation of the patent’s validity. If they perceived that the patent was strong and infringed, the payment to the generic would be relatively small. By contrast, if they perceived the patent was weak, the payment would be large. Even for a very weak patent, however, the parties would have no incentive to shorten the duration of the pay-for-delay agreement.

One consequence that should not be overlooked is that an equilibrium pay-for-delay settlement under the \textit{Actavis} dissenters’ scope-of-the-patent test will \textit{never} result in a production license. The equilibrium settlement will delay generic entry up to the time that the patent expires, but after that, the generic no longer needs a license to enter. The agreement is nothing more than a naked market division.

\textit{D. Statutory Authorization and the Scope of the Patent}

A more helpful understanding of the beyond the scope formulation considers whether the practice in question was or was not authorized by the Patent Act. In \textit{Line Material}, the Supreme Court defined the “limits of the patent monopoly” by observing that “[n]othing in the patent statute specifically gives a right to fix the price at which a licensee may vend the patented article.”\footnote{United States v. Line Material Co., 333 U.S. 287, 310–11 (1948) (citing 35 U.S.C. §§ 40, 47 (1946)).} The \textit{Actavis} majority adopted this formulation. Justice Breyer noted that nothing in the Patent Act authorized the pay-for-delay scheme in question.\footnote{FTC v. Actavis, Inc., 133 S. Ct. 2223, 2231 (2013) (quoting \textit{Line Material}, 333 U.S. at 311).} Later, he observed that “[t]he dissent does not identify any patent statute that it understands to grant such a right to a patentee, whether expressly or by fair implication.”\footnote{\textit{Id.} at 2233.}

This alternative conception of beyond the scope is much more consistent with the ordinary usage of that term. For example, while the scope of legal
rights flowing from real property ownership is substantial, it does not permit murder or battery that occurs within the property's boundaries. Rather, the proper scope of property rights is determined by looking at a large body of law in addition to the metes and bounds of a deed as determining what the owner can and cannot do. The courts have also frequently spoken of things not expressly covered by a statute as being beyond its scope.  

V. ANTITRUST IMMUNITY: PRE-VERSUS POST-ISSUANCE CONDUCT

The scope of the patent test for determining antitrust immunity reflects an approach to antitrust in regulated industries that is no longer used. It comes out of a period when regulatory law immunized everything that was pervasively controlled by a regulatory authority. Once a court concluded that an area was pervasively regulated, nearly everything within that particular regulatory enterprise was regarded as immune from antitrust scrutiny.

The patent system is a form of regulation and must be treated accordingly. Today, we take a more finessed approach to antitrust problems in regulated markets, querying whether the regulator actually authorized the specific practice that is under antitrust scrutiny. This approach looks at the particular conduct being challenged under the antitrust laws, rather than providing a blanket exemption for everything inside the boundary walls. As the Supreme Court has observed:

To be sure, where Congress did intend to repeal the antitrust laws, that intent governs,... but this intent must be clear. Even when an industry is regulated substantially, this does not necessarily evidence an intent to repeal the antitrust laws with respect to every action taken within the industry.... Intent to repeal the antitrust laws is much clearer when a regulatory agency has been empowered to authorize or require the type of conduct under antitrust challenge.

77. E.g., FDA v. Brown & Williamson Tobacco Corp., 529 U.S. 120, 126 (2000) (holding that cigarette coverage is beyond the scope of Food and Drug Act); In re Placid Oil Co., 753 F.3d 151, 158 n.7 (5th Cir. 2014) (ruling that a bankrupt's claims extended beyond the scope of statute); City of Brighton v. Rodriguez, 2014 CO 7, ¶ 30, 30 (exemplifying a debate by a divided court as to whether decision on entitlement to receive worker's compensation extended beyond the scope of the statute).

78. E.g., Hughes Tool Co. v. Trans World Airlines, Inc., 409 U.S. 363, 385 (1973); Pan Am. World Airways, Inc. v. United States, 371 U.S. 296, 305 (1963); see 1A AREEDA & HOVENKAMP, supra note 21, ¶ 244b.

Or as the Court restated the issue in *Trinko*, the question is whether the government’s oversight of the particular challenged practice made it an “effective steward of the antitrust function.”

In this respect, the patent law system divides the territory rather cleanly, providing a great deal of government supervision during the patent application and prosecution process, but very little supervision after the patent has been issued. One important limitation under this approach is that practices that are *explicitly* required or authorized by the government are immune whether or not they are supervised.

The Patent Act itself contains several express authorizations that free the authorized practices from antitrust scrutiny. For example, it authorizes the patentee to license its patent, including the issuance of exclusive licenses and even those that are restricted to a territory within the United States. As a result, a domestic territorial restriction contained in a production license is not reachable under the antitrust laws. The Patent Act also explicitly authorizes a patentee, acting unilaterally, to refuse to license its patent to others. As a result, unilateral refusals to license are not antitrust violations. The Act permits tying, provided that the patentee does not have market power in the tying product.

