No. 12-416

In the Supreme Court of the United States

FEDERAL TRADE COMMISSION, PETITIONER

v.

WATSON PHARMACEUTICALS, INC., ET AL.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE ELEVENTH CIRCUIT

PETITION FOR A WRIT OF CERTIORARI

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QUESTION PRESENTED

Federal competition law generally prohibits an incumbent firm from agreeing to pay a potential competitor to stay out of the market. See *Palmer* v. *BRG of Ga., Inc.*, 498 U.S. 46, 49-50 (1990). This case concerns agreements between (1) the manufacturer of a brand-name drug on which the manufacturer assertedly holds a patent, and (2) potential generic competitors who, in response to patent-infringement litigation brought against them by the manufacturer, defended on the grounds that their products would not infringe the patent and that the patent was invalid. The patent litigation culminated in a settlement through which the seller of the brand-name drug agreed to pay its would-be generic competitors tens of millions of dollars annually, and those competitors agreed not to sell competing generic drugs for a number of years. Settlements containing that combination of terms are commonly known as "reverse payment" agreements. The question presented is as follows:

Whether reverse-payment agreements are per se lawful unless the underlying patent litigation was a sham or the patent was obtained by fraud (as the court below held), or instead are presumptively anticompetitive and unlawful (as the Third Circuit has held).

PARTIES TO THE PROCEEDING

The petitioner is the Federal Trade Commission.

Respondents are Watson Pharmaceuticals, Inc., Solvay Pharmaceuticals, Inc., Par Pharmaceutical Companies, Inc., and Paddock Laboratories, Inc.

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The Solicitor General, on behalf of the Federal Trade Commission (FTC), respectfully petitions for a writ of certiorari to review the judgment of the United States Court of Appeals for the Eleventh Circuit in this case.

OPINIONS BELOW

The opinion of the court of appeals (App., *infra*, 1a-36a) is reported at 677 F.3d 1298. The order of the district court (App., *infra*, 37a-61a) is reported at 687 F. Supp. 2d 1371.

JURISDICTION

The judgment of the court of appeals was entered on April 25, 2012. A petition for rehearing was denied on July 18, 2012 (App., *infra*, 62a-63a). The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

STATUTORY PROVISIONS INVOLVED

Pertinent provisions of the Sherman Act, 15 U.S.C. 1 *et seq.*, the Federal Trade Commission Act, 15 U.S.C. 41 *et seq.*, the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 301 *et seq.*, and Title 35 of the United States Code are reproduced in the appendix to the petition (App., *infra*, 64a-122a).

STATEMENT

This case presents a recurring question of great economic importance that has divided the courts of appeals: how to judge the legality under the federal competition laws of a "reverse payment" agreement between a brand-name drug manufacturer and a potential generic competitor. In such an agreement, a patent holder (the brand-name manufacturer) agrees to pay a large sum of money to an accused infringer (its would-be competitor), and the competitor agrees that it will no longer challenge the patent and will not enter the market for a specified period of time. The court of appeals affirmed the dismissal of the FTC's complaint challenging two related reverse-payment agreements. App., *infra*, 28a. The court held that, "absent sham [patent] litigation or fraud in obtaining the patent, a reverse payment settlement is immune from antitrust attack so long as its anticompetitive effects fall within the scope of the exclusionary potential of the patent," *i.e.*, so long as those exclusionary effects do not restrict generic competition more than would have a successful infringement suit. *Ibid.*

1. Under the Federal Food, Drug, and Cosmetic Act, as amended, 21 U.S.C. 301 *et seq.*, the Food and Drug Administration (FDA) regulates the manufacture, sale,

and labeling of drugs.[1] To obtain FDA's approval to market a new drug, a manufacturer must submit a new drug application (NDA). 21 U.S.C. 355(b). The NDA must contain, *inter alia*, a statement of the drug's components, proposed labeling that describes the uses for which the new drug may be marketed, and scientific data and other information demonstrating that the drug is safe and effective as labeled. 21 U.S.C. 355(b)(1). A drug approved under the NDA process is often referred to as a "brand-name" drug. See generally *Caraco Pharm. Labs. Ltd.* v. *Novo Nordisk A/S*, 132 S. Ct. 1670, 1675-1676 (2012).

In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585, known as the Hatch-Waxman Amendments. Those Amendments are "designed to speed the introduction of low-cost generic drugs to market," *Caraco*, 132 S. Ct. at 1676, both by establishing an abbreviated FDA approval process and by facilitating expeditious resolution of any patent-related disputes between brand-name and generic drug manufacturers. See, *e.g.*, H.R. Rep. No. 857, 98th Cong., 2d Sess., Pt. 1, at 14-17 (1984) (House Report); *id.* Pt. 2, at 5-6. The Hatch-Waxman Amendments provide that, after a brand-name drug's NDA has been approved, and subject to certain periods of NDA exclusivity (see 21 U.S.C. 355(j)(5)(F)), any manufacturer may seek approval to market a generic version by filing an abbreviated new drug application (ANDA) with FDA. See 21 U.S.C. 355(j). The ANDA process does not require the generic manufacturer to provide independent clinical evidence of safety or efficacy. Instead, the ANDA must generally

[1] As used in this petition, "drug" refers to a drug, as defined in 21 U.S.C. 321(g)(1), regulated by FDA under 21 U.S.C. 355.

show, *inter alia*, that the generic drug has the same active ingredient(s) as, and is bioequivalent to, the brand-name drug to which the proposed generic will be compared. 21 U.S.C. 355(j)(2)(A)(ii) and (iv). See generally *Caraco*, 132 S. Ct. at 1676.

