RESOLVING PATENT DISPUTES THROUGH MERGER: A COMPARISON OF THREE POTENTIAL APPROACHES

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Antitrust attorneys and regulators increasingly encounter circumstances where parties to patent litigation have decided to resolve their dispute through a merger.[1] Although some economists would not be

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[1] *See, e.g.,* Flow Int'l Corp., FTC File No. 081-0079 (July 10, 2008), *available at* http://www.ftc.gov/opa/2008/07/flowomax.shtm (analyzing transaction where parties resolved competing infringement lawsuits through merger); United States v. Gemstar-TV Guide Int'l Inc., No. 03-CV-000198, Competitive Impact Statement (D.D.C. Mar. 19, 2003), *available at* http://www.usdoj.gov/atr/cases/f200800/200848.htm (in the context of a gun-jumping investigation, noting that the DOJ did not seek to challenge the merger of TV Guide and Gemstar—which were closest competitors and the only providers of interactive programming guides for the dominant digital formats—after the parties failed to resolve their lengthy patent disputes through license agreement or joint venture); United States v. Boston Scientific Corp., 253 F. Supp. 2d 85, 89 (D. Mass. 2003) (in the context of assessing penalties violating an FTC consent decree, the court notes that prior to Boston Scientific's simultaneous acquisition of CVIS and SCIMED, resulting in 90 percent share of the catheter market, all three companies were involved in intense patent infringement litigation); *see also* Geoffrey D. Oliver, *Living on the Fault Line: Counseling Clients at the Interface of Antitrust and Intellectual Property Law,* Antitrust, Spring 2008, at 38, 40 ("A recent trend involves resolution of patent infringement litigation by merger of the parties or acquisition of the alleged infringer by the patent holder. . . . Parties have asserted [a *Schering-Plough* styled] argument, and avoided challenge, in at least a small number of transactions.").

This issue was raised and discussed by several participants at the DOJ and FTC hearings concerning the intersection of antitrust and intellectual property. See the following exhibits and testimony appended to U.S. Department of Justice and Federal Trade Commission, Antitrust Enforcement and Intellectual Property Rights: Promoting Innovation and Competition, *available at* http://www.usdoj.gov/atr/public/hearings/ip/222655.pdf (2007) [hereinafter DOJ/FTC IP Report]: Carl Shapiro, *Antitrust Limits to Patent Settlements,* 34 RAND J. Econ. 391, 402–07 (2003) [hereinafter *Antitrust Limits*], *available at* http://www.ftc.gov/opp/intellect/020502shapiro.pdf (submitted May 1, 2001); Robert N. Cook, Settling Patent Disputes by Merger: Some Antitrust Considerasurprised by this development,[2] the agencies and the courts to date have not articulated an antitrust framework for analyzing a merger where the competing products at issue are subject to a legitimate dispute over intellectual property infringement or misappropriation.

In the absence of such guidance, it may be useful to consider the analytical framework that the agencies and courts have brought to bear in another context where competitors have resolved their patent disputes through settlement: the settlement of infringement cases arising out of the Hatch-Waxman Act.[3] In particular, we believe that the Federal Trade Commission's unsuccessful litigation in *Schering-Plough Corp. v. FTC*,[4] may provide a useful lens through which to consider various approaches that might be pursued by the agencies, the merging parties, and the courts in evaluating the effect of a patent dispute between the merging parties.

To begin with, unlike most Hatch-Waxman cases,[5] *Schering-Plough* involved the settlement of a case where there was a substantial question regarding infringement, not just validity. As we will discuss later in more detail, unlike validity, questions related to infringement typically are not binary (valid/invalid), but rather are a matter of degree (given different interpretations of the claim, how expensive and time-consuming is it to design around them). Pharmaceutical patent cases are unusual in that

tions, Remarks Presented at Hearing Before DOJ Antitrust Div. and FTC (May 2, 2002), *available at* http://www.ftc.gov/opp/intellect/020502cooka.pdf; Joseph Kattan, Evaluating Patent Infringement and Validity in Antitrust Analysis, Remarks Presented at Hearing Before DOJ Antitrust Div. and FTC (May 14, 2002), *available at* http://www.ftc.gov/opp/intellect/020514kattan.pdf; Carl Shapiro, Competition and Intellectual Property Law and Policy in the Knowledge-Based Economy: A Competition View of Patent Settlements: Patent Settlements, Testimony Before the DOJ Antitrust Div. and FTC, Transcript at 50, 60–61 (May 2, 2002), *available at* http://www.ftc.gov/opp/intellect/020502trans.pdf; Douglas Melamed & Joseph Kattan, Practical Issues Encountered in Antitrust Analysis of Licensing Practices: The Problem of Dealing With Uncertain or Disputed Patent Rights, Testimony Before the DOJ Antitrust Div. and FTC, Transcript at 174–77, 185–93 (May 14, 2002), *available at* http://www.ftc.gov/opp/intellect/020514trans.pdf.

[2] *See, e.g.,* Alan C. Marco & Gordon C. Rausser, *The Role of Patent Rights in Mergers: Consolidation in Plant Biotechnology*, 90 AM. J. AGRIC. ECON. 133, 136 (Feb. 1, 2008) (internal citations omitted) (predicting that an increasing number of patent disputes would be settled via merger given the "numerous patent interferences, disputes, and infringement suits that have arisen over the last decade. Uncertain and overlapping patent rights in the midst of significant merger activity suggest an interesting link between industry concentration and the control of patent rights. It may be that uncertainty in patent rights causes a breakdown in arms-length contracting that provides incentives for consolidation.").

[3] Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified at 21 U.S.C. § 355).

[4] 402 F.3d 1056 (11th Cir. 2005), *cert. denied*, 126 S. Ct. 2929 (2006).

[5] *See, e.g., In re* Tamoxifen Citrate Antitrust Litig., 466 F.3d 187 (2d Cir. 2006), *cert. denied*, 127 S. Ct. 3001 (2007).

infringement is often undisputed.[6] Outside the Hatch-Waxman context, however, in most differentiated product markets, the complex interplay of claim interpretation, design-around, and validity issues can make highly uncertain the extent to which the patent constitutes a substantial barrier to entry. Moreover, *Schering-Plough* is unusual not only because it involved substantial infringement issues in the underlying patent case, but also because the parties in the antitrust case litigated the matter—including the merits of the parties' infringement claims—through trial.

Schering-Plough is instructive not only because of the record in the case, but also because it provides an opportunity to compare the views of the FTC and the Justice Department regarding their approach to patent settlements, at least in the Hatch-Waxman context, as a result of the contrasting briefs they filed in connection with the FTC's attempt to obtain Supreme Court review of the Eleventh Circuit's decision.[7] At the same time, *Schering-Plough* provides an opportunity to assess how at least one court of appeals responded to the arguments advanced by the FTC, and how, in turn, both the FTC and the DOJ (as reflected in their Supreme Court briefs) might respond to similar arguments advanced by parties in connection with a merger.

After providing additional background regarding the complex interaction of claim interpretation, infringement, and validity issues under the patent laws below, we attempt to explain the three approaches taken in *Schering-Plough* to the analysis of patent settlements in the Hatch-Waxman context. The first might be called the "exclusionary potential" approach (which parties might argue was adopted by the Eleventh Circuit); the second the "objective" approach (favored by the DOJ); and the third the "expectations" approach (favored by the FTC). Then, we try to work through some of the questions and unresolved issues raised by each of these approaches if applied in the merger setting.

It is not our purpose in this article to advocate one or the other of these approaches. Rather, it is to make three more modest points. First, each of these approaches raises numerous, as-yet unaddressed issues when transmuted from the Hatch-Waxman context to the regulatory review of a merger. Second, as vigorous and unresolved as the debate has

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[6] Where molecule patents are involved, they are blocking in a way that is rare outside the pharmaceutical context, and even where other claims are at issue, bioequivalence requirements often lead to minimal differentiation between brand and generic products.

[7] *Compare* Brief for the United States as *Amicus Curiae*, Federal Trade Comm'n v. Schering-Plough Corp., No. 05-273 (May 2006) [hereinafter U.S. Brief], *available at* http://www.justice.gov/atr/cases/f216300/216358.htm, *with* Supplemental Brief for the Petitioner, Federal Trade Comm'n v. Schering-Plough Corp., No. 05-273 (June 2006), *available at* http://www.ftc.gov/os/adjpro/d9297/060612certiorarisupplementalbrief.pdf.

been regarding the proper evaluation of Hatch-Waxman settlements,[8] it is likely to become even more challenging when the question becomes, as it will in most merger cases, *how high* the patent barrier to entry might be, and not simply (as in most of the Hatch-Waxman cases) whether or not it exists. Third, and finally, as important as the Hatch-Waxman cases have been in the pharmaceutical industry, we believe that their long-term significance from the perspective of antitrust analysis may have been principally to serve as a preface to a debate under Section 7 that is only just now getting under way.

I. BACKGROUND: PATENTS AND THE PATENT LITIGATION SYSTEM

Under the terms of the consent order entered recently by the FTC in the merger of Flow International Corporation and OMAX Corporation, the FTC analyzed the effect of patent infringement litigation resolved by a merger of the litigating parties. As part of the consent, the FTC required Flow to "grant a royalty-free license to two OMAX patents relating to waterjet controllers to any firm that seeks a license."[9] As the FTC explained in its Analysis to Aid Public Comment, the merger in that case would "settle the long-running and expensive patent litigation between Flow and OMAX," in which OMAX had filed suit alleging patent infringement by Flow, and Flow had counterclaimed asserting its own patents against OMAX.[10]

Notably, the FTC's order required relief only with respect to the licensing of OMAX's patents, not Flow's. The FTC explained that the reason was that "OMAX's two patents make the development of such a controller substantially more expensive and risky"; by comparison, "Flow has two patents relating to controllers, its patents are significantly narrower in scope than the OMAX patents and, as a result, do not prevent current or future competitors from offering a viable waterjet cutting system."[11] The FTC concluded that "current and future competitors will

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[8] *See, e.g.*, Kevin D. McDonald, *Hatch-Waxman Patent Settlements and Antitrust: On Probabilistic Patent Rights and False Positives*, ANTITRUST, Spring 2003, at 68; Herbert J. Hovenkamp et al., *Anticompetitive Settlement of Intellectual Property Disputes*, 87 MINN. L. REV. 1719, 1761 (2003); *see also* Shapiro, *Antitrust Limits*, *supra* note 1 (embracing the probabilistic theory of patent rights).