But when a patentee makes use of a patent in a way that the Patent Act does not authorize, antitrust can be brought to bear. This does not mean that the presence of a patent issue is irrelevant. Antitrust law is properly quite sensitive to questions about how patents function in the market and what the purpose or effects of a particular practice are likely to be. In fact, here antitrust law has a distinct advantage over patent law, which is largely indifferent to such questions and has not developed useable litigation tools for addressing them.

In this respect antitrust law can be a serious aide to patent law, providing analysis of patent function and diverse effect that is completely absent from patent law. The fact is that antitrust law has always tried hard to accommodate patent law—indeed, over history it has been fairly obsessed with the issue of making patents fit into its rules about competition. It is

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precisely because antitrust has rules about how markets should perform that it does so.

By contrast, patent law has never accommodated antitrust concerns or, for the most part, even considered them relevant. A good recent example is the Federal Circuit’s decision in *Trebro Manufacturing, Inc. v. FireFly Equipment.* The patentee was a dominant firm in a market with a small number of sellers. It acquired from an outside inventor a patent on a technology that was an alternative to the technology it was actually using. However, the patentee continued to use its established technology, so the acquired patent was unused. When a competitor entered the market with a machine that infringed on the dominant firm’s unused patent, the Federal Circuit allowed an injunction. Subsequent to the Supreme Court’s *eBay* decision, injunctions for patent infringement are not a matter of right, and the courts have been generally disinclined to grant injunctions on patents that are not practiced. The Federal Circuit made a distinction in this case, however. While the patentee was not using the infringed patent, it was an actual participant in the product market and thus was injured by the infringement defendant’s entry into the market.

In *Trebro*, the Federal Circuit made patent law in complete disregard of competition policy. Indeed, the amount of harm to competition brought about by the injunction was substantial. Further, the court’s rule did nothing to advance innovation because the acquired patent was already invented before the patentee acquired it. Moreover, its production value to the acquirer was not even sufficient to induce it to employ the patent’s technology. The only effect of the patent in this case was to remove

86. *Id.* at 1170.
87. *See id.* at 1171.
88. *Id.*
89. *Id.*
technology from the market rather than permit its deployment. Nearly four decades ago, the Supreme Court held in *Brunswick* that one cannot use antitrust law to complain about more, rather than less, competition in the market.\(^{93}\) That decision fostered a revolution in antitrust that required plaintiffs to link their theory of harm to the underlying goals of antitrust law. For patent law, that road is as yet untaken.\(^{94}\)

Another example of intellectual property policy making in disregard of competition policy are several post-*Actavis* decisions\(^ {95}\) concluding that a pioneer’s promise not to introduce an “authorized generic” into the market should not be regarded as a qualifying payment for delay.\(^ {96}\) While consumers often distinguish between branded and generic drugs, they typically do not distinguish between different generics. This makes it possible for a pioneer to exercise a form of price discrimination that is beneficial to consumers because it increases overall market output. Of course, it is generally harmful to the entering generic to the extent that the authorized generic steals sales. The *Effexor* decision cited evidence that generic output if an authorized generic was placed on the market would be about half of what the generic would have attained if it did not have to compete with a second generic.\(^ {97}\) It also cited evidence that the generic price would

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94. Developing this point is BOHANNAN & HOVENKAMP, supra note 18, at 33–59.

95. *In re Effexor XR Antitrust Litig.*, No. 11-5479, 2014 WL 4988410, at *21–*23 (D.N.J. Oct. 6, 2014); *In re Lipitor Antitrust Litig.*, 46 F. Supp. 3d 523, 542–46 (D.N.J. 2014) (ruling that provision in agreement under which patentee promised not to enter with authorized generic during 180-day exclusivity period was not a “payment” for delay and thus did not invoke *Actavis* doctrine); *In re Loestrin 24 FE Antitrust Litig.*, 45 F. Supp. 3d 180, 189–94 (D.R.I. 2014) (holding *Actavis* applies only to cash payments, which means that promise not to enter with authorized generic could not be counted); *In re Lamictal Direct Purchaser Antitrust Litig.*, 18 F. Supp. 3d 560, 565 (D.N.J. 2014) (similar). *Contra In re Niaspan Antitrust Litig.*, 42 F. Supp. 3d 735, 751 (E.D. Pa. 2014) (deciding settlement agreement provision preventing pioneer from entering with authorized generic could be counted together with other promises in determining existence of large reverse payment); *In re Nexium (Esomeprazole) Antitrust Litig.*, 42 F. Supp. 3d 231, 264 (D. Mass. 2014) (similar).