An ANDA must also explain how the generic drug can be marketed without infringing certain of the brand-name manufacturer's patents. See 21 U.S.C. 355(j)(2)(A)(vii)-(viii). Of particular relevance here, the generic manufacturer may file a "so-called paragraph IV certification," which states that a given patent asserted by the brand-name manufacturer to cover its brand-name drug "'is invalid or will not be infringed by the manufacture, use, or sale of the [generic] drug.'" *Caraco*, 132 S. Ct. at 1677 (quoting 21 U.S.C. 355(j)(2)(A)(vii)(IV)). "The patent statute treats such a filing as itself an act of infringement, which gives the brand an immediate right to sue." *Ibid.* (citing 35 U.S.C. 271(e)(2)(A)). The Hatch-Waxman Amendments prescribe intricate rules specifying when FDA may and may not approve an ANDA while litigation is pending. See 21 U.S.C. 355(j)(5)(B). In general, however, the process enables the parties to obtain fairly definitive rulings on patent infringement and invalidity before the would-be generic manufacturer engages in the commercial sale of its product.

2. a. The agreements at issue here concern AndroGel®, a prescription gel used to treat hypogonadism, a medical condition involving the underproduction of testosterone associated with advancing age, certain cancers, diabetes, and HIV/AIDS, among other conditions. Second Amended Complaint (Complaint) ¶ 33. Besins Healthcare, S.A., developed AndroGel® and licensed the marketing rights in the United States to

respondent Solvay Pharmaceuticals, Inc. in 1995. *Id.* ¶ 32. FDA approved AndroGel® in February 2000, and the product had sales of more than $400 million in 2007. *Id.* ¶¶ 33, 34.

Although patents on the synthesized testosterone used in AndroGel® expired decades ago, in August 2000 Solvay applied for a patent on certain pharmaceutical formulations containing specified amounts of testosterone and certain other ingredients. Complaint ¶¶ 31, 38-39. In January 2003, the Patent and Trademark Office (PTO) issued a patent to Solvay. *Id.* ¶ 42. In May 2003, respondents Watson Pharmaceuticals, Inc. and Paddock Laboratories, Inc. submitted separate ANDAs to FDA seeking approval for generic versions of AndroGel®. *Id.* ¶ 44. The Watson and Paddock ANDAs each included a paragraph IV certification asserting that the applicant's generic product would not infringe Solvay's formulation patent and that the patent was invalid. *Ibid.* Shortly after Paddock submitted its ANDA, respondent Par Pharmaceutical Companies, Inc. agreed to partner with Paddock by sharing in Paddock's litigation costs and, eventually, promoting Paddock's generic version of AndroGel®. *Id.* ¶ 46.

In August 2003, Solvay sued Watson and Paddock for patent infringement. Complaint ¶ 47. During the ensuing patent litigation, Watson and Paddock amassed substantial evidence that their products would not infringe Solvay's formulation patent, and that the patent was invalid. *Id.* ¶¶ 86-89. By late 2005, Watson and Paddock had filed motions for summary judgment detailing much of this evidence. *Id.* ¶ 90.

In January 2006—at the expiration of the 30-month stay of FDA approval during patent litigation provided in 21 U.S.C. 355(j)(5)(B)(iii), and while the patent litiga-

tion was still pending—FDA approved Watson's ANDA. Complaint ¶ 52. Watson and Paddock/Par expected to begin selling their products no later than 2007. *Id.* ¶ 54. They predicted that prices for generic versions of AndroGel® would fall to as little as 15% or 25% of the price of Solvay's branded AndroGel®. *Id.* ¶¶ 50-51. Solvay anticipated losing approximately 90% of its AndroGel® sales within a year of the launch of a generic version, cutting its profits by $125 million a year. *Id.* ¶ 49.

Solvay internally evaluated its own and the generic firms' expected returns from continued litigation and settlement respectively. Complaint ¶ 57 & Exh. A. Solvay concluded that Watson and Paddock/Par might be willing to defer entry into the market, without receiving any monetary payment from Solvay, as part of a settlement of the patent litigation. *Ibid.* Solvay further concluded, however, that without a reverse payment, Watson and Paddock/Par would insist on an entry date that Solvay viewed as undesirably early. *Ibid.* In Solvay's view, a payment to its would-be competitors was necessary in order to secure their agreement not to compete before 2015 (the date by which Solvay anticipated shifting its customers to a new product with no generic equivalent). *Id.* ¶¶ 57, 63 & Exh. A.

Solvay's analysis was correct. Watson and Paddock/Par each insisted on receiving a payment in exchange for assenting to Solvay's preferred entry date. Complaint ¶¶ 61, 67, 70-71, 79. Solvay ultimately agreed to pay Watson an estimated $19 to 30 million annually, ostensibly for Watson to market AndroGel® to urologists. *Id.* ¶¶ 65-67. Solvay agreed to pay $2 million annually to Paddock and $10 million annually to Par, ostensibly for Paddock to serve as a back-up supplier of

AndroGel® and for Par to market the drug to primary care physicians. *Id.* ¶¶ 74-75. Even net of these payments, Solvay expected to make more profits from AndroGel® by maintaining its monopoly until 2015 than by continuing to litigate. *Id.* ¶ 58. Indeed, the agreements made economic sense only as a mechanism for Solvay to pay its nascent generic competitors to delay competing with it, because the marketing agreements and the back-up manufacturing deal had little value to Solvay. *Id.* ¶¶ 81-85.

3. The FTC filed suit under Section 5 of the Federal Trade Commission Act, 15 U.S.C. 45, to challenge respondents' agreements. The FTC asserted that the generic competitors' agreements not to compete with Solvay, in exchange for payments from Solvay, were unfair methods of competition. Complaint ¶¶ 106, 108 The FTC further alleged that Solvay had unlawfully extended its monopoly on AndroGel®, not on the basis of its patent, but by compensating its potential competitors. *Id.* ¶¶ 110-111. The FTC sought declarations that the agreements and Solvay's course of conduct were unlawful, and a permanent injunction against the parties' conduct pursuant to 15 U.S.C. 53(b). Complaint 43 (Prayer for Relief).