[9] Analysis of the Agreement Containing Consent Order to Aid Public Comment, Flow Int'l Corp., FTC File No. 081-0079 (July 10, 2008), *available at* http://www.ftc.gov/os/caselist/0810079/080710analysis.pdf.

[10] *Id.* at 1.

[11] *Id.*

not need licenses to these narrow [Flow] patents in order to compete effectively in this market."[12]

The FTC does not explain in *Flow* how it went about making this assessment regarding the scope of the Flow and OMAX patents, but that evaluation obviously was central to its determination regarding which (if any) patents constituted significant barriers to entry into the market, and what relief would be required to gain regulatory approval. No relief was required with respect to the Flow patents, not because of questions regarding their validity, or OMAX's possible infringement, but rather because of their narrow scope. Because, for merger purposes, such issues as patent breadth and the commercial feasibility of design-arounds are likely to loom as large as issues of validity, we briefly summarize here some of the pertinent aspects of patent law.

A. CLAIM INTERPRETATION, INFRINGEMENT, AND VALIDITY

In the modern American patent system, a patent includes one or more "claims," which "particularly point[ ] out and distinctly claim[ ] the subject matter which the applicant regards as his invention."[13] Because the claim "defines the scope of a patent grant," victory in an infringement suit "requires a finding that the patent claim covers the alleged infringer's product or process, which in turn necessitates a determination of what the words in the claim mean."[14] Determining whether a patent claim is infringed therefore "requires a two-step inquiry: First, the claim must be properly construed to determine its scope and meaning. Second, the claim as properly construed must be compared to the accused device . . . ."[15]

The uncertainty created regarding the scope of the patent prior to the first "claim interpretation" step has important consequences for antitrust analysis. The claims of the patent are presumed to be valid (although this presumption can be rebutted),[16] but precisely what they cover may be unknown until after a court has interpreted the claims, generally during what has come to be known as a *Markman* hearing. (The hearing is named after the Supreme Court decision cited above.) The *Markman* hearing is often a pivotal event in the course of the patent

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[12] *Id.* at 3.

[13] 35 U.S.C. § 112.

[14] Markman v. Westview Instrs., Inc., 517 U.S. 370, 373–74 (1996) (citations and internal quotation marks omitted).

[15] Wolverine World Wide, Inc. v. Nike, Inc., 38 F.3d 1192, 1196 (Fed. Cir. 1994) (citation and internal quotation marks omitted).

[16] Kegel Co. v. AMF Bowling, Inc., 127 F.3d 1420, 1425 (Fed. Cir. 1997). *See also* Laitram Corp. v. Rexnord, Inc., 939 F.2d 1533, 1535 (Fed. Cir. 1991).

litigation because the meaning of particular words in the claim typically is hotly contested, and the outcome of the case often turns in substantial part on how those contested terms are construed.

At least until the *Markman* hearing (and often afterwards, as these rulings are frequently the subject of appeal), it may be difficult to know how substantial a barrier to entry the patent claims might prove to be. This uncertainty regarding the scope of a patent claim makes the assertion of a patent claim very different, as a practical matter, from (for example) the assertion of a real property claim. Ordinarily, the bounds of a piece of real property are reasonably established. In the case of patents, by contrast, even where it is not reasonably disputed that the patent holder owns *something*, it might be a matter of considerable uncertainty whether that grant is, by analogy, to 2, 20, or 200 acres.

Moreover, issues of validity and infringement can become intertwined with claim interpretation in ways that make the potential outcome of the patent litigation even more complex. Thus, for example, patent holders do not necessarily argue for the broadest possible interpretation of their claims, because such broad coverage might cause the patents to be held invalid.[17] Instead, where they can, they argue for the broadest possible interpretation consistent with limitations that preserve the patent's validity. Alleged infringers, by contrast, often argue for narrow interpretations of some claim language that would avoid infringement (or allow for a simple work-around) and broad interpretations of other terms that would render the claims invalid.

The range of potential outcomes in a patent litigation matter, therefore, may extend along a continuum that reaches from non-infringement, through infringement that is of little commercial significance because it is easy to design around, to infringement that is more costly to design around, to infringement that cannot be successfully contested but may render the patent invalid. For antitrust purposes, consequently, there are likely to be many permutations that reasonable persons could adopt regarding the potential scope of the patent.

The variety of these possible permutations is illustrated, for example, in the case of *Cross Medical Products, Inc. v. Medtronic Sofamor Danek, Inc.*,[18] where five terms used in the patent claims were in dispute. In reversing a grant of summary judgment finding infringement, the Federal Circuit

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[17] Generally, the validity of a patent claim depends upon whether the invention or process described is novel, useful, non-obvious, and adequately disclosed, all of which can be comprised by a vague and overbroad articulation of what the patent covers. *See* U.S. Patent Act, 35 U.S.C. §§ 101–103, 112.

[18] 424 F.3d 1293 (Fed. Cir. 2005).

affirmed the district court's *Markman* interpretation of three of the patent terms, but modified two others.[19] It then reversed the district court's holding that Medtronic infringed two of the elements of the claim and one of the claims modified by the court of appeals, ruling that there was a genuine dispute as to those three elements.[20] Further, it upheld the validity of the patent, but only in light of the limiting interpretations that it adopted. In other words—and stating the obvious—the decisions involved complex determinations about the many claims in dispute, and the reviewing courts reached different conclusions about the same claims.

Had the *Cross Medical* patent come before the antitrust agencies prior to the district court's summary judgment ruling, the agencies could have found substantial evidence to support at least three different conclusions, namely: (1) that the patent was valid and infringed (as the district court found); (2) that the patent, if read as broadly as the district court found, was invalid (as the Federal Circuit suggested); or (3) that the patent was valid, but properly should be interpreted more narrowly, with the result that infringement is an open question (as the Federal Circuit found). In most industries, the complexities raised by the patent in the *Cross Medical* example are the norm, not the exception.[21] The effect of patent claims on competition in a particular market (or from a particular competing product) therefore generally cannot be reduced to a simple binary proposition, but rather can range across a spectrum of possibilities that defy simple resolution.

B. Patent Law Presumptions

As we noted earlier, patent claims are presumed to be valid. The opposite is true, however, with respect to infringement. The patent owner bears the burden of proving that every element set forth in the asserted claim is found in the challenged product.[22] In other words, a product is *not* presumed to infringe a patent claim. The burden is on the patent

[19] *Id.* at 1297.

[20] *Id.*

[21] Indeed, the situation can become even more complicated where the proper interpretation of one claim is affected by the interpretation of other similarly phrased claims, because the doctrine of "claim differentiation" instructs that each independent claim is presumed to be non-duplicative in meaning and scope. *See* ROBERT C. KAHRL, PATENT CLAIM CONSTRUCTION § 4.03(F) (Supp. 2007); *see, e.g.,* Kraft Foods, Inc. v. Int'l Trading Co., 203 F.3d 1362, 1370 (Fed. Cir. 2000).

[22] *See, e.g.,* Kegel Co. v. AMF Bowling, Inc., 127 F.3d 1420, 1425 (Fed. Cir. 1997); Wolverine World Wide, Inc. v. Nike, Inc., 38 F.3d 1192, 1196 (Fed. Cir. 1994); Laitram Corp. v. Rexnord, Inc., 939 F.2d 1533, 1535 (Fed. Cir. 1991). This rule is one of longstanding authority. *See, e.g.*, Parks v. Booth, 102 U.S. 96, 99 (1880).

owner to prove that it does.[23] The patent holder also bears the burden of proving that injunctive relief is appropriate, rather than monetary damages, even after infringement has been proven. Traditionally, courts treated proof of infringement as sufficient to justify the entry of an injunction against the infringing party, but in *eBay v. MercExchange*, the Supreme Court raised questions regarding whether at least business method patents and patents that are not practiced by the patent holder would satisfy the traditional four-factor test for determining whether, and to what extent, equitable relief is justified.[24]

For antitrust purposes, therefore, the default position under the patent law is that, until the plaintiff has prevailed on its infringement claim, the defendant is free to compete in the market. The patent owner is presumed to have a valid property right but is also presumed not to have the ability to prevent the defendant from competing in the market. There is no support in the patent law for presuming, simply from the commencement of patent litigation, that the patent owner has any lawful basis for excluding its rivals from the market.

The default position under the patent law thus is that existing competition between the litigating parties is lawful—much as antitrust law assumes that monopoly power alone is not sufficient to make out a Section 2 claim when a rival brings suit against a monopolist. Although it may be shown in each case, by a preponderance of the evidence, that the patent has been infringed, or the monopolist's market power has been illegally acquired or maintained, at the outset it is presumed that neither the alleged infringer nor the monopolist is restricted in its ability to compete in the market against its rival simply because the rival has brought suit under the patent or antitrust laws.

II. *SCHERING-PLOUGH*: THREE APPROACHES TO THE ANALYSIS OF PATENT SETTLEMENTS

In *Schering-Plough*, the Eleventh Circuit set aside the decision of the FTC and vacated the FTC's entry of a cease and desist order with respect to patent settlements entered into between Schering-Plough, the manufacturer of a branded drug called K-Dur 20, and two generic manufacturers, Upsher-Smith Laboratories and ESI Lederle.[25] In the Upsher

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[23] *See id.*

[24] *See* eBay v. MercExchange, 547 U.S. 388, 395–97 (2006) (Kennedy, J., Stevens, J., Souter, J., and Breyer, J., concurring); *but see id.* at 394–95 (Roberts, C.J., and Scalia, J., and Ginsberg, J., concurring) (indicating that judges should accord "great weight" to the long tradition of issuing injunctive relief upon a finding of infringement).

[25] Schering-Plough Corp. v. FTC, 402 F.3d 1056, 1058 (11th Cir. 2005), *cert. denied*, 126 S. Ct. 2929 (2006).

settlement, Schering paid Upsher $60 million as part of the settlement of its infringement litigation against Upsher, and in the ESI settlement, Schering-Plough paid ESI $10 million as part of the settlement of its infringement litigation against ESI.[26]

The Eleventh Circuit, the FTC, and the Department of Justice each took a significantly different position with respect to how these settlements should be analyzed. Although some aspects of these settlements reflect the distinctive context in which they arose—the assertion of patent claims against generic manufacturers prior to market entry pursuant to the Hatch-Waxman Act—of greater interest here are aspects of the analysis that may be applied more generally to patent litigation settlements, including settlements involving the merger of the litigating parties.