96. The right of the patentee to enter with an authorized generic was recognized in *Sanofi-Aventis v. Apotex Inc.*, 659 F.3d 1171, 1174–75 (Fed. Cir. 2011); *Mylan Pharm., Inc. v. FDA*, 454 F.3d 270, 271, 275–77 (4th Cir. 2006); and *Teva Pharm. Indus. Ltd. v. Crawford*, 410 F.3d 51, 53–55 (D.C. Cir. 2005). See Edlin, et al., *The Actavis Inference*, supra note 35, at 8; see also David C. Kurlander, *Note, Rebalancing Pay-for-Delay: Why No-Authorized Generic Agreements Should Be Subject to Higher Antitrust Scrutiny*, 32 CARDOZO ARTS & ENT. L.J. 683, 693–96 (2014) (arguing agreements to refrain from marketing authorized generics are reverse payments that should be subjected to antitrust scrutiny). The pioneer patentee’s own generic entry, of course, does not count as an act of patent infringement triggering the Hatch-Waxman process.

be about 16% lower if an authorized generic entered into the market.\textsuperscript{98} Nevertheless, the court concluded that the value of the “no authorized generic” agreement was so “vague and amorphous” that it could not be counted as a reverse payment.\textsuperscript{99} But that is a little like saying that an incipient cartel or market division agreement cannot be regarded as socially costly simply because one cannot predict accurately exactly how much harm it will do. If \textit{Actavis} makes anything clear, it is that courts need to take more seriously the anticompetitive consequences of challenged horizontal agreements.

“No authorized generic” agreements effectively place a second market exclusion agreement—generic versus generic, for 180 days following generic entry—on top of the first one, which was at issue in \textit{Actavis} itself (pioneer versus generic for the term of the settlement). The outcome is actually far worse than a large payment for delay. The large payment, which reflects the extent of the parties’ belief that the patent is invalid, is nothing more than a wealth transfer between the patentee and the generic. Consumers are largely unaffected. By contrast, the “no authorized generic” provision compensates the generic with something far more nefarious—a second market division that serves to keep prices higher during the 180-day period when other generic firms are unable to enter the market.

The likely equilibrium resulting from this arrangement is that the parties will delay the generic’s production for the remaining duration of the patent, but the generic would have the additional inducement of a further market exclusion agreement keeping the authorized generic out for 180 days after the independent generic began production. The additional value of that extra inducement would serve to reduce or eliminate the pay-for-delay reverse payment. For their part, consumers would still feel the full burden of the pay-for-delay agreement during the time covered by the settlement up to the day that the generic begins production, but they would then have the additional burden of lessened competition during the 180-day period of initial generic production.


\textsuperscript{99} Effexor, 2014 WL 4988410, at *21.
VI. APPLYING ANTITRUST’S RULE OF REASON TO PATENT PRACTICES

When a post-issuance patent practice is neither compelled nor expressly permitted by the patent laws, it should be subject to antitrust scrutiny. This hardly entails that the practice is an antitrust violation or that the presence of patents is irrelevant, but it does mean that antitrust’s more empirical, market-focused tools can be brought to bear.

Under antitrust’s rule of reason, the plaintiff must initially show that the defendant has sufficient market power to affect market competition and that the challenged practice threatens competition by facilitating either collusion or anticompetitive exclusion. At this point, the burden shifts to the defendant to provide evidence of a justification or legitimate objective. Then the plaintiff has an opportunity to answer that the same objective could be achieved by a less restrictive alternative.

This section addresses two issues. First, what is the role of patent validity or scope in antitrust assessments of licensing agreements? Second, does the involvement of a patent affect the ordinary antitrust rule of reason requirements of proof of market power and anticompetitive effects or the way that presumptions or burdens of proof should be assigned?

A. Analyzing Settlements: When Must a Court Assess Patent Validity or Infringement?

An often-debilitating problem with the scope of the patent test formulated as the Actavis dissenters did is that it makes questions about patent validity or scope essential to the analysis of the challenged practice. In the context of patent settlements this entails that the very questions that the parties were seeking to avoid through settlement come right back in. For example, a pay-for-delay settlement that terminates prior to expiration of the patent is no more restrictive than a court finding of validity and infringement, which will exclude the generic from the market in any event. On the other hand, if the patent is invalid, then delayed entry in exchange for the payment is a naked restraint. The parties to a patent infringement dispute settle in order to avoid such difficult questions. But should antitrust analysis

100. See Hovenkamp, Antitrust and the Patent System, supra note 2, at 518.
then require the court to answer this very question in order to determine legality under the antitrust laws? Recognizing that this is absurd, the courts typically resort to something far less—holding, for example, that the settlement will be approved unless the patent is “obviously” invalid or very weak. With that, close review becomes unnecessary.103

The Actavis majority quite properly observed that courts should be able to evaluate settlements in at least some cases without addressing issues of patent validity or infringement.104 This is particularly true when the settlement is both prima facie anticompetitive and includes a practice that is not authorized by the Patent Act. Most patent infringement disputes are settled by license agreements, sometimes accompanied by territorial or field-of-use restrictions.105 Most are thus either explicitly authorized by the Patent Act and exempt from antitrust scrutiny or else treated under the rule of reason. Product price fixing and market division in the product market, as opposed to the licensing market, are not authorized and should be assessed under ordinary antitrust rules that do not require an assessment of patent validity or infringement. The fact that these agreements were negotiated in settlement of a legal dispute is largely irrelevant.

Antitrust assesses the competitiveness of conduct from the time the conduct occurs. As an economic discipline, it bases its analysis on an ex ante view of the parties’ objectively reasonable expectations rather than an ex post view of how the patent validity decision subsequently turns out. This is consistent with the economic approach to legal analysis generally, and particularly of litigation settlements, which emphasize rational predictions rather than ex post results. For example, when business firms negotiate a contract they make ex ante predictions about how markets will perform. We do not ordinarily permit them to abrogate the contract later if their predictions turn out to be incorrect. The relevant competition law question in a pay-for-delay settlement agreement is what the parties reasonably knew and expected at the time they entered their agreement, not what subsequently turned out to be the case.