4. The district court dismissed the FTC's complaint for failure to state a claim. App., *infra*, 37a-61a. Relying on *Valley Drug Co.* v. *Geneva Pharmaceuticals, Inc.*, 344 F.3d 1294 (11th Cir. 2003), cert. denied, 543 U.S. 939 (2004), and *Schering-Plough Corp.* v. *FTC*, 402 F.3d 1056 (11th Cir. 2005), cert. denied, 548 U.S. 919 (2006), the court held the complaint insufficient because it "d[id] not allege that the settlements between the Defendants exceed the scope of [Solvay's] patent." App., *infra*, 48a. The court emphasized that the settle-

ments exclude generic versions of AndroGel® from the market only until August 31, 2015, which is "five years less exclusion than [Solvay's] patent" provides. *Ibid.* The court concluded that, absent allegations that the patent litigation itself was a sham, neither "the likelihood that [Solvay] could assert its claims in court and win" nor Solvay's promise to pay tens of millions of dollars annually to its potential competitors was a relevant consideration. *Id.* at 49a-52a.[2] The court also rejected, as inconsistent with circuit precedent, the FTC's contention that reverse-payment agreements should be deemed presumptively unlawful. *Id.* at 51a-52a.

5. The court of appeals affirmed. App., *infra*, 1a-36a. In its brief to the court of appeals, the FTC recognized that the Eleventh Circuit had already suggested on three occasions—in *Valley Drug*, *Schering-Plough*, and *Andrx Pharmaceuticals, Inc.* v. *Elan Corp.*, 421 F.3d 1227, 1234-1236 (2005)—that reverse-payment agreements were subject to very limited antitrust scrutiny. The FTC argued, however, that those decisions should be understood to permit a court to consider the likely exclusionary strength of the brand-name manufacturer's patent in evaluating the anticompetitive effect of a reverse-payment agreement. The FTC contended that, under such an analysis, the allegations of its complaint—in particular, that Solvay was not likely to prevail in its

[2] The district court has since rejected, in private antitrust litigation challenging the reverse-payment agreements at issue here, the claim that Solvay's infringement suits were a sham, concluding as a matter of law that they were not objectively baseless. *In re Androgel Antitrust Litig. (No. II)*, No. 09-md-2084 Docket entry No. 830 (N.D. Ga. Sept. 28, 2012).

infringement suit—were sufficient to withstand a motion to dismiss. See FTC C.A. Br. 22-43.

The court of appeals rejected the FTC's interpretation of its earlier decisions. The court explained that, under its prior rulings, the brand-name manufacturer's patent made "traditional [antitrust] analysis * * * inappropriate." App., *infra*, 23a. Instead, the court held that, "absent sham litigation or fraud in obtaining the patent, a reverse payment settlement is immune from antitrust attack so long as its anticompetitive effects fall within the scope of the exclusionary potential of the patent." *Id.* at 28a. The court of appeals stressed that, under its approach, "a patent's *actual* exclusionary power * * * does not count." *Id.* at 20a. Rather, the court explained, what matters is the patent's "*potential* exclusionary power," *ibid.*, which the court described as "the exclusionary rights appearing on the patent's face and not the underlying merits of the infringement claim." *Id.* at 26a n.8.

The court of appeals offered several reasons for rejecting an approach that would treat "a patent [as having] *no* exclusionary potential if its holder was not likely to win the underlying infringement suit." App., *infra*, 29a. First, the court stated that such an approach "equates a likely result (failure of an infringement claim) with an actual result, but it is simply not true that an infringement claim that is 'likely' to fail actually will fail." *Id.* at 30a. Second, the court expressed concern that, given the high stakes of patent litigation, "it obviously makes sense [for the patentee] to settle the infringement action if it is 'not likely to prevail,' even though [the patentee] may have a substantial (up to 49%) chance of winning." *Id.* at 31a. Third, the court adverted to the difficulty and unreliability of making "an

after-the-fact calculation of how 'likely' a patent holder was to succeed in a settled lawsuit if it had not been settled." *Id.* at 32a.

The FTC also urged that prior Eleventh Circuit decisions had misapplied general antitrust principles and had failed to heed congressional policy regarding patent disputes affecting generic drugs. It contended that, treating the issue *res nova*, reverse-payment agreements should be recognized as presumptively anticompetitive under the antitrust laws because "[i]n the absence of another explanation for them, * * * the patent holder is obtaining a greater degree of exclusion than it could have achieved without the payment * * * or with the expected outcome of litigation." FTC C.A. Br. 52; see *id.* at 43-56. The court of appeals acknowledged the FTC's fundamental position, App., *infra*, 4a, but adhered to its precedent.

6. The court of appeals denied the FTC's petition for rehearing en banc, which urged the court to revisit its precedent and treat reverse-payment agreements as presumptively unlawful. App., *infra*, 62a-63a.

REASONS FOR GRANTING THE PETITION

This case is a superior vehicle for resolving a circuit conflict on a well-defined legal issue of exceptional importance to the national economy. The court below, along with the Second and Federal Circuits, has held that federal competition law categorically permits reverse-payment agreements unless the underlying patent litigation was a sham or the patent was obtained by fraud. See App., *infra*, 1a-36a; *In re Tamoxifen Citrate Antitrust Litig.*, 429 F.3d 370 (2d Cir. 2005), amended, 466 F.3d 187 (2d Cir. 2006), cert. denied, 551 U.S. 1144 (2007); *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323 (Fed. Cir. 2008) (*Cipro*),

cert. denied, 557 U.S. 920 (2009). The Third Circuit, by contrast, has recognized that such agreements closely resemble practices condemned as per se anticompetitive, and that court accordingly treats reverse-payment agreements as presumptively anticompetitive and unlawful. See *In re K-Dur Antitrust Litig.*, 686 F.3d 197 (2012), petitions for cert. pending, No. 12-245 (filed Aug. 24, 2012) and No. 12-265 (filed Aug. 29, 2012).