As explained below, the Eleventh Circuit's position (subsequently endorsed by the Federal Circuit and Second Circuit in the recent *Cipro* and *Tamoxifen*[27] decisions) may be more favorable to settling parties than that of the agencies. The positions of the FTC and DOJ differ in their analysis of the resolution of such disputes. Although these differences might often yield the same outcome, they are sufficiently dissimilar that, as explained in Part III *infra*, each could produce a different result, particularly in situations where the litigation record has not been well developed. Finally, it bears noting that, to the extent there are differences in how the courts, the FTC, and the DOJ would analyze a merger that resolves a significant patent dispute, those differences are limited to how they assess the loss of competition between the litigating parties that occurs until the expiration of the patent or a final litigated judgment, whichever is shorter. The agencies and federal courts share the view that the existence of a patent dispute is irrelevant to the extent that the merger would substantially lessen competition even without a valid patent.[28]

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[26] *Id.* at 1060–61.

[27] *See In re* Ciprofloxacin Hydrochloride Antitrust Litig., 544 F.3d 1323 (Fed. Cir. 2008); *In re* Tamoxifen Citrate Antitrust Litig., 466 F.3d 187 (2d Cir. 2006).

[28] *See* FTC Commissioner J. Thomas Rosch, FTC Litigation at the Antitrust/Intellectual Property Interface, Remarks at the Meeting of Law Seminars International, Pharmaceutical Antitrust (Apr. 26, 2007), *available at* http://www.ftc.gov/speeches/rosch/070426si_pharma.pdf (explaining that there is no inconsistency between the analytical approaches of the FTC or the courts in *Schering*, *Tamoxifen*, or *Cardizem*, to the extent a settlement agreement restrains competition beyond the scope or remaining life of the patents at issue).

A. THE ELEVENTH CIRCUIT'S APPROACH *SCHERING-PLOUGH*

The Eleventh Circuit began by stating that neither of the standards applied under Section 1 antitrust analysis—rule of reason or per se—properly should be applied to the analysis of patent settlements.[29] The court reasoned that "[b]y their nature, patents create an environment of exclusion, and consequently, cripple competition. The anticompetitive effect is already present."[30] From this foundation, the court held that a proper analysis of patent settlements required an examination of (1) the scope of the exclusionary potential of the patent; (2) the extent to which the agreements exceed that scope; and (3) the resulting anticompetitive effects.[31]

On the critical question of what the Eleventh Circuit meant with respect to the all-important first step in this analysis—the "scope of the exclusionary potential" of a patent—the court made two important observations. First, the court stated that "[b]y virtue of its '743 patent, Schering obtained the legal right to exclude Upsher and ESI from the market until *they* proved either that the '743 patent was invalid or that their products, Klor-Con and Micro-K 20, respectively, did not infringe Schering's patent."[32]

There are a number of potential ways to understand what the Eleventh Circuit meant by that statement, and the opinion itself is not clear on the point. One possibility is that the Eleventh Circuit simply made a mistake regarding the allocations of burdens of proof in patent law. As noted earlier, the burden of persuasion on infringement rests with the patent holder.[33] Here, the court of appeals appears to be reversing that burden, stating that the alleged infringers had to prove that their products did not infringe. One reason to believe the Eleventh Circuit may simply have gotten this key issue wrong is that the administrative law judge (ALJ) in the case clearly made just such a mistake, holding that it was "well settled precedent" that there is a presumption of infringement in the patent law.[34] It seems difficult to believe that the Eleventh Circuit could have made such a fundamental error, however, particularly inas-

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[29] *Schering-Plough*, 402 F.3d at 1065.

[30] *Id.* at 1065–66.

[31] *Id.* at 1066.

[32] *Id.* at 1066–67 (emphasis added).

[33] *See, e.g.*, Kegel Co. v. AMF Bowling, Inc., 127 F.3d 1420, 1425 (Fed. Cir. 1997); Wolverine World Wide, Inc. v. Nike, Inc., 38 F.3d 1192, 1196 (Fed. Cir. 1994); Laitram Corp. v. Rexnord, Inc., 939 F.2d 1533, 1535 (Fed. Cir. 1991).

[34] *See* Schering-Plough Corp., FTC Docket No. 9297, slip. op. at 34 (June 27, 2002) [hereinafter Initial Decision], *available at* http://www.ftc.gov/os/adjpro/d9297/020627id.pdf.

much as it failed to "correct" its opinion even after the FTC pointed out the mistake in its petition for rehearing.[35]

Another potential explanation is that the court was not referring to the infringing parties' burden under patent law but was stating that the antitrust plaintiff (i.e., the FTC), as part of its affirmative case under the antitrust laws, must demonstrate that the parties' agreement is the cause of the anticompetitive effect. Although the language in the Eleventh Circuit's statement seems to refer to the allegedly infringing parties ("they"), merging parties may reasonably assert to the agencies (or to a court in a merger challenge) that the Eleventh Circuit was intending to allocate the burden of proof where it lies in antitrust cases—with the antitrust plaintiff. That interpretation would be consistent with the court's observation that "[p]erhaps most important, and which the ALJ duly noted, is that FTC complaint counsel acknowledged that it could not prove that Upsher and ESI could have entered the market on their own prior to the '743 patent's expiration."[36]

This statement by the court of appeals itself is something of a puzzle, however, depending upon what one believes the court meant when it said that the FTC acknowledged that it "could not" prove that the alleged infringers would have entered the market prior to patent expiration. While the FTC staff had taken the position that they did not *need* to prove non-infringement in order to prevail, they had in fact submitted voluminous evidence at trial in support of the conclusion that the patent defendants did not infringe Schering-Plough's patents.[37] This evidence was easily sufficient to show, if accepted by a fact-finder, that Schering was unlikely to prevail in its infringement claims. For example, complaint counsel's patent expert, Professor Martin J. Adelman, had testified that Upsher's arguments regarding non-infringement created so many hurdles for Schering to overcome that Schering-Plough's likelihood of winning "approaches zero."[38]

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[35] Brief of Respondent FTC for Rehearing *En Banc* at 3, Schering-Plough v. FTC, No. 04-10688 (Apr. 21, 2005), *available at* http://www.ftc.gov/os/2005/04/050421ftcpetrehearenbanc.pdf.

[36] Schering-Plough Corp. v. FTC, 402 F.3d 1056, 1068 (11th Cir. 2005), *cert. denied*, 126 S. Ct. 2929 (2006).

[37] *See, e.g.*, Brief of Respondent FTC at 36, Schering-Plough v. FTC, No. 04-10688, 2004 WL 3557972 (11th Cir. July 23, 2004)). This evidence included the '743 prosecution history, the opinions of experts for Upsher and ESI in the underlying patent litigation (Drs. Christopher T. Rhodes and Harold B. Hopfenberg), and the testimony of technical and patent experts for complaint counsel (Dr. Umesh V. Banaker and Prof. Martin J. Adelman).

[38] *See, e.g.*, Appendix to Complaint Counsel's Reply Br. in Support of Findings of Fact and Conclusions of Law at A-8 (May 14, 2002) (citing Tr. 15:7735 (Adelman)), *available at* http://www.ftc.gov/0s/adjpro/d9297/020514ccrb.pdf.

The Eleventh Circuit may simply have meant that the FTC did not meet its burden by a preponderance of the evidence on the question of infringement. If so, however, it would have been making that assessment *de novo*, because both the ALJ and the FTC had expressly declined to evaluate the evidence submitted at trial by complaint staff and the defendants regarding how the underlying patent case would have been resolved.[39] Given the extensive nature of the evidence, and its highly fact-specific nature, it would seem surprising that the Eleventh Circuit would not remand to the FTC or ALJ for this determination if this was what it believed was necessary. This interpretation seems particularly strained inasmuch as the court itself made no mention of the conflicting evidence. Instead, the court simply observed that there was no allegation that the '743 patent was invalid "or that the resulting infringement suits against Upsher and ESI were *'shams.'*"[40]

The reference to "shams" suggests another interpretation of the Eleventh Circuit's decision: it was imposing a standard of proof significantly higher than a mere preponderance, and it was that level of proof that the FTC had never claimed it could meet. This interpretation may be supported by the fact that, in connection with the ESI settlement, the only evidence that the court of appeals noted (and seemed to view as sufficient) was that the litigation between Schering-Plough and ESI had been "fierce and impassioned"—evidence more relevant to the question whether the litigation was a sham than to which party was likely to prevail.[41] It seems reasonable to infer that the court of appeals in *Schering-Plough* may have intended to impose a very high standard on plaintiffs: in the absence of evidence that the litigation was a sham, infringement should be taken as established for purposes of the antitrust analysis of patent settlements.[42]

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[39] Initial Decision, *supra* note 34, at 74, 104; Schering-Plough Corp., FTC Docket No. 9297, slip. op. at 34 (Dec. 18, 2003) [hereinafter Commission Decision], *available at* http://www.ftc.gov/os/adjpro/d9297/031218commissionopinion.pdf.

[40] *Schering-Plough*, 402 F.3d at 1068 (emphasis added). The claim that there had been no challenge to the '743 patent's validity was not correct. At trial, Schering-Plough's own patent counsel conceded that if Schering-Plough had prevailed on its broad reading of the patent's claim language, it might have raised validity concerns.

[41] *Id.* at 1072.

[42] In *Tamoxifen*, the Second Circuit expressly embraced the holding that "[i]t is only when settlement agreements are entered into in bad faith and are utilized as part of scheme to restrain or monopolize trade that antitrust violations may occur." *In re* Tamoxifen Citrate Antitrust Litig., 466 F.3d 187, 203 (2d Cir. 2006) (citation and internal quotation marks omitted). *See also* Loctite Corp. v. Ultraseal Ltd., 481 F.2d 861, 876–77 (Fed. Cir. 1985), *overruled on other grounds*, Nobelpharma AB v. Implant Innovations, Inc., 141 F.3d 1059 (Fed. Cir. 1998) (a patentee's decision to enforce its IP rights generally should be shielded from antitrust review, absent "clear and convincing evidence" that the patentee enforced in "bad faith").

This interpretation of the standard adopted by the court in *Schering-Plough* would impose a much stiffer standard on the antitrust agencies than the standards they themselves have proposed. These alternatives are discussed immediately below.