Requiring a court to analyze an IP settlement by determining whether the patent is valid and infringed improperly swaps the ex ante and ex post

105. See 12 HOVENKAMP, supra note 30, ¶ 2046.
perspectives. It also asks the court to do in the antitrust context what the
parties had been unwilling to do for themselves in the context of the patent
litigation. In patent infringement litigation, the appropriate question for
the court is whether the patent is valid and infringed. In an antitrust
challenge to a settlement of such litigation, the correct approach is not to
ask the validity and infringement questions all over again, but rather to
determine what the parties’ reasonable expectations and motivations were
at the time of settlement.106 That is why the Eleventh Circuit was wrong
to describe the antitrust analysis of pay-for-delay patent settlements as
presenting “a turducken task”—one that would involve deciding a patent
case baked inside an antitrust case.107

B. Patent Validity, Scope, or Value: Rational Expectations

If a practice poses a significant competitive threat and is not authorized
by the Patent Act, then its antitrust legality can typically be assessed
without a determination of patent validity or scope. By contrast, if a practice
is expressly authorized by the Patent Act, then the antitrust legality of the
practice may depend on the validity or scope of the patent. For example,
the Patent Act’s authorization of exclusive territorial licenses encompasses
horizontal market division agreements that could be unlawful under the
antitrust laws.108 A patent license in which company A licenses company
B to produce a patented chemical for sale east of the Mississippi River,
while reserving to itself the territory west of the Mississippi, would be
shielded from antitrust scrutiny if the patent were valid and infringed. But
this agreement could be per se unlawful market division if the patent were
known by the parties to be invalid. The relevant antitrust query would be
the parties’ rational expectations at the time the market division license
was negotiated. If the parties reasonably believed at that time that the
patent was valid and covered company B’s product, then a subsequent
finding of patent invalidity should not serve to create antitrust liability for
the agreement up to that point.

As an example of a practice that is not authorized by the Patent Act,
consider patent license agreements that fix product prices as opposed to
license prices. Parties to a patent dispute have a strong motive to engage
in product price fixing, provided that market conditions permit it. The

106. See Edlin et al., The Actavis Inference, supra note 35, at 2.
107. See FTC v. Watson Pharm., Inc., 677 F.3d 1298, 1315 (11th Cir. 2012) (“[W]e
would be deciding a patent case within an antitrust case about the settlement of the patent
price fix can compensate the patentee with higher returns. Further, the availability of product price fixing gives the parties to an infringement dispute a highly favorable joint maximizing position that serves to limit adversity between them. If the price fix lasts no longer than the duration of the patent, then at first glance it might seem to be no more harmful to customers than a patentee’s simple solo production under its patent, which will also produce the monopoly price. As a result, a product price fix of limited duration passes the scope of the patent test.

On the other hand, while license prices have to be determined by the parties, product prices do not. Nothing in the Patent Act authorizes product price fixing. A product price fix contained in a patent license agreement might be a cover for a dubious patent, as Judge Posner suggested in the *Asahi Glass* case.109 Firms wishing to fix product prices might identify some relatively weak or useless patent and then place the price fix into a license agreement. But assessing such an agreement would require an inquiry into patent validity or strength.

In most cases the validity question is the wrong one, however. The competitive consequences of product price fixing through a patent license has much less to do with patent validity than with patent value. An invalid patent certainly has no value once it has been established as invalid. But many perfectly valid patents have little value for the simple reason that they add little to a licensee’s technology or alternative patents or technological routes are available that serve the same purpose.

As an empirical matter, patents are worth much less than the value of cartel formation. An assortment of studies suggest that cartel markups in industries prone to collusion run in the range of 20% to 50% over the pre-cartel price.110 By contrast, average royalty rates on licensed patents run

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in a range of 0.5% to 6% of the wholesale product price. One study found the median rate to be about 3%. In patent-rich technologies such as electronic devices royalty rates can be much less, simply because there are so many patents. Significantly, licensed patents that are subject to these royalty rates are assumed to be valid and also practiced—infringed—by the licensees. Further, only a small percentage of patents are licensed—as few as 3-4% by some estimates—and these patents are generally regarded as more valuable than the vast majority that are not licensed.

A rule invalidating a product price fix only if the patent is likely to be invalid does not adequately address the problem these facts expose. Even a valid patent is likely to claim a royalty that is much smaller than the typical returns to product price fixing. When that is the case, the parties are attributing to the patent the entire monopoly markup value of a cartel in the same market—a value that is rarely conferred by even relatively strong patents.

These facts suggest, first, that the markup resulting from product price fixing can be much greater than the returns to patent licensing alone, even if we assume that the patents in question are valid and infringed. Consumer harm is proportionately greater as well. Second, in the settlement context a judicial determination of patent validity is not adequate for assessing this problem. The patent could be perfectly valid but worth very little to the licensee, or at least worth only a small fraction of the markup contained in the product price fix.