The decision below is incorrect. In the Eleventh Circuit's view, a reverse-payment agreement is lawful unless it imposes greater restrictions on generic competition than would a judicial ruling that the brand-name manufacturer's patent is valid and infringed. That approach effectively equates a brand-name manufacturer's *allegation* of infringement with a judgment in the manufacturer's favor. But defendants often prevail in patent-infringement suits; the Hatch-Waxman Amendments are designed to facilitate judicial resolution of validity and infringement issues in the generic-drug context; and the federal antitrust laws flatly prohibit potential competitors from forming naked agreements not to compete. The anticompetitive potential of reverse-payment agreements—which are estimated to cost consumers billions of dollars annually—is sufficiently clear that they should be treated as presumptively unlawful under the federal competition laws.

The division of authority among lower courts has already led to inconsistent results in separate challenges to the same reverse-payment agreements. The circuit conflict is particularly untenable given the forum-shopping opportunities created by the flexible venue provisions that apply to review of FTC enforcement decisions and to private actions under the antitrust laws. This Court's intervention is therefore warranted to

resolve the conflict. This case is a superior vehicle for addressing the question presented because it is brought by an agency charged by Congress with challenging unfair methods of competition, and it comes to the Court in the straightforward posture of a final judgment following the dismissal of the FTC's complaint for declaratory and injunctive relief.

A. The Circuits Are In Acknowledged Conflict Over The Correct Antitrust Analysis Of Reverse-Payment Agreements

1. Three courts of appeals—the Eleventh Circuit below (App., *infra*, 28a & n.10), the Second Circuit (*Tamoxifen*, 466 F.3d at 212-213), and the Federal Circuit (*Cipro*, 544 F.3d at 1336), evaluate reverse-payment agreements under the so-called scope-of-the-patent approach. In those circuits, a reverse-payment agreement that excludes competition "within the scope of the exclusionary potential of the patent," App., *infra*, 28a, is categorically lawful under federal competition law, except when the underlying patent litigation was a sham or the patent was procured by fraud. The court below confirmed the rigidity of its approach by holding that its rule would insulate the reverse-payment agreements here from antitrust scrutiny even if the FTC proved its allegations that Solvay was not likely to prevail in its patent-infringement suit against its generic competitors. The court explained that the scope-of-the-patent approach "focus[es] on the potential exclusionary effect of the patent"—that is, the scope of the patent as asserted by the patentee in its patent-infringement complaint—and "not [on] the [patent's] likely exclusionary effect." *Id.* at 30a; see *id.* at 20a, 26a n.8. In substance, the scope-of-the-patent approach treats each reverse-payment agreement as valid so long as it does

not impose greater restrictions on generic competition than a successful infringement suit would have done. The practical effect of that approach is virtually to immunize reverse-payment agreements from antitrust scrutiny.

The Third Circuit, by contrast, has explicitly rejected the scope-of-the-patent rule. See *K-Dur*, 686 F.3d at 214-218. That court held instead that reverse-payment agreements are subject to a "quick look rule of reason analysis" under which "any payment from a patent holder to a generic patent challenger who agrees to delay entry into the market [is] *prima facie* evidence of an unreasonable restraint of trade." *Id.* at 218. Under the Third Circuit's approach, that presumption of unlawfulness can "be rebutted by showing" either "that there is in fact no reverse payment because any money that changed hands was for something other than a delay," or "that the reverse payment offers a competitive benefit that could not have been achieved in the absence of a reverse payment" and thereby "increases competition." *Ibid.* Although the Sixth and D.C. Circuits have not adopted specific standards to determine the legality of reverse-payment agreements, they have likewise recognized the potential anticompetitive effects of similar arrangements. See *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896, 905-909 (6th Cir. 2003), cert. denied, 543 U.S. 939 (2004); *Andrx Pharms., Inc.* v. *Biovail Corp. Int'l*, 256 F.3d 799, 806-815 (D.C. Cir. 2001) (*Biovail*), cert. denied, 535 U.S. 931 (2002).

2. This divergence among the circuits has been outcome-determinative in prior cases challenging reverse-payment agreements. Antitrust defendants in the Second, Eleventh, and Federal Circuits have typically prevailed as a matter of law in cases involving a reverse-

payment agreement.[3] By contrast, the Third, Sixth, and D.C. Circuits have consistently ordered further proceedings.[4]

That divergence in outcomes traces directly to the circuits' different starting points. The scope-of-the-patent approach begins with the premise that reverse-payment agreements are lawful, and it considers only limited exceptions to that rule. Conversely, the "quick look" approach presumes that such agreements are anticompetitive, and considers the antitrust defendants' case in rebuttal. The contrast between the Third Circuit's decision in *K-Dur*, *supra*, and the Eleventh Circuit's decision in *Schering-Plough Corp.* v. *FTC*, 402 F.3d 1056 (2005), cert. denied, 548 U.S. 919 (2006), vividly illustrates the conflict. Although both those cases involved the same set of reverse-payment agreements, the two circuits applied contrasting legal rules to reach conflicting results.