B. The Justice Department's Approach

In response to the Supreme Court's request for the views of the Solicitor General regarding the FTC's petition for a writ of certiorari in *Schering-Plough*, the DOJ filed a brief with the Court urging denial of the petition.[43] In doing so, the DOJ, consistent with the views of the Antitrust Division, outlined how it would approach the analysis of a patent settlement. According to the DOJ, a proper analysis of a patent settlement should "take into account the relative likelihood of success of the parties' claims, viewed *ex ante*."[44] The DOJ suggested that such an analysis should be conducted as a "more objective assessment of the claims based on evidence extrinsic to the settlement," rather than "the parties' subjective views of the strength of the claims."[45] The DOJ envisioned something akin to a mini-trial on the patent merits, which it described as follows:

> A court would not need to conduct a full trial on the merits of the patent claims in order to make a determination regarding the likelihood of a patent owner's litigation success. Rather, a court could conduct a limited examination into the relative merits of the patent claims and other relevant factors surrounding the parties' negotiations.[46]

The DOJ thus appears to endorse an abbreviated review of the issues raised in the patent litigation, including presumably all of the claim interpretation, infringement, and validity issues raised by the case. In deciding whether to sue, given the technical nature of the inquiry, the DOJ might be expected in the first instance to retain its own expert, who then would be charged with conducting a review of the patent's prosecution history, undertaking a search of the prior art, and carrying out an examination of the allegedly infringing product (including potential tests or other steps necessary to ascertain whether the product carries out particular steps described in the patent). If the patent case has not proceeded through the filing of expert reports, however, this task might

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[43] U.S. Brief, *supra* note 7.

[44] *Id.* at 11.

[45] *Id.* at 12.

[46] *Id.* at 11 n.1.

prove dauntingly difficult, especially with respect to infringement and design-around issues.[47]

In the event of suit, the DOJ has analogized the potential merits review to the review of proposed class action settlements.[48] A court would, however, need to conduct an analysis in considerably greater depth than the review applied to class action settlements, which require only a finding that the settlement is fair, adequate, and reasonable.[49] Indeed, the facts in *Cross Medical* show that even an abbreviated examination could quickly prove to be quite complex.[50] For example, suppose that a fact finder concluded that there was a 40 percent chance a court would find the patent to be completely blocking with no possibility of design

[47] In its Amicus Brief, the DOJ critiques the FTC's analytical approach for failure to make "any direct effort to evaluate the likelihood that the patent holder would prevail on its claim," preferring instead to focus only on the parties' subjective valuation of their prospects in litigation. U.S. Brief, *supra* note 7, at 11. However, the DOJ also acknowledges that the two approaches likely will achieve the same the result, "as the expected value of the lawsuit should be a product of the relative strength of the competing claims." *Id.* at 12. As such, it is difficult to understand how the FTC approach would be inferior, particularly in those situations where the settlement occurs before the litigation record is well developed, leaving the DOJ with few practical options for making an "objective assessment of the claims based on evidence extrinsic to the settlement." *Id.*

[48] *Id.* at 15–16.

[49] Class action settlements are reviewed only to ascertain whether they are fair, adequate, and reasonable. *See, e.g.*, Miller v. Republic Nat'l Life Ins. Co., 559 F.2d 426, 428–29 (5th Cir. 1977). But even under this limited standard of review, the design of the class certification approval process affords trial judges with additional tools—unavailable to the reviewing agencies under the DOJ approach—which are invaluable to a trial judge attempting to gauge the equity of a particular class settlement. First, the settlement approval process automatically includes an extensive notice and comment process, allowing parties adversely affected to object and educate the court on deficiencies. *Id.* at 429. Second, before a class is certified, trial judges are obligated to engage in a rigorous analysis of the evidence, which entails issuing a decision that often resolves several key factual disputes relating to plaintiffs' theory of liability and harm. *See In re* IPO Sec. Litig., 471 F.3d 24, 38–43 (2d Cir. 2006). Finally, it bears noting that the class settlement approval process will be administered by the same trial judge already familiar with the underlying litigation. *Cf.* Van Horn v. Trickey, 840 F.2d 604, 606–07 (8th Cir. 1988) ("Great weight is accorded [to the trial judge's] views because he is exposed to the litigants, and their strategies, positions and proofs. He is aware of the expense and possible legal bars to success. Simply stated, he is on the firing line and can evaluate the action accordingly.").

[50] FTC Commissioner J. Thomas Rosch noted recently that conducting such a mini-trial to determine validity, infringement, and the blocking nature of patents is "expensive" and requires extensive "expertise" that the antitrust agencies do not presently have in-house. *See* FTC Commissioner J. Thomas Rosch, *supra* note 28, at 7; *see also* Joseph Kattan, Remarks, Hearing on Practical Issues Encountered in Antitrust Analysis of Licensing Practices: the Problem of Dealing with Uncertain or Disputed Patent Rights, Testimony Before the DOJ Antitrust Div. and FTC, Transcript at 174–77, 185–93 (May 14, 2002), *available at* http://www.ftc.gov/opp/intellect/020514trans.pdf (noting that the agencies are not equipped to tackle IP disputes in the context of a merger review because "[a] patent case may last many, many years, and how do you compress a patent case into the life span of a short antitrust case? And this is particularly true in the context of mergers . . . [with] four or five months of the Hart-Scott-Rodino review period.").

around; a 20 percent chance that it was infringed but not blocking; a 20 percent chance that it was not infringed at all; and a 20 percent chance that the patent was invalid. There would then be a greater than even chance that the product would be found to infringe (60 percent), but also a greater than even chance (again 60 percent) that the alleged infringer would be able to continue competing in the market, either because it would prevail at trial or because it could design around the patent. Resolution of the merits from an antitrust perspective in those circumstances would seem to require an extremely granular look at the precise limits of the patent, the cost of implementing the design-around, and its effect on the subsequent competitiveness of the alleged infringer.

In its brief opposing certiorari, the DOJ noted that, while the Eleventh Circuit's decision "does not expressly address the strength of the patent claim,"[51] this omission potentially could be explained by the Eleventh Circuit's reliance on the initial decision of the ALJ.[52] In fact, however, the DOJ appears to have misunderstood the ALJ's position. The ALJ stated in his initial decision, as noted earlier (and as he repeatedly had stated through trial), that he did not believe that a merits review of the type suggested by the DOJ was feasible: "The evidence presented at trial confirms that the likely outcome of the patent disputes cannot reliably be predicted. And because the outcome of the patent disputes cannot be predicted, the date on which Upsher-Smith and ESI could have entered, but for the agreements, cannot be determined."[53] The ALJ explained:

> There is no way to determine the date or the outcome of the judicial determination of a patent litigation. Schering's expert, Mr. James O'Shaugnessy, a patent trial lawyer testified that patent litigation is by its very nature unpredictable. Schering's patent expert, Mr. Charles Miller testified there is no recognized methodology for handicapping trials or for testing the reliability of predictions of litigation outcomes. Opinions on the merits of cases that settle before the court decides them can never be tested. . . . Intellectual property litigation is more uncertain than other types of litigation. The Federal Circuit, which hears intellectual property appeals, had a 50 percent reversal rate, making it extremely difficult to predict the outcomes of intellectual property litigation.[54]

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[51] U.S. Brief, *supra* note 7, at 18.

[52] *Id.*

[53] Initial Decision, *supra* note 34, at 104 (citations omitted).

[54] *Id.* at 74 (citations omitted).

Notably, at no level of review in *Schering-Plough*—before the ALJ, the Commission, or the Eleventh Circuit—did any fact finder appear to conduct the kind of merits review of the patent issues that the DOJ urged in its brief in *Schering-Plough*. The case may have provided a missed opportunity to test the feasibility of the kind of review urged by the DOJ, inasmuch as complaint counsel, even though they objected to the propriety or feasibility of such a review in the context of a Hatch-Waxman settlement, had submitted evidence sufficient to conduct precisely the kind of review the DOJ appears to contemplate. In both of the underlying patent litigations, the record was substantially developed, with expert witness testimony submitted by the parties on both sides; and further expert testimony had been submitted by both sides in the antitrust trial. Despite this record, however, at all three levels of review in *Schering-Plough*, the fact finder found occasion not to reach the merits of the issue: the ALJ because he did not believe it could be done; the Commission, as explained in more detail below, because it did not believe it needed to reach the issue; and the Eleventh Circuit, possibly because complaint counsel had failed to show that the infringement claim was a sham.

C. The FTC's Approach

In litigating the case before the ALJ and the Commission, complaint counsel had argued that it was not possible to predict the outcome of patent litigation with sufficient specificity to be able to identify whether a Hatch-Waxman settlement included payment for delay: even an assessment with accuracy within 10 percent, they argued, might miss agreements that could cost consumers tens or hundreds of millions of dollars.[55] Complaint counsel also asserted that resolution of the patent merits was unnecessary to resolve whether the payment from the brand manufacturer was for delay.

Neither of these arguments is necessarily applicable to the question of how the settlement of patent litigation should be analyzed in the context of a merger of the litigating parties. The final reason given by complaint counsel, however, is of broader application—the assertion that, if any assessment were to be made, the burden would lie with the *parties, not complaint counsel*, to prove non-infringement.

In its decision, the Commission set the question of resolution of the patent merits in a broader context. The Commission noted that there might be significant practical issues with conducting an after-the-fact re-

[55] *See, e.g.,* Complaint Counsel's Post-Trial Brief, *supra* note 38, at 73–74.

view of the merits of the patent litigation—such as the fact that the interests of the formerly contending parties would now be aligned—but it was prepared to embark on such an inquiry if necessary.[56] The Commission made clear, however, that it agreed with complaint counsel that if such an inquiry were necessary, the patent owner would bear the burden of proof of infringement, just as it bore the burden of proof of infringement in the underlying litigation.[57]

The Commission's position was consistent with its view that the strength of a patent depends not simply on its technical expiration date, but also on the probability that litigation will or will not prove the patent to be valid or infringed. In other words, as complaint counsel put it in the FTC's petition for certiorari, a patent "is not a right to exclude, but rather a right to *try* to exclude."[58]

The Commission also indicated concern that an ex post analysis might undermine the certainty of the parties' expectations, insofar as they would not know until after the fact whether their agreement might subject them to antitrust liability, based on an assessment of their litigation chances that differed from their own.[59] Accordingly, the Commission held, "we focus on the state of the world as it was perceived by the parties at the time that they entered into the settlement agreement, when they could not be sure how the litigation would turn out."[60] In focusing on the parties' expectations at the time of the settlement, the Commission suggested that it would be the parties' subjective belief regarding their chances, rather than some "objective" assessment, that would be relevant to the Commission's assessment.