In order to determine the harmfulness of such a price fix, we would have to establish the excess of the cartel markup over the patent’s appropriate royalty rate. This means an inquiry into validity, infringement, and licensing value. Answering these questions is likely to be monumentally difficult.


113. See, e.g., VirnetX, Inc. v. Cisco Sys., Inc., 767 F.3d 1308, 1330–31 (Fed. Cir. 2014) (noting plaintiff’s testimony employing 1% of device as reasonable royalty; court affirming findings of validity and infringement and accepting the 1% royalty figure but disputing the base).

A serious antitrust assessment of a product price fix contained in a settlement agreement would be even more complex than the patent infringement suit that was settled. That lawsuit would address questions of validity and infringement, but not of patent value.

But the availability of a less restrictive alternative enables the tribunal to avoid more difficult inquiries. Questions about patent validity, scope, and market value can be completely discounted into a patent license agreement that sets the terms of the license fee, without specifying anything about the product price. If the patent is likely to be invalid, or not infringed, or if it is not valuable to the licensee because reasonable alternatives exist, then the licensee will not pay very much for the license. By contrast, if the patent scores high on all these points, the outcome will be reflected in a higher license fee. With respect to the license fee itself, the parties have complete adversity across all three elements of patent validity, infringement, and value. The licensee wants a lower fee and the patentee wants a higher one. This is in sharp contrast to the product price fix, where the parties share in the cartel markup.

Rule of reason analysis of pay-for-delay settlements is similar. In a pay-for-delay settlement agreement such as the one the Supreme Court assessed in *Actavis*, the parties bargained along two important vectors, including the generic entry date and the size of the payment from the pioneer to the generic. The entry date establishes the size of the monopoly pie, and the size of the payment represents how the pie is to be divided up. Being able to bargain along these two vectors simultaneously enables the parties to select an entry date as remote as the antitrust authorities will accept, thus maximizing the overall size of the gains. Then they can bargain over the size of the payment in order to resolve issues about patent validity, risk aversion, and anticipated litigation costs. The parties do not have significant adversity on the question of entry date: the longer they delay, the better for them, provided that they keep the entry date short of patent expiration. They do have adversity over the size and terms of the payment, with weaker patents resulting in higher payments to the generic. Even if the two parties privately conceded that the patent is completely worthless, they would still have every incentive to bargain for the remote entry date, but the generic would insist on a very high pay-for-delay price.

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115. *See* discussion *supra* notes 67–69 and accompanying text on the entry date under a scope of the patent durational formulation.
Under the scope of the patent formulation, the equilibrium entry date would be the patent expiration date, and consumers would be heavy losers, no matter the strength of the patent.

In this case, a less restrictive alternative is available as well: we can permit the parties to bargain over the entry date, but without a side payment or any other value transfer. Such a bargain provides all of the value that the parties are entitled to, but without the additional consumer harm caused by an unnecessarily anticompetitive agreement. The parties are still able to consider patent strength, anticipated litigation costs, and degree of risk aversion. If the parties believe that the patent is strong, the outcome may still be one that sets a generic entry date relatively close to the expiration of the patent, but in that case, considerations of patent strength will have determined the duration of the agreement rather than joint maximization of a monopoly profit stream without regard to patent strength. If the parties believe that the patent is weak, they can bargain for an early entry date, or else the generic will refuse to bargain and litigate to the end. By the same token, if the patentee believes that its patent is valid but is risk-averse, it can trade away uncertainty over the litigation outcome against the certainty of an assured entry date. The parties can also take reasonably anticipated litigation costs and duration into effect, although the Actavis decision permits a payment sufficient to cover expected litigation costs in any event.116

C. Are Anticompetitive Practices Appropriate Returns to Patenting?

Product price fixing in patent licenses and pay-for-delay settlements of pharmaceutical patent disputes both serve to increase the returns to patents. By contrast, antitrust rules limiting these practices serve to reduce those returns. One argument against antitrust rules of this sort is that by reducing the returns to patenting they also reduce the incentive to innovate.117 For example, if a patent could reasonably claim a royalty of 3%, but a product cartel of that patent’s users could exact a 25% markup, then the returns to that patent are higher under product price fixing and there would be more incentive to innovate.

Patents are tradable goods, and the price a buyer is willing to pay presumptively reflects a patent’s value to that buyer. Product price fixing

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cartels obtain high royalties by giving the patent an effective value equal to the entire monopoly markup for that particular product. If a patent would command a royalty of 3% but yields a 25% product overcharge when licensed along with a product price fix, then this particular patent is commanding much more than its market-determined innovation value. Overvalued patents can cause just as much deadweight loss as undervalued ones.

The relevant policies to be applied here are identical to those we use for traditional nonintellectual property interests. For example, the production value of a plant might be $3 million in a competitive market but $5 million in a cartelized market. But antitrust law does not permit people to organize cartels in order to obtain a larger return on their property, even if the larger return increases incentives to acquire or develop the property in the first place.