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[3] See App., *infra*, 1a-36a; *Arkansas Carpenters Health & Welfare Fund* v. *Bayer AG*, 604 F.3d 98 (2d Cir. 2010), cert. denied, 131 S. Ct. 1606 (2011); *Cipro*, *supra*; *Tamoxifen*, *supra*; *Schering-Plough Corp.* v. *FTC*, 402 F.3d 1056 (11th Cir. 2005), cert. denied, 548 U.S. 919 (2006); see also *K-Dur*, 686 F.3d at 214 ("[N]o court applying the scope of the patent test has ever permitted a reverse payment antitrust case to go to trial."). But see *Andrx Pharms., Inc.* v. *Elan Corp.*, 421 F.3d 1227, 1234-1236 (11th Cir. 2005) (permitting an antitrust challenge to a settlement agreement between a brand-name drug manufacturer and a would-be generic competitor based on the generic competitor's anticompetitive agreement to create a bottleneck to FDA approval of other potential generic competitors' products); *Valley Drug Co.* v. *Geneva Pharms., Inc.*, 344 F.3d 1294, 1312 (11th Cir. 2003) (remanding for a determination whether "provisions of the [reverse-payment] [a]greements * * * have effects beyond the exclusionary effects of [the] patent"), cert. denied, 543 U.S. 939 (2004).

[4] See *K-Dur*, *supra*; *Cardizem*, *supra*; *Biovail*, *supra*.

3. This circuit split is particularly untenable because the sharp differences in circuit precedent transform the liberal venue rules that apply to private antitrust suits and to petitions for review of FTC decisions into open invitations to forum shopping. If the circuits' rules are left in place, private antitrust plaintiffs can be expected in the first instance to lay venue within the Third Circuit, which is feasible because drug manufacturers typically "may be found or transact[] business," 15 U.S.C. 22, in judicial districts within that circuit. By contrast, a drug manufacturer seeking judicial review of an administrative order of the FTC can be expected to lay venue in the Eleventh Circuit, as a place "where such * * * corporation * * * carries on business," 15 U.S.C. 45(c). The near certainty of facing judicial review in a circuit that applies the scope-of-the-patent approach has effectively disabled the FTC from proceeding administratively against any reverse-payment agreement. Resolution of the substantive issue of competition law that has divided the circuits therefore would not only secure the consistency of substantive law, but also ensure that outcomes are controlled by substantive legal rules and the facts of particular cases, rather than by the procedural tactics of the parties involved.[5]

[5] At least two courts have stayed antitrust challenges to reverse-payment agreements pending this Court's action on petitions for writs of certiorari presenting the question of the correct approach to scrutinizing such agreements. See *King Drug Co. of Florence, Inc.* v. *Cephalon, Inc.*, No. 06-cv-1797 Docket entry No. 479 (E.D. Pa. Aug. 29, 2012); *In re Cipro Cases I & II*, No. S198616 Docket entry (Cal. Sept. 12, 2012).

B. The Question Presented Is Of Exceptional Importance

Reverse-payment agreements tend to support monopoly pricing of brand-name drugs by delaying the onset of generic competition, and they are increasingly common in the drug industry. Accordingly, the question presented is of exceptional importance to one of the largest commercial markets in the United States.

1. The 2011 domestic market for drugs totaled approximately $245 billion. See IMS Inst. for Healthcare Informatics, *The Use of Medicines in the United States: Review of 2011*, at 27 (Apr. 2012), http://www.imshealth.com/ims/Global/Content/Insights/IMS%20Institute%20for%20Healthcare%20Informatics/IHII_Medicines_in_U.S_Report_2011.pdf. A central purpose of the Hatch-Waxman Amendments was to manage increasing costs in that market by "mak[ing] available more low cost generic drugs" through a streamlined approval process. House Report, Pt. 1, at 14. Consistent with Congress's design, as generic competition sets in, the price for a generic drug settles, on average, at approximately 15% of the price charged for the brand-name drug before generic competition. See FTC, *Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions* 8 (Jan. 2010) (*Pay-for-Delay Report*), http://www.ftc.gov/os/2010/01/100112payfordelayrpt.pdf. At the same time, the brand-name manufacturer typically loses about 90% of its market share (by unit sales) to its generic competitors. *Ibid.* As a result, substantially lower costs are paid by a wide range of participants in the market—by individuals (who may pay for drugs out-of-pocket), by health-insurance companies (which reimburse the cost of prescription drugs), by employers (which pay health-insurance premiums), and by taxpayers (who support programs such as Medicare and Medicaid).

The speed with which generic competition arrives—and thus the point in time when these savings first accrue—often depends on the patent rights held by the brand-name manufacturer. Although the patent laws grant an inventor the right to exclude others from practicing an invention for a limited time, 35 U.S.C. 154, 271(a), a brand-name manufacturer's patent will prevent competition only from generic products that would infringe the patent, and only if the patent survives any challenges to its validity. The Hatch-Waxman Amendments recognize that a brand-name manufacturer's patents will not always satisfy those criteria, since they authorize the would-be generic competitor to certify that the patent in question "is invalid or will not be infringed by the manufacture, use, or sale of the [generic] drug." 21 U.S.C. 355(j)(2)(A)(vii)(IV).

In particular, a generic competitor may be able to design its product to satisfy FDA regulations regarding generic drugs yet avoid infringing a patent that claims only particular features of the brand-name drug product (such as an inactive ingredient, or a coating that affects how the active ingredient is released into the body). See, *e.g.*, *Pharmacia & Upjohn Co.* v. *Mylan Pharms., Inc.*, 170 F.3d 1373, 1377-1379 (Fed. Cir. 1999) (finding non-infringement where the generic drug was designed to avoid a patent claiming an inactive ingredient); see generally *Caraco Pharm. Labs., Ltd.*, v. *Novo Nordisk A/S*, 132 S. Ct. 1670, 1676 (2012) (noting that drug "patents come in different varieties"); 21 C.F.R. 314.53. Some scholars have concluded that the patent portfolios of brand-name drug manufacturers have grown in recent years with the addition of patents that may be particularly susceptible to being avoided, in whole or in part, by generic competitors. See C. Scott Hemphill &

Bhaven N. Sampat, *When Do Generics Challenge Drug Patents?*, 8 J. Empirical Legal Stud. 613, 615, 619-623 (2011). And as for invalidity, a substantial fraction of fully litigated patent cases have, historically, resulted in a finding of patent invalidity. See John Allison & Mark Lemley, *Empirical Evidence on the Validity of Litigated Patents*, 26 AIPLA Q.J. 185, 194, 205 (1998) (*Validity of Litigated Patents*) (finding that 46% of all litigated patents were declared invalid based on examination of all written, final validity decisions by district courts and the Federal Circuit between 1989 and 1996).