In making this subjective assessment, presumably the best evidence would be the parties' own private estimates of their chances of success—estimates likely to be shielded by the attorney-client and work product privileges. Under the Commission's analysis, with the burden of proof lying with the parties to prove infringement, such a rule appears to put considerable pressure on the parties to waive the applicable privileges. Neither Schering-Plough nor the generic manufacturers in fact waived the privilege, which might have been one way of rebutting the inference complaint counsel tried to draw regarding the purpose of the payments

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[56] Commission Decision, *supra* note 39, at 34.

[57] *Id.* at 30.

[58] FTC Petition for a Writ of Certiorari at 16, Schering-Plough v. FTC, No. 04-10688 (11th Cir. Aug. 2005) (quoting Hovenkamp et al., *supra* note 8, at 1761); *see also* Shapiro, *Antitrust Limits*, *supra* note 1 (embracing the probabilistic theory of patent rights).

[59] Commission Decision, *supra* note 39, at 32–33.

[60] *Id.* at 32.

from Schering-Plough to Upsher and ESI. Instead, Schering-Plough gambled on preserving the privilege (unless, of course, its internal estimates showed that it was likely to lose, in which case it was likely an easy choice). If the Commission had conducted an analysis of the patent merits, but with the burden on Schering-Plough to prove infringement, it is not clear how much Schering-Plough's efforts would have been handicapped by its continued assertion of the privilege.

Notably, the outcome of the *Schering-Plough* case at all three levels of decision making followed the allocation of the burden of proof on the question of how the patent merits should be resolved. The ALJ held that complaint counsel bore the burden of proof on this question, although he viewed the answer as effectively unknowable;[61] the Commission viewed the burden of proof as lying with Schering-Plough, although it did not need to reach the issue;[62] and the Eleventh Circuit appeared to view the burden of proof as lying with complaint counsel—possibly not merely to prove non-infringement, but to show that the assertion of infringement was a sham.

III. APPLICATION OF *SCHERING-PLOUGH* TO PATENT SETTLEMENTS RESOLVED BY MERGER

The application of the different analyses articulated in Hatch-Waxman cases by the Eleventh Circuit, the DOJ, and the FTC, potentially can lead to very different outcomes when applied to patent litigation settlements resolved through merger. Certainly, the unique characteristics of Hatch-Waxman litigation, where the generic manufacturer is permitted and encouraged to challenge the intellectual property of the branded drug prior to entry, are unlikely to be present in other industries, particularly where the patent settlement involves existing and established competitors. It is important to consider, nonetheless, how the different perspectives reflected in *Schering-Plough* might be brought to bear when applied to the analysis of mergers that resolve patent disputes.

Indeed, as discussed below, it is possible to reach very different conclusions as to whether a particular merger violates Section 7 of the Clayton Act[63] using the different modes of analysis suggested by the agencies and the *Schering-Plough* court. This section will focus on those differences, and how such distinctions might affect merger review. For these purposes, we will consider the following hypothetical. Suppose that

[61] Initial Decision, *supra* note 34, at 104.
[62] Commission Decision, *supra* note 39, at 30.
[63] Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18.

Party A and Party B have been involved in protracted patent litigation, which has adversely affected at least one party's sales, market value, research and development plans, or ability to attract providers of derivative products and support services. The companies are the only two major competitors in the product market in which they compete; they command a substantial portion of a locked-in customer base; and the likelihood of new entry or expansion appears remote. The parties propose to resolve their lengthy and expensive litigation through A's acquisition of B, before any final determination has been made as to the validity of A's patent or B's potential infringement. To further complicate the antitrust analysis, suppose that A's internal documents discussing the deal with B refer to the ability of the merged entity to sustain long-term price hikes, with no apparent fear of discipline from other vendors once the merger is complete.

This hypothetical is not too far afield from matters that actually have been before the agencies. How should the courts and the agencies analyze the transaction in light of the pending patent dispute?

A. The "Exclusionary Potential" Approach

The starting point for the court's analysis in *Schering-Plough* was preservation of the efficiency benefits to be derived from litigation settlements. The Eleventh Circuit's solicitude for the parties' settlement in *Schering-Plough* clearly was driven, at least in part, by its view that a prohibition on reverse payments would mean "no more patent settlements" in Hatch-Waxman cases.[64] Nothing in the court's analysis suggests that this concern about discouraging settlements would apply with equal weight to patent disputes occurring outside of the Hatch-Waxman regime. It might be the case, however, that, after protracted and intense litigation in a particular case, a merger might appear to be a *reasonable* means of resolving the dispute, with no other feasible alternatives available.[65] In such situations, where the parties, acting in good faith, were unable to resolve their differences through less-restrictive means (e.g., a license or

[64] Schering-Plough Corp. v. FTC, 402 F.3d 1056, 1074 (11th Cir. 2005), *cert. denied*, 126 S. Ct. 2929 (2006) (citations and quotation marks omitted); *but see* Jon Leibowitz, Commissioner, Fed. Trade Comm'n, Exclusion Payments to Settle Pharmaceutical Patent Cases: They're B-a-a-a-ck!, Remarks Before the Second Annual In-House Counsel's Forum on Pharmaceutical Antitrust, (Apr. 24, 2006), *available at* http://www.ftc.gov/speeches/leibowitz/060424PharmaSpeechACI.pdf (noting that the FTC has studied every patent settlement under the Hatch-Waxman Act, and concluded that "parties can—and did—settle patient litigation without money flowing to the generic.").

[65] *See supra* notes 1 and 2 and accompanying text (indicating why parties to an intensely fought patent dispute, such as TV Guide and Gemstar, may be unable to resolve their differences through any means other than merger).

a joint venture), one must ask how a court employing the Eleventh Circuit's analysis in *Schering-Plough* would account for the efficiency-enhancing aspects of settlements in analyzing the proposed merger.

An initial question is whether a reviewing court would apply conventional Section 7 analysis at all, or whether it would replace it with an inquiry into the "scope of the exclusionary potential" of the patent, much as the court replaced ordinary Section 1 standards in *Schering-Plough*. Under such an "exclusionary potential" approach, the parties would argue that a merger should be permitted to go forward so long as the patent holder's infringement claim was not a sham, and the merger did not have anticompetitive effects beyond those caused by the acquisition of the product subject to the patent challenge. The merging parties would argue that they should not be required to show that the patent was a "blocking" one, or that the infringement claim was likely to prevail. Indeed, even if the agency showed that the non-infringement argument was relatively stronger, it would not suffice. So long as it was a plausible claim—as demonstrated, for example, by protracted litigation—a merger that resolved this claim should be permitted to proceed.[66]

Under this "exclusionary potential" standard, the hypothetical described earlier would be easily resolved. The fact that the two parties were the only competitors in a market with high entry barriers would not be pertinent. Nor would the fact that the parties anticipated that prices would rise after the merger, for such price increases would be presumed to be simply the consequence of the anticompetitive effect of the patent—and, unless the patent claim was a sham, that presumption would be deemed conclusive. Moreover, because the hypothetical parties had been engaged in lengthy and expensive litigation prior to the settlement, it would be clear that the patent claim was not a sham. On that ground, a court might conclude that the hypothesized merger should be permitted to proceed, unless the agencies are prepared to launch a direct attack on the patent dispute at issue and prove invalidity or non-infringement so conclusively as to convince a court that the resulting merger would have eliminated substantial and non-infringing competition from the market.

Even if the hypothetical is straightforward, however, there are still circumstances where a court applying an "exclusionary potential" analysis might conclude that the merger goes beyond the patent's scope. For

[66] *See, e.g., In re* Tamoxifen Citrate Antitrust Litig., 466 F.3d 187, 203 (2d Cir. 2006) (holding that a court should not second-guess the decision to settle absent a finding that the settlement was a sham).

example, the Eleventh Circuit did not explain (because the issue was not before it) how to analyze the situation where there is a good-faith claim that a party's product infringes another party's patent but the defendant could work around the patent claims at issue.[67] Where a particular design-around could remedy the infringement, any settlement—such as a merger—that also excludes the non-infringing product (i.e., the product employing the design-around solution) would necessarily exceed the exclusionary scope of the patents at issue. At least in theory, under *Schering-Plough*, such a merger should be subject to possible condemnation.

To guide this inquiry, a court presumably would focus on such factors as the time and expense of designing around the patent, the likelihood of success, whether the remedy will affect the quality of the product or ability to price at competitive levels, or whether others in the industry perceive the patents at issue as blocking or capable of navigation. If the parties have been mired in litigation for a significant amount of time, then most likely the alleged infringer has already invested substantial time toward developing a work-around, thus providing the court with a reference point for projecting the future competitive landscape. Under *Schering-Plough*'s deferential standard, there is the further crucial question of whether the agency or the merging parties bear the burden of demonstrating that the infringement was blocking or could be worked around.

Mergers also may go beyond the exclusionary potential of the patent because they last beyond the patent's term. Imagine, for example, a case where the patent term is set to expire before litigation is likely to resolve. Assuming there are no continuation patents that the patent owner could file, then even an adverse decision on infringement and damages would not automatically result in permanent market exit. Instead, the assets could return to the market as non-infringing competition after the patent expired. How long must the remaining life of the blocking patent be for a court to conclude that its ability to exclude competition is sufficiently broad to permit the permanent end to competition through merger? Would the two-year time horizon set forth in the

[67] Due to the unique context of the Hatch-Waxman Act and pharmaceutical industry generally, a finding (or presumption) that valid patents have been infringed is often enough to deter the entry of generic drug manufacturers who are unwilling to risk substantial damage awards. *See* McDonald, *supra* note 8 (noting that the Hatch-Waxman Act creates an "artificial act of infringement," allowing the generics to test the waters without damage exposure) (noting that infringement is not a contested issue when the generic is claiming bio-equivalency to the pioneer's patent over the active ingredient, though infringement is a disputed issue for formulation patents). This is not the case in industries where the alleged infringer is already an established player in the market.