Economically, the pay-for-delay settlement operates in much the same way as the product price fix, permitting the parties to obtain the full cartel value until the settlement terminates. The outcome is about the same as one in which the generic entered but the pioneer and generic then fixed product prices. The price charged by the single pioneer without competition would be the same as that charged by a perfectly functioning, two-firm cartel. In the pay-for-delay case, the principal gains to the patentee result from the settlement’s lengthening of the effective patent term, prolonging this cartel outcome. Most large pay-for-delay settlements involve extension, or secondary, patents rather than original primary molecules. The failure rate on these extension patents is far higher than on pioneer molecule patents, but Hatch-Waxman gives the parties the same protection that would occur if the patent were ironclad.

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118. See HOVENKAMP, FEDERAL ANTITRUST POLICY, supra note 33, § 4.1.
Is a pay-for-delay patent extension of this sort a reasonable return to patenting? While longer patent terms are worth more than shorter ones, the difference is less than one might think. Landes and Posner concluded that, measured *ex ante*, the value of a 20-year patent is roughly 85% of that of an infinitely long patent. Once they calculate in an estimate for market depreciation, the number is closer to 95%. The depreciation number is important. While the quality of a patented drug does not change over the patent’s term, the number and quality of its competitors is likely to increase. A blockbuster drug that has no good alternatives when first patented may have a half-dozen differentiated substitutes within a few years. These alternatives are not generics, which would be patent infringers, but drugs that use different compounds to treat similar conditions. Other things being equal, the patent becomes less valuable over time even without bioequivalent generic entry.

Most importantly for antitrust purposes, the Patent Act itself regulates patent value by defining the length of the term and also by metering patent scope. Beyond that there is no good reason for treating patent practices that are not authorized by the Patent Act any differently than the law treats other kinds of property. The argument that restraining price-fixing, horizontal product market division, or boycotts can increase the returns to patenting proves far too much. Cartels can increase the rate of return to *all* types of productive property, hardly limited to intellectual property. But the law’s authorization to own and transact in property does not carry by implication the right to do so anticompetitively. Nor is there any such general authorization in the Patent Act. If pharmaceutical patents require a longer term of protection in order to make investment in new drugs profitable, that is an issue for Congress.

121. Id. at 297.
123. The Supreme Court made this clear in *FTC v. Phoebe Putney Health Sys., Inc.*, 133 S. Ct. 1003, 1012 (2013) (holding state statute that authorized one corporation to acquire another did not implicitly authorize an anticompetitive acquisition).
D. Presumptions, Burdens of Proof, and the Rule of Reason

Actavis held that the rule of reason should be applied to a pay-for-delay patent infringement settlement on the facts of that case.\footnote{FTC v. Actavis, Inc., 133 S. Ct. 2223, 2237 (2013).} In so doing it rejected alternatives suggesting that pay-for-delay settlements should be legal per se if they fall within the scope of the patent or are assessed under a quick look analysis as the FTC had urged.

The Court’s insistence on a rule of reason reflects its antipathy toward quick look analysis. It also tracks the approach taken in the Antitrust Law treatise that prefers to think of the mode of antitrust analysis as a “sliding scale,” composed of varying presumptions.\footnote{See id. at 2237–38 (quoting a previous edition of 7 PHILLIP E. AREEDA & HERBERT HOVENKAMP, ANTITRUST LAW ¶ 1507 (1986) (cited in Cal. Dental Ass’n v. FTC, 526 U.S. 756, 780 (1999))).} Rather than placing antitrust analysis into three silos dominated “per se,” “quick look,” and “rule of reason,” it is better to think of the problem as setting proof requirements that vary with the circumstances. The less factually plausible a party’s case, the greater its burden should be. Proof burdens also shift with the availability of evidence.

By contrast, the quick look analysis that the Actavis Court envisioned and ultimately rejected began with a presumption of per se illegality, which could be defeated if the defendant could “show empirical evidence of procompetitive effects.”\footnote{Id. at 2237 (quoting Cal. Dental Ass’n, 526 U.S. at 775 n.12).} By rejecting that approach, the Court was hardly eliminating the use of presumptions in antitrust litigation under the rule of reason. To the contrary, the rule of reason contains far more presumptions than the per se rule or any alternative truncated approach. These presumptions are ubiquitous and an essential part of rule of reason analysis.\footnote{On the use of presumptions under the rule of reason, see 7 AREEDA & HOVENKAMP, ANTITRUST LAW, supra note 101, ¶ 1507; see also Frank H. Easterbrook, The Limits of Antitrust, 63 Tex. L. Rev. 1, 14–17 (1984) (discussing the importance of presumptions in rule of reason cases).} For example, courts sometimes say that a high market share creates a presumption of market power, but this presumption can be defeated by evidence of low entry barriers or rivals who can readily expand their output.\footnote{E.g., Rebel Oil Co. v. Atlantic Richfield Co., 51 F.3d 1421, 1438 n.10 (9th Cir. 1995); FTC v. ProMedica Health Sys., Inc., No. 3:11-cv-47, 2011 WL 1219281, at *20,} Alternatively, in exclusive dealing cases under the rule of reason,
the courts presume competitive harm from contracts of long duration or presume lack of harm from shorter-term contracts.\footnote{\textsc{46} (N.D. Ohio Mar. 29, 2011); see also Allen v. Dairy Farmers of Am., Inc., 748 F. Supp. 2d 323, 340 (D. Vt. 2010) (noting that market shares are given “weight and not conclusiveness” (quoting Tops Mkts., Inc. v. Quality Mkts., Inc., 142 F.3d 90, 99 (2d Cir. 1998))).} Historically, the courts presumed market power if a tying product was patented, but that is no longer the case.\footnote{\textsc{129}. \textit{E.g.}, Omega Envtl., Inc. v. Gilbarco, Inc., 127 F.3d 1157, 1172 (9th Cir. 1997).}  