Overall, in cases litigated to decision, would-be generic competitors have prevailed three quarters of the time in paragraph IV patent litigation against brand-name manufacturers. See FTC, *Generic Drug Entry Prior to Patent Expiration* 10, 19-20 (July 2002) (*Generic Drug Entry*) (finding that generic competitors prevailed over brand-name manufacturers with respect to 73% of the drug products that were the subject of a court decision on paragraph IV patent litigation initiated between 1992 and 2000), http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf; see also Paul Janicke & LiLan Ren, *Who Wins Patent Infringement Cases?*, 34 AIPLA Q.J. 1, 5 (2006) (finding that accused infringers had a 75% success rate in Federal Circuit decisions between 2002 and 2004 with a final ruling on drug-patent claims). Consumers have in turn reaped enormous benefits from successful challenges of that nature. See, *e.g.*, *Generic Pharmaceuticals: Marketplace Access and Consumer Issues: Hearing Before S. Commerce Comm.*, 107th Cong., 2d Sess. 56, 61 (2002) (Statement of Kathleen D. Jaeger, President & CEO, Generic Pharmaceutical Association) (estimating successful challenges to patents related to the widely used drugs Prozac, Zantac, Taxol,

and Platinol alone as saving consumers more than $9 billion).

2. If reverse-payment agreements are treated as presumptively lawful, such arrangements will be highly attractive to both brand-name manufacturers and their would-be generic competitors. Such agreements allow all parties to obtain greater profits from avoiding or delaying generic competition than they could obtain from litigating the patent case or settling it on other terms.

Standard economic theory predicts that a brand-name manufacturer's monopoly profits will greatly exceed the combined profits that the brand-name and generic manufacturers could earn if they competed against each other for sales of the same drug. All parties to the patent litigation therefore will be better off if they agree to delay competition and share the resulting profits. See 12 Herbert Hovenkamp, *Antitrust Law* ¶ 2046c, at 338 (3d ed. 2012) (*Antitrust Law*) ("In such cases a settlement agreement effectively 'preserves' the patent, thus giving the two firms the joint-maximizing, or monopoly, output."). Indeed, the continuing stream of monopoly profits is large enough to pay the generic competitors more than they could hope to earn if they entered the market at competitive prices, while leaving the brand-name manufacturer greater profits than it could earn in the face of generic competition. See C. Scott Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem*, 81 N.Y.U. L. Rev. 1553, 1581-1582 (2006) (*Pharmaceutical Patent Settlement*).

3. In short, under the decision below, drug companies will have a substantial financial incentive to shift away from conduct that benefits consumers (generic

entry following the generic manufacturer's successful defense against a patent-infringement suit) toward conduct that harms consumers (preserving monopoly pricing through reverse-payment agreements). A large fraction of the drug market is susceptible to this influence. At the end of Fiscal Year 2008, an estimated $90 billion of brand-name drug sales were under threat from one or more ANDAs containing a paragraph IV certification, potentially setting the stage for a multiplicity of reverse-payment agreements. See *Pay-for-Delay Report* 9. The number of reverse-payment agreements settling paragraph IV patent litigation has grown markedly in the years since Congress first required drug manufacturers to notify the government of settlements of paragraph IV patent litigation. See Bureau of Competition, FTC, *Agreements Filed with the Federal Trade Commission Under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Overview of Agreements Filed in Fiscal Year 2011*, at 1-2 (2011),http://www.ftc.gov/os/2011/10/1110mmaagree.pdf; Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, §§ 1111-1117, 117 Stat. 2461-2463 (21 U.S.C. 355 note) (requiring such notifications).

Reverse-payment agreements demonstrably delay the entry of generic competition, costing consumers billions of dollars each year. The average delay of generic entry following settlement of patent litigation with a reverse-payment agreement is nearly 17 months longer than the delay of generic entry agreed to following a settlement without a reverse payment. See *Pay-for-Delay Report* 2. That difference both signals the magnitude of the harm to consumers from such agreements and confirms the common-sense inference that

the payment from the brand-name manufacturer to its potential competitor purchases the competitor's agreement not to compete. Reverse-payment agreements impose costs on consumers and businesses sufficiently substantial to warrant this Court's review. See *ibid.*

C. The Court Of Appeals' Decision Is Incorrect

The scope-of-the-patent approach in general, and the decision of the court below in particular, reflect a misapplication of federal competition law. The Third Circuit's approach, which treats reverse-payment agreements as presumptively anticompetitive, reflects the appropriate balance between the competing interests implicated by such agreements. This Court should correct the Eleventh Circuit's error and remand the case to allow the FTC's suit to proceed under that approach.[6]

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[6] The view that reverse-payment settlements are presumptively anticompetitive is the longstanding position of the FTC, and it has been the position of the United States in recent briefs filed in the Second and Third Circuits, see note 8, *infra*. In three prior cases, in response to invitations from this Court, the United States has filed petition-stage briefs discussing the proper treatment of such agreements. See *Andrx Pharms., Inc.* v. *Kroger Co.*, 540 U.S. 1160 (2004) (Court invitation); *FTC* v. *Schering-Plough Corp.*, 546 U.S. 974 (2005) (same); *Joblove* v. *Barr Labs., Inc.*, 549 U.S. 1277 (2007) (same). In those briefs, the United States did not endorse the FTC's view that reverse-payment settlements are presumptively anticompetitive. The United States did contend, however, that the scope-of-the patent rule is an "insufficiently stringent standard" for determining the propriety of those settlements. U.S. Br. at 8, *Joblove*, *supra*; see *id.* at 12-15. The United States argued, albeit without advocating any specific test, that the antitrust inquiry should include an assessment of the likelihood that the brand-name manufacturer would have prevailed in the underlying infringement suit. See *id.* at 12 ("In determining whether the exclusionary effect of a settlement involving a reverse payment renders the settlement unreasonable and anti-