Merger Guidelines control such an analysis?[68] One would expect that, if the infringing party could "re-enter" the market within two years, then such entry might be considered "timely, likely, and sufficient" such that a court should prohibit the merger, in order to allow such future competition to continue.[69]

B. The Antitrust Division's "Objective" Approach

Whereas the court in *Schering-Plough* began its analysis from the perspective of the benefits of patent settlements, the DOJ began from an "objective" assessment of the patent merits. Based on the DOJ's *Schering-Plough* brief, we can expect that, if the DOJ were presented with a merger that settles a significant patent litigation, it would "conduct a limited examination into the relative merits of the patent claims" in order to "make a determination regarding the likelihood of a patent owner's litigation success."[70] It is similarly likely that this review would entail a first-hand inspection of the patent claims, litigation record, and other direct evidence that bears on the ultimate merits of the infringement claims.[71]

Beyond these basic tenets, it is not clear how the DOJ would approach the analysis of the resolution of a patent infringement dispute through merger. Three questions in particular stand out. First, and perhaps most importantly, which party would the Antitrust Division contend (or expect a court to hold) bears the burden of proof on these patent issues? Second, would the Antitrust Division focus its inquiry on the question of whether the patent owner was likely to succeed in *blocking* the alleged infringer, or more simply on questions of validity and infringement? Finally, how would the Antitrust Division go about conducting its limited examination, and what evidence would it consider most probative?

1. *Who Bears the Burden?*

With regard to the burden of proof, the fact that the DOJ stands ready to conduct a mini-hearing into the likelihood that the patent holder will prevail on its claims suggests that the Antitrust Division believes it must assume the initial burden of proving that the merger eliminates competition that likely otherwise would have occurred because the plaintiff

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[68] *See* Dep't of Justice and Federal Trade Comm'n, Horizontal Merger Guidelines § 3.2 (1992, revised 1997), *available at* http://www.ftc.gov/bc/docs/horizmer.htm [hereinafter Merger Guidelines].

[69] *Id.* § 3.0.

[70] U.S. Brief, *supra* note 7, at 11 n.1.

[71] *Id.*

would not have prevailed in the underlying patent litigation.[72] In this regard, there seem to be at least two plausible avenues for the DOJ to take in analyzing the effect of the patent litigation under the Merger Guidelines: the pendency of the patent dispute could be viewed as a factor that alters the competitive landscape under Section 1.521, or it could be viewed as a variant of the "failing firm" defense under Section 5.0.[73]

As a general rule, the agencies view market concentration and share data as useful indicators of the likely competitive effects of a merger.[74] Where the combined market shares and increase in market concentration levels are very high, the proposed merger is presumed to be anticompetitive. This data is only the starting point of the analysis,[75] however, as the agencies fully recognize that current or "historical evidence may provide an incomplete [or inaccurate] answer to the forward-looking inquiry" of whether a proposed merger will substantially lessen competition.[76] For that reason, the agencies are required to examine the full body of facts and economics to determine whether share estimates accurately reflect the firm's future competitive significance.[77]

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[72] Rather than embrace the FTC's notion that "a patent is not a right to exclude, but rather a right to try to exclude," the DOJ articulates a more deferential standard toward patent settlements, noting that a "valid patent thus confers on the patent holder the lawful right to exclude others from profiting by the patented invention. . . . At the same time, competitive restraints adopted as part of patented settlement are subject to invalidation under the antitrust laws if the patent holder obtains protection from competition which the patent law, unaided by restrictive agreements, does not afford." *Id.* at 9.

[73] If the alleged infringer had not yet entered the market, but was poised to do so, the agencies likely would apply the potential competition framework to determine the competitive significance of that potential entrant. In such an instance, the agencies would have the burden to demonstrate that the alleged infringer (and potential entrant) would have been able to enter the market, and would not have been blocked by the patent holder from doing so. In *United States v. Marine Bancorporation*, the Supreme Court held that a merger involving potential competitors would only violate Section 7 if the agencies could demonstrate that the potential entrant would in fact enter the market. 418 U.S. 602, 638–39 (1974). Although there is a split among the circuits as to the appropriate quantum of proof the agencies must proffer in order to meet this standard, the courts agree that the standard is relatively high, with, for example, the Second Circuit requring evidence that the entrant "would likely" have entered, and the Fourth Circuit requiring "clear proof." *Compare* Tenneco, Inc. v. FTC, 689 F.2d 346, 352 (2d Cir. 1982) (adopting the "would likely have entered" standard), *with* FTC v. Atlantic Richfield Co., 549 F.2d 289, 294–95 (4th Cir. 1977) (adopting the "clear proof" standard).

[74] Merger Guidelines, *supra* note 68, § 1.5 (General Standard).

[75] *Id.* § 2.0; Dep't of Justice & Federal Trade Comm'n, *Commentary on the Horizontal Merger Guidelines* (Mar. 2006) [hereinafter *Merger Guidelines Commentary*], *available at* http://ftc.gov/os/2006/03/commentaryonthehorizontalmergerguidelinesmarch2006.pdf.

[76] Merger Guidelines, *supra* note 68, § 0 (Purpose, Underlying Policy Assumptions and Overview).

[77] *Merger Guidelines Commentary*, *supra* note 75, at 15–16. *See also* United States v. Gen. Dynamics Corp., 415 U.S. 486, 497–98 (1974) (notwithstanding high combined market

At a general level, Section 1.52 of the Merger Guidelines addresses the "factors affecting the significance of market shares and concentration."[78] More specifically, in Section 1.521, for example, the Merger Guidelines state that "recent or ongoing changes in the market may indicate that the current market share of a particular firm either understates or overstates the firm's future competitive significance. . . . The Agency will consider reasonably predictable effects of recent or ongoing changes in market conditions in interpreting market concentration and market share data."[79]

Pending patent litigation might reasonably be considered an "ongoing change in the market" that causes the market share of the alleged infringer to be significantly overstated.[80] Under this view, to assess the merger's impact on competition, the agencies must compare the merger to the baseline state of the world, where the parties continue to compete—and to litigate. If the infringer was forced to litigate, it might face dire, even if not completely debilitating, results because of the pending litigation; hence it would not provide the same competitive threat to the patent owner in the relevant market as it did prior to the litigation. Relevant considerations, for example, would include: (1) evidence that the mere cost and distraction of the patent litigation, coupled with the perceived risk of being eliminated from the market, has resulted in lost or deferred sales (or the related customer concern that, if it purchased products from an infringing party, then the customer would be exposed to potential infringement litigation as well); (2) decreased levels of support from service or product vendors in derivative markets; (3) lost engineering talent or other diminishment of company assets that compromise its ability to compete; and (4) declines in share value and revenue streams that cause the company to forego R&D projects needed to ensure competitive viability.[81] Depending on what these factors showed, the DOJ could conclude that the merger is unlikely to harm competition substantially, regardless of how the patent dispute is ultimately resolved, if the parties would likely litigate for sev-

shares, "weakness as a competitor mandated a conclusion that no substantial lessening of competition occurred or was threatened").

[78] Merger Guidelines, *supra* note 68, § 1.52.

[79] *Id.* § 1.521.

[80] *Id.*

[81] *See, e.g.*, *Merger Guidelines Commentary, supra* note 75, at 16 (notwithstanding combined market shares in excess of 60 percent in highly concentrated market, the government decided not to challenge the Boeing-McDonnell Douglas merger because the evidence showed that McDonnell Douglas no longer constituted a meaningful competitive force because, among other things, it stopped making continual investments and fell behind, ending its ability to land big contracts).

eral more years, while the downward trend in the competitive stature of the alleged infringer continues.

Conversely, if the agency believed that these debilitating effects from litigation would prove to be only short term, and that the alleged infringer will quickly rebound upon receiving a favorable ruling, then the pending litigation might actually be viewed as causing the alleged infringer's competitive significance to be understated (i.e., the merger will cause a greater competitive harm).

Although "changed circumstances" is one approach to analyzing the effect of patent litigation (and a patent settlement) in a merger, an alternative approach under the Merger Guidelines would be to view the issue as a version of a "failing firm" argument.[82] Under Section 5.0 of the Merger Guidelines, "a merger is not likely to create or enhance market power or to facilitate its exercise, if imminent failure . . . of one of the merging firms would cause the assets of that firm to exit the relevant market. In such circumstances, post-merger performance in the relevant market may be no worse than market performance had the merger been blocked and the assets left the market."[83] Professor Joseph Scott Miller has argued that a merger settling patent litigation properly should be analyzed under the failing firm defense, contending that "an antitrust agency should be no worse off when assessing the erstwhile competitor's good faith basis for sacrificing its independence to the patentee than it would be if it were challenging a merger that the parties defend on failing firm grounds."[84]

Considered as a particular instance of a "failing firm defense," this approach would put the burden squarely on the merging parties to show that the alleged infringer would be forced out of the market by the owner's patent. Following the Merger Guidelines and Supreme Court precedent, the availability of the failing firm defense is governed by the following three-prong test: (1) the company to be acquired must be in "imminent danger of failure;" (2) the failing firm must have no realistic

[82] An alternative analysis, if the potentially infringing product is not yet on the market, but is poised to enter, is the actual potential competition doctrine. *See supra* note 74. The analytical framework is similar to the *General Dynamics* and failing firm rubrics discussed throughout—i.e., a determination both of infringement and whether the alleged infringing product could enter through design-around—but the burdens of proof may be different, and different parties may bear the initial burden under each of the analyses. *See id.*

[83] Merger Guidelines, *supra* note 68, § 5.0.

[84] Joseph Scott Miller, *This Bitter Has Some Sweet: Potential Antitrust Enforcement Benefits from Patent Law's Procedural Rules*, 70 ANTITRUST L.J. 875, 884 (2003).

prospect for salvaging its fate; and (3) there are no other viable purchasers who would pose less anticompetitive risk.[85]

If the DOJ were to apply these criteria strictly, as the case law instructs, then in order to satisfy the first component, the merging parties would need to prove by a preponderance of the evidence that a court would find that the alleged infringer is likely to be blocked from the market by a finding of infringement and an injunction against future sales. To satisfy the second component, they would also need to prove that the alleged infringer will not be able to design around the patent in a commercially reasonable time. The third prong might be satisfied by the fact that the infringing assets are worthless to all other purchasers, though it is an open question whether the parties would have to be able to prove that they made a good-faith effort to dispose of the assets if there are participants in the market who are patent licensees or who have the intellectual property or other assets successfully to design around the patent.[86]

Although the "failing firm" defense thus provides one possible analytical framework to the issue, it seems unlikely that it is an approach that the Division would adopt, given its articulated views in the *Schering-Plough* case.[87] It seems more likely that the Division would view an objective assessment of the patent merits as part of its own burden of proof (or assume that a court would impose that burden upon it).