The \textit{Actavis} majority also suggested presumptions such as these would apply in any rule of reason case. For example, “[a]n unexplained large reverse payment itself would normally suggest that the patentee has serious doubts about the patent’s survival.”\footnote{\textsc{130}. \textit{Ill. Tool Works, Inc. v. Indep. Ink, Inc.}, 547 U.S. 28, 40 (2006).} The Court added that “[t]he size of the unexplained reverse payment can provide a workable surrogate for a patent’s weakness, all without forcing a court to conduct a detailed exploration”\footnote{\textsc{131}. \textit{Id.} at 2236-37 (citing 12 \textsc{HOVENKAMP}, supra note 30, ¶ 2046).} of the validity of the patent itself.\footnote{\textsc{132}. On the relevance of litigation costs, see \textit{id.} at 2236.} The term \textit{unexplained} means that the Court was creating a presumption: a large payment requires an explanation, obligating the defendant to produce something that justifies the payment insofar as it exceeds anticipated litigation costs.\footnote{\textsc{133}. \textit{King Drug Co. of Florence, Inc. v. Cephalon, Inc.}, No. 2:06-cv-1797, 2015 WL 356913, at *1, *11 (E.D. Pa. Jan. 28, 2015): “Plaintiffs must present evidence of a large reverse payment as part of their initial burden of demonstrating anticompetitive effects under the rule of reason . . . . [I]f Plaintiffs meet this standard, the burden shifts to Defendants to justify the reverse payment as procompetitive.”} At least one decision has indicated that the burden of proving a large payment is on the plaintiff or government. Once that burden is met, then the burden to show that the payment is “explained” or “justified” should be on the defendants, who hold the evidence relevant to that question.\footnote{\textsc{134}. \textit{Actavis}, 133 S. Ct. at 2236 (quoting 12 \textsc{PHILLIPA. AREEDA & HERBERT HOVENKAMP, ANTITRUST LAW} ¶ 2046).}  

The Supreme Court also indicated that the size of a reverse payment is a “strong indicator” of market power,\footnote{\textsc{135}. \textit{Actavis}, 133 S. Ct. at 2236 (quoting 12 \textsc{PHILLIPA. AREEDA & HERBERT HOVENKAMP, ANTITRUST LAW} ¶ 2046).} but later suggested that a large payment might partly reflect compensation for other services that would
serve to weaken that inference.\textsuperscript{136} The traditional presumption used in antitrust analysis relates market power to share of a properly defined relevant market. However, that presumption can be defeated or weakened by evidence of low entry barriers, market instability, or rival or customer mobility.\textsuperscript{137} Market power can also be measured “directly,” typically by technical tools that assess residual demand or price-cost margins.\textsuperscript{138} A large payment is a rational act only if the payer has price cost margins worth protecting. More specifically, the payer’s willingness to pay will be limited by the anticipated price-cost margins of exclusive sales over the remaining life of the settlement. If price-cost margins were zero, then the seller would be unwilling to pay anything. So to the extent high margins indicate power, the high payment is a good presumptive signal.

One possible objection is that high price-cost margins reflect only variable costs. A firm may have high margins but still not be able to recover its fixed cost investment, making the product unprofitable over its lifecycle. While that might be factually true, it is not ordinarily relevant to power assessments in antitrust cases. All of our direct measures for assessing power focus exclusively or heavily on variable costs. For example, the Lerner Index and its variations measure market power by looking to margins between short-run marginal cost and price, and the impact of changes in demand. All of these are variable cost measures.\textsuperscript{139} Even market share measures the extent to which the firm responds to changes in demand or short-run costs. The market power question for antitrust purposes is not whether a firm is earning enough to cover its fixed costs, but whether it has the ability to profit by reducing market output and raising price. So inferring power from a large pay-for-delay settlement is not different in principle from inferring power from other types of evidence more conventionally used to estimate market power. Finally, the critique from fixed costs confuses the power issue and the liability issue. On the one hand, we do not want to punish firms for having high fixed costs and the

\begin{itemize}
\item \textsuperscript{136} \textit{Id.} at 2237.
\item \textsuperscript{137} See \textit{e.g.,} Matsushita Elec. Indus. Co. v. Zenith Radio Corp., 475 U.S. 574, 591 n.15 (1986) (“[Y]et without barriers to entry it would presumably be impossible to maintain supracompetitive prices for an extended time.”).
\item \textsuperscript{139} See HOVENKAMP, FEDERAL ANTITRUST POLICY, \textit{supra} note 33, § 3.1a.
\end{itemize}
high margins that ordinarily accompany them. On the other, they are clearly relevant to a determination of whether the firm is capable of profiting from an anticompetitive act.¹⁴⁰

In any event, the Actavis Court was not inferring power simply from high price–cost margins but from an exclusion payment. Particularly, in intellectual property markets, products are sold under at least moderately competitive conditions and yet have high margins.¹⁴¹ For example, an app store that sells software for an electronic device such as an iPad or Kindle may offer many product alternatives that have very low variable costs of distribution, sometimes approaching zero. The same thing is true of electronic books and streamed movies or digital music. Any price represents a significant short-run price–cost margin, but these products may not even be able to recover fixed investment costs over their product lives.