1. The correct approach, taken by the Third Circuit, is to treat reverse-payment agreements as presumptively anticompetitive. Such agreements most closely resemble agreements through which an incumbent firm pays a potential competitor to stay out of the market—a practice ordinarily condemned as a per se violation of Section 1 of the Sherman Act, 15 U.S.C. 1. See *Palmer* v. *BRG of Ga., Inc.*, 498 U.S. 46, 49-50 (1990). Such agreements between rivals are generally anticompetitive because they directly restrict output and raise price. See, *e.g.*, Dennis W. Carlton & Jeffrey M. Perloff, *Modern Industrial Organization* 123-125 (4th ed. 2005). This bedrock principle of competition law applies even if the would-be competitor's prospects of successful market entry were uncertain. See 12 *Antitrust Law* ¶ 2030b, at 220 ("[T]he law does not condone the purchase of protection from uncertain competition any more than it condones the elimination of actual competition."); *United States* v. *Microsoft Corp.*, 253 F.3d 34, 79 (D.C. Cir.) (en banc), cert. denied, 534 U.S. 952 (2001); *Engine Specialities, Inc.* v. *Bombardier Ltd.*, 605 F.2d 1, 9 (1st Cir. 1979), cert. denied, 446 U.S. 983 (1980).

The Third Circuit in *K-Dur* appropriately emphasized that its decision does not "limit[] the ability of the parties [in the Hatch-Waxman context] to reach settlements based on a negotiated entry date for marketing of the generic drug." 686 F.3d at 217-218. When the brand-name and generic manufacturers agree to a date

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competitive, a court at a minimum should take into account the relative likelihood of success of the parties' claims, viewed ex ante."); U.S. Br. at 11, *Schering-Plough*, *supra*. This Court denied certiorari in all three cases. See *Andrx Pharms., Inc.* v. *Kroger Co.*, 543 U.S. 939 (2004); *FTC* v. *Schering-Plough Corp.*, 548 U.S. 919 (2006); *Joblove* v. *Barr Labs., Inc.*, 551 U.S. 1144 (2007).

of entry before the date of patent expiration, the particular date chosen is likely to reflect the parties' assessment of their respective prospects of success in the infringement suit. At least in the aggregate, settlements of that character are unlikely to reduce the volume of generic competition below the level that would occur if all Hatch-Waxman infringement suits were litigated to judgment. The court in *K-Dur* explained that "the only settlements subject to antitrust scrutiny" under its decision "are those involving a reverse payment from the name brand manufacturer to the generic challenger." *Id.* at 218. Reverse-payment agreements raise particular concerns because, absent some other persuasive explanation, a reverse payment is most naturally understood as consideration for the generic manufacturer's agreement to delay market entry.

Even with respect to reverse-payment agreements, per se condemnation is not appropriate because it would foreclose consideration of legitimate efficiencies that could plausibly be claimed to flow from settlement of patent litigation. See *NCAA* v. *Board of Regents*, 468 U.S. 85, 103-104 (1984) (holding per se condemnation appropriate only if "the likelihood of anticompetitive conduct [is] so great as to render unjustified further examination of the challenged conduct"); cf. *McDermott, Inc.* v. *AmClyde*, 511 U.S. 202, 215 (1994) ("[P]ublic policy wisely encourages settlements [of legal disputes]."). Rather, a "so-called 'quick look' or 'truncated rule of reason' analysis" is appropriate because, in the first analysis, respondents "ha[ve] engaged in practices similar to those subject to per se treatment." *K-Dur*, 686 F.3d at 209 (emphasis omitted). Under that approach, the restraints embodied in reverse-payment agreements are presumed to be anticompetitive, and the

antitrust defendants—who, after all, have settled litigation against each other by agreeing not to compete—bear the burden of advancing "some countervailing procompetitive virtue." *FTC* v. *Indiana Fed'n of Dentists*, 476 U.S. 447, 459 (1986).

Under the "enquiry meet for the case" at hand, *California Dental Ass'n* v. *FTC*, 526 U.S. 756, 781 (1999), the FTC's complaint stated a claim upon which relief can be granted by alleging the existence and circumstances of a presumptively anticompetitive reverse-payment agreement. Nothing in the FTC's complaint provides a basis for inferring, at this stage of the litigation, the sort of procompetitive justifications that the Third Circuit hypothesized might overcome that presumption, see *K-Dur*, 686 F.3d at 218. Accordingly, the Eleventh Circuit erred in affirming the dismissal of the FTC's complaint.

2. The scope-of-the patent approach applied by the court below has most frequently been defended on three related rationales. None of those justifications is persuasive on its own terms, let alone sufficient to support the nearly categorical treatment of reverse-payment agreements as lawful.