2. *Infringement Versus Blocking Position*

A second question that remains open regarding the Division's approach to mergers that were prompted by a desire to settle patent disputes is whether the Division would attempt to ascertain the actual degree of foreclosure from the suit or limit itself to a more narrow investigation of the possibility of a "win" or "loss." This distinction may be important because the evidentiary record regarding potential "design-arounds" (that is, changes to the product that would avoid infringement) often develops relatively late in patent litigation, after (at a mini-

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[85] Citizen Publ'g v. United States, 394 U.S. 131 (1969). *See also* Merger Guidelines, *supra* note 68, § 5.2 (note, the failing firm defense can apply to the whole company, or to any smaller subset that satisfies the same basic conditions that the assets will inevitably exit the market).

[86] See *supra* note 74 for a discussion of the agencies' burden where the alleged infringer has not yet entered the market and acts more as a "potential competitor" to the party bringing suit for infringement.

[87] *See* U.S. Brief, *supra* note 7, at 11. If the infringing product is not yet on the market, it is possible that the DOJ would apply the potential competition analytical framework instead. The analysis is similar, but in the potential competition rubric the agency bears the substantial burden to demonstrate likely entry. *See supra* note 74.

mum) the *Markman* hearing and potentially not until close to the damages phase of the trial. From an antitrust perspective, however, the question of potential design-arounds ultimately is the most significant issue, not whether an accused infringer might be held liable under a judgment for nominal damages. If design-arounds are possible, the infringer will not be forced to exit the market upon a finding of liability; instead, it only must invest resources to design a non-infringing product.

Because the antitrust inquiry is how substantial the patent is as a barrier to entry, not whether it poses any barrier at all, we expect that the Division would attempt to ascertain the actual degree of foreclosure caused by the patent, not simply handicap the owner's chance of prevailing even on narrow grounds. The importance of this distinction, however, easily can be overlooked, and the complexity of the task of evaluating foreclosure underestimated. In any case in which infringement is a substantial issue (which in most industries is virtually all cases), the question of design-around is a crucial part of the defendant's case. Until the *Markman* hearing establishes the limits of the claim language, however, it is likely to remain a closely guarded aspect of the defendant's work product. Absent waiver of work-product protection by the alleged infringer, it is difficult to imagine how a reviewing agency readily could ascertain the defendant's ability to work around the patent. That especially is the case inasmuch as the merging parties will be motivated to deny the technical and commercial feasibility of potential workarounds. The ability of a reviewing agency (or court) to analyze how a product might be re-designed to avoid the patent, and to assess the costs and commercial impact of such alteration, poses potentially daunting hurdles when not assisted by the patent defendant. Thus, the Antitrust Division's suggestion in *Schering-Plough* that it would conduct a mini-trial on the merits may be especially challenging in the merger context, where the Division may have to prove not only that there was infringement but also that the infringement would have led to market exit.[88]

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[88] Another important question is whether the parties would need to prove (or the DOJ would need to disprove) that the litigation could not have been settled by a license that allowed the allegedly infringing competitor to continue to compete. The Horizontal Merger Guidelines contemplate a "less restrictive alternative" analysis in similar circumstances, *see* Merger Guidelines, *supra* note 68, § 4, although such less restrictive alternatives must be more than simply "theoretical" possibilities. *See id.* In the context of patent litigation resolved through merger, oftentimes a license is a far less desirable alternative for the party asserting the patent right, as it enables competition unclouded by the possibility of infringement litigation where it did not exist previously. Nevertheless, where a license is a realistic alternative to a merger, this "less restrictive analysis" becomes more important. The same issues as discussed throughout would arise in this context, including a determination of who bears the burden to prove or disprove the existence of a less

3. *What Evidence to Rely Upon?*

Finally, with respect to what evidence the Antitrust Division would find most probative in carrying out its patent review, the Antitrust Division noted its disagreement with the FTC's focus on the parties' "subjective" assessment of the patent merits. Instead, the Antitrust Division may have had in mind an approach more analogous to the one it has taken in the context of patent pools. There, the Antitrust Division has approved pools where the parties hire a disinterested expert to assess which technology was essential to the standard (i.e., blocking or commercially infeasible to design around) and, therefore, suitable for inclusion in the pool.[89]

Even in conducting such an "objective" review, however, the confidential and privileged assessments of the parties' patent litigators likely would provide valuable evidence regarding the relative merits of the case, particularly with respect to those issues as to which the evidentiary record has not yet been developed.

Unless the parties bear the burden of proof on the issue, however, it can be expected in most cases that the parties will not waive the privilege. The earlier the settlement, the more difficult the assignment for the patent expert tasked by the agency with replicating this work, especially as the expert (unlike the patent litigators) will not have the cooperation of engineers and scientists at the companies with respect to the operation of the products at issue. Nor will the expert have the time normally afforded during a patent infringement litigation. The agencies may find that developing a reasonable assessment under these circumstances entails a substantial commitment of time and resources, and still will leave them at the end with a substantial range of plausible outcomes.

A mini-trial, including conducting claims construction hearings, accepting expert testimony on the issue of infringement, and surveying the evidence to determine the consequence of infringement (e.g., whether infringement would result in market exit, or whether there is a relatively easy work-around) is a difficult task. If the Antitrust Division were required to conduct that analysis each time it was confronted with determining the question of infringement, then the benefits of settlement—certainty, cost reduction, and closure—would largely be eliminated. And in the merger context, where speed is essential, such a full

restrictive alternative (the agency or the merging parties), and by what quantum of evidence must the party with the burden prove its point.

[89] *See supra* notes 1–2 and accompanying text.

merits trial seems implausible—meaning that something less than such a mini-trial likely would need to be considered.

C. The FTC's Approach

Based on its approach in *Schering-Plough*, the FTC can be expected to take the position that the burden lies with the merging parties to demonstrate that, at the time of the merger, the parties believed that the patent would have forced the alleged infringer from the market, or would have substantially damaged its position in the market. The Commission's analysis in *Schering-Plough* conceptualizes the patent litigation as simply a variant of the failing-firm defense (where the patent forces the infringer to exit from the market) or a *General Dynamics* "changed market condition" defense (where the patent substantially limits the infringer's ability to compete).[90] What remains to be seen, however, is whether the FTC would get a more sympathetic reception in the courts for this approach in the merger context than it has received under Hatch-Waxman. Courts tend to be solicitous of the importance of fostering settlements, and in circumstances where the parties plausibly can argue that the only alternative to the merger is continued litigation, the Commission might find itself facing evidentiary burdens that as a practical matter it cannot sustain, such as establishing that some other settlement was achievable between the parties or that the patent litigation was not brought in good faith.[91]

1. *Proving Infringement Through Subjective Intentions: Waiving the Privilege*

In the meantime, the Commission's analytic approach is likely to place heavy pressure on the parties to waive the attorney-client privilege, at least where the parties' confidential assessments would support a finding that the patent was likely to be "blocking." A decision to waive the privilege, however, can be fraught with peril. For example, although the parties could agree not to use the privileged materials against one another if the patent litigation were to resume, the privilege would still be waived, and any third party potentially could gain access to that informa-

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[90] Where the IP dispute (if followed through to judgment) would have debilitated the acquired party or lessened its competitive impact going forward, then surely this would be a significant factor in explaining that current high market shares "overstate the likely future competitive significance of" the acquired party, and the FTC, in all likelihood, would consider that "changed market condition" in its analysis. *See* Merger Guidelines, *supra* note 68, § 1.52; *see also* United States v. Gen. Dynamics Corp., 415 U.S. 486 (1974).

[91] *See* Asahi Glass Co. v. Pentech Pharm., Inc., 289 F. Supp. 2d 986, 991 (N.D. Ill. 2003) ("The general policy of the law is to favor the settlement of litigation, and the policy extends to the settlement of patent infringement cases.") (citations omitted).

tion in the discovery process in some unrelated proceeding.[92] In that event, it is not difficult to imagine securities plaintiffs, for example, scrutinizing confidential briefings to determine whether there were any discrepancies between those assessments and the company's public statements regarding its litigation chances.

For parties contemplating whether to waive the privilege, a host of additional questions arise. For example, will the FTC commit to closing the merger investigation if patent counsel for the alleged infringer shares a memorandum to the company's Board (corroborated by supporting testimony) indicating that the company's main product line more than likely infringes a patent that will be very difficult, if not commercially infeasible, to design around? If not, what degree of certainty would the FTC require in order to accept the failing-firm defense? Must the likelihood that the patent at issue blocks the infringer's products be greater than 50 percent, and if so, what percent certainty would be required (e.g., 60 percent, 70 percent, near certainty).

Stepping back, is it fair and reasonable to expect that counsel to the Board would ever speak in such certitudes, regardless of how formidable the adversary's evidence might be? Or is it more likely that that counsel's candid discussion would simply reveal the relative strength (e.g., strong, weak, toss-up, unknowable at this time) of the company's defense at several key decision points in the case? Thus, the parties' subjective beliefs with regard to the relative strengths of the patent case are not likely to provide the FTC with the degree of comfort it likely would need to conclude that the merging parties clearly have met their burden that the infringement litigation would result in market exit by the alleged infringer.

Lastly, it is important to consider to what extent the FTC would provide the parties with a degree of "administrative protection" if they agree to waive privilege to meet their burdens under Section 7. As a starting point, several courts recognize the doctrine of selective waiver, allowing the parties to maintain privilege against third parties over documents

[92] Different circuits take different approaches to the issue of selective waiver of the attorney-client privilege and, thus, resolution of the issue depends upon the jurisdiction where the litigation is pending. While some courts would allow the parties to waive the attorney-client privilege for some limited purposes without effectuating a waiver for other unrelated proceedings, *see, e.g.,* Diversified Indus. Inc. v. Meredith, C.A., 572 F.2d 596 (8th Cir. 1977), other courts are decidedly less predisposed to recognizing limited waiver, concluding that such "selective waiver" is not available under the rules of evidence. *See* Permian Corp. v. United States, 665 F.2d 1214, 1220 (D.C. Cir. 1981); *see also* Bittaker v. Woodford, 331 F.3d 715, 720 & n.5 (9th Cir. 2003) ("Although we do not decide the case under express waiver doctrine, we note the law in this area is not [ ] settled.").

shared with a government agency in an unrelated investigation, provided the reviewing agency agrees to several conditions, including: (1) representing that the disclosures are made for the benefit of the reviewing agency to facilitate a more expeditious and accurate investigation; (2) limiting the scope of disclosure to no more than is necessary to aid the investigation; (3) agreeing not to use the privileged documents for any other purpose, including in any prospective litigation against the disclosing parties; and (4) agreeing to treat the documents in a manner befitting their confidentiality.[93] Notably, the DOJ has declined to consent to selective waiver in analogous investigations, specifically, in connection with criminal investigations into corporate governance and securities matters, choosing instead to offer leniency to entice parties to waive privilege.[94] It remains to be seen what position the FTC might take in these different circumstances.