Very high exclusion payments are a different matter. A manufacturer with large fixed costs and high margins would not agree to make a large payment if it could not anticipate being able to recoup this investment over the duration of the settlement. The issue here is similar to the one used for analyzing “recoupment” in predatory pricing cases. Namely, a firm will invest in a strategy if the reasonably anticipated payoff exceeds the reasonably anticipated investment.¹⁴² Presumably, one of a dozen manufacturers of notepad apps for an iPad would not pay large amounts to a different app manufacturer to withdraw from the market. The market is competitive, and the removal of one supplier would not make much difference. In sum, the absence of competition from other firms is what makes a payoff to one firm a rational act.

In any event, the argument from high fixed costs proves too much. A firm with high fixed costs might be able to stay profitable—or earn greater profits—if it has a monopoly, but unless constrained, it will produce at the monopoly level. For example, a firm with high fixed costs might maximize its profits by producing 1000 units. The competitive market output in this industry—producing a return just large enough to maintain investment—might be 2000 units. Permitting collusion would take us to the 1000 unit outcome. That is why the Supreme Court was correct to reject “ruinous competition” defenses to collusion in industries with high fixed costs.¹⁴³ Competitors with high fixed costs may have a motive to fix prices, but

¹⁴⁰ See Kaplow, supra note 138, at 500.
¹⁴¹ See 2B Areeda & Hovenkamp, supra note 138, ¶¶ 516g, 518e2–3.
¹⁴² On the recoupment requirement in predatory pricing, see 3A Philip E. Areeda & Herbert Hovenkamp, Antitrust Law ¶¶ 726–27.
¹⁴³ E.g., United States v. Trans-Missouri Freight Ass’n, 166 U.S. 290, 329–30 (1897).
when they do, they can be expected to set prices at the cartel level, not at the level just sufficient to provide competitive returns.

VII. CONCLUSION

Applying the rule of reason to antitrust claims involving patent licensing and related practices has been made unnecessarily difficult by the scope of the patent rule. First, identifying practices that fall within and without the scope of the patent yields indeterminate results, particularly when vertical integration is available to place certain uses inside the firm. Second, many settlements, including both product price restraints and payment-for-delay, can be properly assessed under this rule only by judicial determination of patent validity, infringement, and in many cases market value. This makes a full-scale evaluation even more difficult than the assessment made in a patent infringement lawsuit, which ordinarily inquires only into validity and infringement. In any event, the antitrust approach to restraints requires examining them as of the time they occur, taking the parties’ reasonable expectations into account. An ex post inquiry into patent validity is not helpful except insofar as it informs what the parties’ rational expectations must have been.

A better pair of rules divides patent practices into pre- and post-issuance, generally immunizing the former from antitrust scrutiny. Post-issuance practices must then be divided into those that are authorized by the Patent Act and those that are not. A post-issuance practice that is not authorized by the Patent Act should ordinarily be subject to antitrust review. In his Actavis dissent, Chief Justice Roberts observed that “patent policy encompasses a set of judgments about the proper tradeoff between competition and the incentive to innovate over the long run. Antitrust’s rule of reason was not designed for such judgments and is not adept at making them.”144 True enough, but the Chief Justice did not point to any place where patent policy had made these particular judgments either. They are neither in the language of the statute nor its legislative history.

While antitrust policy is not particularly adept at trading off short- and long-run judgments when there is something to trade off, in this case there is not. The short-run competitive harm from these settlements has been

144. Actavis, 133 S. Ct. at 2246 (Roberts, C.J., dissenting) (quoting 1 HOVENKAMP et al., IP AND ANTITRUST § 7.3 (2d ed. 2010)).
empirically evaluated over and over. On the long run, “incentive to innovate” side of the scale there is nothing in the patent statute and precious little in the economic literature. The one relevant thing that we have is Congress’s clear interest, expressed in the Hatch-Waxman Act, to encourage generic entry.

While the antitrust decision maker must be circumspect about assessing the competitive and innovation effects of challenged practices, these assessments largely involve questions of antitrust law, not of patent law. Outside of damages measurement, patent law has no tool kit for assessing either the market or even the innovation effects of a particular practice.

While that criticism may seem harsh, the reality is that patent law has developed in relative isolation from any significant inquiry into how patents function in the marketplace. The result gives antitrust policy a comparative advantage, not only for assessing competition effects but ironically, even for assessing innovation effects.