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[93] *See* Diversified Indus. Inc. v. Meredith, C.A., 572 F.2d 596 (8th Cir. 1977) (to encourage voluntary disclosure and cooperation with governmental authorities, a "limited waiver" is justified, allowing the party to share information with the government in one setting, while still maintaining privilege for the disclosed documents in separate litigation matters); United States v. New Wrinkle, Inc., 1954 Trade Cas. (CCH) ¶ 69,855 (S.D. Ohio 1954) (following rule of *Diversified Industries*); United States v. Goodman, 289 F.2d 256, 259 (4th Cir. 1961) (same); Saito v. McKesson HBOC, Inc., No. 18553, 2002 WL 31657622 (Del. Ch. No. 13, 2002) (purporting to follow Second Circuit law, holding, "I adopt a selective waiver rule for disclosures made to law enforcement agencies pursuant to a confidentiality agreement. Confidential disclosure of work product during law enforcement agency investigations relinquishes the work product privilege only as to that agency, not as to the client's other adversaries. The selective waiver rule encourages cooperation with law enforcement agencies without any negative cost to society or private plaintiffs."). *See also* Teacher's Ins. & Annuity Ass'n v. Shamrock Broad. Co., 521 F. Supp. 638, 646 (S.D.N.Y. 1981) (adopting the "compromise position" where "waiver [of privilege is appropriate] if documents were produced without reservation; [but] no waiver [of privilege should occur] if the documents were produced to the SEC under a protective order, stipulation or other express reservation of the producing party's claim of privilege as the material disclosed. It does not appear that such a reservation would be difficult to assert or substantially curtail the investigatory ability of the SEC."); *In re* Steinhardt Partners, 9 F.3d 230, 236 (9th Cir. 1993) ("We decline to adopt a per se rule that all voluntary disclosures to the government waive work product protection. Crafting rules relating to privilege in matters of governmental investigations must be done on a case-by-case basis. Establishing a rigid rule would fail to anticipate . . . situations in which the SEC and the disclosing party have entered into an explicit agreement that the SEC will maintain the confidentiality of the disclosed materials."); Westinghouse Elec. Corp. v. Republic of the Phil., 951 F.2d 1414 (3d Cir. 1991); M&L Bus. Mach. Co. v. Bank of Boulder, 161 B.R. 689 (D. Colo. 1993).

[94] *See, e.g.*, *Steinhardt*, 9 F.3d at 236. For the DOJ's guidelines regarding leniency and waiving privilege under its Corporate Leniency Policy, see Dep't of Justice, Principles of Federal Prosecution of Business Organizations (Dec. 12, 2006) (issued by then-Deputy Attorney General Paul J. McNulty) [hereinafter McNulty Memorandum], *available at* http://www.usdoj.gov/dag/speeches/2006/mcnulty_memo.pdf. The McNulty Memorandum superseded the previous Principles of Federal Prosecution of Business Organizations, which also allowed the DOJ to consider waiver of privilege in its leniency decisions. *See* Dep't of Justice, Principles of Federal Prosecution of Business Organizations (Jan. 20,

2. *Other Evidence Parties Might Use to Meet Their Evidentiary Burden*

In *Schering-Plough*, the Commission emphasized that the parties' own subjective assessments of the litigation merits provided the starting point for its analysis. In the merger context, however, there are many other potential sources of relevant evidence. Consider the following pieces of indirect evidence relating to the merits of the patent dispute, and whether—if the quantum of this evidence suggests that the parties have met their initial burden that patent position was blocking and could not be worked around—the burden of proof would switch to the FTC to prove non-infringement or the availability of commercially feasible design-arounds.[95]

- ***Customer Reactions***: Have customers delayed or deferred their purchases out of fear that the infringer might be knocked out of the market? Have they demanded and received sizeable purchase discounts and service support guarantee or warranties? Have customers (particularly large ones with reserves) been threatened with infringement litigation? If so, have such customers insisted on significant indemnification coverage as a condition to making purchases?
- ***Derivative Products & Services***: Similar to the situation with customers, have the leading developers of applications, components, and other derivative products showed hesitation about making substantial investments in supporting the infringer's platform, for fear that

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2003) (issued by then-Deputy Attorney General Larry D. Thompson), *available at* http://www.usdoj.gov/dag/cftf/corporate_guidelines.htm.

The Securities and Exchange Commission, under its voluntary disclosure program, similarly considers waiver of privilege. *See Steinhardt*, 9 F.3d at 236 ("The SEC has continued to receive voluntary cooperation from subjects of investigations, notwithstanding the rejection of the selective waiver doctrine by two circuits and public statements from Directors of the Enforcement Division that the SEC considers voluntary disclosures to be discoverable and admissible.").

[95] The intuitive appeal of such a burden-shifting paradigm is that it allows the parties to take advantage of a well-developed litigation record and wealth of supporting market evidence to differentiate between meritorious versus suspect settlement agreements. At the same time, it quite properly forces the parties to come forward with affirmative proof of infringement where the litigation record has not yet been developed—a clear practical limitation of the Division proposal that all patent settlements should be reviewed on the basis of objective evidence, even if there is none to evaluate.

Note that the FTC acknowledges that where the legality of patent settlement comes down to the issue of patent validity, rather than infringement, the FTC would have the burden of establishing invalidity, regardless of the practical difficulties of doing so. *In re* Schering-Plough Corp., No. 9297, 2003 WL 22989651, at *17 (FTC Dec. 8, 2003), *rev'd,* Schering-Plough Corp. v. FTC, 402 F.3d 1056 (11th Cir. 2005). *See also* McDonald, *supra* note 8, at 68 (indicating that the issue of infringement and validity is essentially assumed in pharmaceutical patents cases relating to the active ingredient, as opposed to the formulation or delivery mechanism).

it will be blocked? Have they retreated from what appeared to be a profitable sales opportunity due to such concerns?

- ***Rivals***: What can be inferred from the absence of competitors, particularly if the merging parties market a lucrative, high-margin product? Do competitors perceive high entry barriers? Do they have an opinion as to whether the patent holder has a blocking position? Is there a history of patent litigation in this area?
- ***Judicial Bodies and Milestone Decisions***: Has the patent at issue been re-examined by the PTO or defended in other jurisdictions? Has there been a mediation, and do the proposed settlement terms suggest that the patent holder has a strong case?
- ***Prescient Changes in Share Price or Analyst Ratings***: Has the infringing party seen its stock price and rating fall in tandem with the progress of the case? Have there been sharp and immediate corrections in the capital markets in response to unexpected rulings on important issues, such as re-examination, claim construction, validity, adverse inferences, noteworthy discovery rulings, etc.? Conversely, to the extent the merging parties are close competitors that regularly capture one another's sales, has the patent holder received equal and offsetting upward adjustments to its share price and rating following the same milestone developments?
- ***Internal Defections***: Has there been a significant degree of attrition among engineers, sales staff, and marketing personnel? Was it motivated by concern over the patent litigation?
- ***Suspicious Entry History***: Relative to the patent holder and similarly situated rivals in the industry, how quickly was the allegedly infringing product developed? Were any of the developers of the infringing product former employees of the patent holder?
- ***R&D Budgets & Strategy***: Has the infringing firm diverted funds and attention away from new initiatives in order to focus on improvements to the allegedly infringing product? Is it fair to characterize such investments as efforts to design around patent claims?[96]

3. *Merger Consideration as Relevant Evidence*

Beyond the conundrum the parties face regarding whether to waive privilege, they should also expect that the FTC will probe the calculus

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[96] This evidence, of course, is also relevant to the question whether the allegedly infringing party is currently (and perhaps permanently) being harmed by the pendency of patent litigation, thus diminishing its competitive significance in the market.

underlying the consideration for the merger and whether it supports the parties' arguments relating to the strength of the patent holder's claims. In theory, if the patent defendant were going to be forced to exit the market as a result of an adverse finding on infringement, the patent owner would not need to offer consideration in excess of the sum of the cost of the litigation, the present value of assets likely to spoil through protracted litigation (such as lost engineering talent, compromised goodwill, and the loss of positive externalities if the customer base declines), and possibly a substantial discount in defendant's market value, if the probability of success for the patent plaintiffs is less than 100 percent.[97]

Thus, if the merging parties argue for a "blocking" patent, they can expect to face questions regarding any consideration that exceeds (a) the avoided litigation cost, and (b) the savings accrued from an early resolution that avoids deterioration in the value of the asset as the defendant's customers and derivative product or service providers switch to other alternatives. Even here, the Commission's approach, and that of the courts, may vary substantially. Might any additional consideration be viewed by a court as simply the price required to close the deal, much as the *Schering-Plough* court viewed the payments from Schering to the generic manufacturers? Until one of these cases is actually litigated, that is a question—like so many others in this area—to which neither the agencies nor the parties yet have the answer.

IV. CONCLUSION

The resolution of patent litigation through a merger or acquisition may raise substantial antitrust issues, particularly in instances of "bet the company" litigation. The *Schering-Plough* case reflects the nascent development of different approaches at the two agencies and suggests that we are still at the beginning, rather than the end, of the process of developing a workable conceptual framework for handling these issues. As we hope this article makes clear, under any of these approaches, the issues are complex and likely case-specific. That said, with such transactions becoming more commonplace, it is imperative for the agencies and the courts to begin to articulate a workable framework to review such transactions and establish, at a minimum, issues, including burden of proof, quantum and character of evidence required to meet the burden, and, most fundamentally, the degree to which the agencies will provide deference to such mergers to encourage the settlement of such litigation.

[97] *See* Shapiro, *Antitrust Limits*, *supra* note 1, at 402–03 (describing how the merger consideration for an early resolution of the patent dispute should reflect the strength of the patent case).