First, courts endorsing the scope-of-the-patent approach have concluded that, because the core right conferred by a patent is the right to exclude competition, a reverse-payment agreement is not *unlawfully* anticompetitive so long as it permits generic entry on or before the date when the patent is scheduled to expire. See, *e.g.*, App., *infra*, 23a-24a; *Tamoxifen*, 466 F.3d at 201-202, 213-214; *Valley Drug*, 344 F.3d at 1304-1306. In effect, those courts assess (and discount) the anticompetitive potential of a reverse-payment agreement by comparing the level of generic competition it permits

to the level of competition that would have occurred if the infringement suit had been litigated to judgment and the patent holder had prevailed. But while a valid patent confers a right to exclude within its scope, 35 U.S.C. 154(a)(1), the possession of an untested patent does not result in the automatic exclusion of potential rivals. See *K-Dur*, 686 F.3d at 214-215. Instead, when a patentee seeks to enforce its patent, it bears the burden of proving that the accused product or process falls within the scope of the patent's claims as properly construed. See *Markman* v. *Westview Instruments, Inc.*, 517 U.S. 370, 374 (1996) ("Victory in an infringement suit requires a finding that the patent claim covers the alleged infringer's product or process.") (internal quotation marks omitted). And although a patentee enjoys a statutory presumption that its patent is valid, see 35 U.S.C. 282, that presumption is rebuttable, see *Microsoft Corp.* v. *i4i Ltd. P'ship*, 131 S. Ct. 2238, 2245 (2011); *Lear, Inc.* v. *Adkins*, 395 U.S. 653, 670 (1969), and patents are often held invalid despite it, see *Validity of Litigated Patents*, 26 AIPLA Q.J. at 205.

Thus, when a reverse-payment agreement provides for deferred entry of a generic competitor, "the exclusion is a consequence of the payment, not of the patent itself," and "nothing in the Patent Act justifies the exclusion payment." 12 *Antitrust Law* ¶ 2046c1, at 347. As explained above (see p. 22, *supra*), moreover, a potential competitor's agreement to forgo market entry in exchange for a payment is ordinarily unlawful per se, even if the prospect of entry was uncertain to begin with (*i.e.*, even if other forces might have produced the same result). The fact that a potential generic competitor *might* have been excluded from the market if the infringement suit had been litigated to judgment thus

does not mean that the same result can lawfully be achieved through an agreement between competitors.

A patent holder may enforce its patent through (non-sham) litigation without fear of antitrust consequences. See *Walker Process Equip., Inc.* v. *Food Mach. & Chem. Corp.*, 382 U.S. 172, 176-177 (1965); see also *Professional Real Estate Investors, Inc.* v. *Columbia Pictures*, 508 U.S. 49, 56-57 (1993). When a patentee chooses this protected avenue of enforcement, however, it faces the risk that it could lose. A patentee may instead choose the certainty of settlement over the risks of litigation. But private agreements that settle litigation, like all other private contracts, do not enjoy the antitrust immunity afforded to litigation itself. The scope-of-the-patent approach unjustifiably permits patentees to use collusive agreements to avoid the risk that patent litigation could lead to an unfavorable outcome, while simultaneously enjoying the protection from antitrust scrutiny that the patent laws afford to enforcement through litigation.

Second, courts that have adopted the scope-of-the-patent approach have emphasized the general public policy favoring voluntary settlement of litigation. See, *e.g.*, *Cipro*, 544 F.3d at 1333; *Tamoxifen*, 466 F.3d at 202-203; *Valley Drug*, 344 F.3d at 1308. But settlement of litigation is not an unalloyed good; parties to a reverse-payment agreement can claim that mantle only by pointing to how "resolution of the case will benefit the public." *Tamoxifen*, 466 F.3d at 202 (citation omitted). Although reverse-payment agreements (like all settlements) conserve judicial resources, there are significant countervailing considerations in the patent context.

Judicial resolution of challenges to patent validity is a public good, see *K-Dur*, 686 F.3d at 215 (citing *Cardinal*

Chem. Co. v. *Morton Int'l Inc.*, 508 U.S. 83, 100-101 (1993)), as is judicial construction of patent claims in connection with litigation over infringement. "It is as important to the public that competition should not be repressed by worthless patents, as that the patentee of a really valuable invention should be protected in his monopoly." *Lear*, 395 U.S. at 663-664 (quoting *Pope Mfg. Co.* v. *Gormully*, 144 U.S. 224, 234 (1892)). Those considerations have particular force in the context of the Hatch-Waxman Amendments, which specifically contemplate the possibility that brand-name manufacturers' patents may be invalid or not infringed, and which were designed to facilitate efficient resolution of patent disputes to prevent uncertainty on those issues from obstructing the entry of generic competition. See *K-Dur*, 686 F.3d at 217; *Pharmaceutical Patent Settlement*, 81 N.Y.U. L. Rev. at 1614 (explaining how reverse-payment agreements undermine the plan of the Hatch-Waxman Amendments).

In any event, the Third Circuit's approach neither precludes nor treats as presumptively anticompetitive all voluntary settlements of patent-infringement suits between brand-name and generic drug manufacturers. To the contrary, the court in *K-Dur* expressly limited its holding to settlements "involving a reverse payment from the name brand manufacturer to the generic challenger." 686 F.3d at 218; see pp. 22-23, *supra*. Payments from the plaintiff to the defendant are scarcely an essential or traditional feature of settlement practice—to the contrary, they appear to be largely unknown outside the Hatch-Waxman context. Indeed, even in the Hatch-Waxman setting, "[d]ata analyzed by the FTC suggest that [the Third Circuit's rule] will

leave the vast majority of pharmaceutical patent settlements unaffected." *K-Dur*, 686 F.3d at 218.

Third, courts favoring the scope-of-the-patent approach have expressed the view that "reverse payments are particularly to be expected in the drug-patent context because the Hatch-Waxman [Amendments] created an environment that encourages them." *Tamoxifen*, 466 F.3d at 206; see *Schering-Plough*, 402 F.3d at 1074. But the competition laws exist precisely to counteract commercial "environment[s] that encourage[]" collusive and anticompetitive behavior. Observations about the opportunities and incentives for anticompetitive behavior that the Hatch-Waxman Amendments may create no more justify reverse-payment agreements than "the age-old cry of ruinous competition and competitive evils [is] a defense to price-fixing conspiracies," *United States* v. *Socony-Vacuum Oil Co.*, 310 U.S. 150, 221 (1940). Firms agree to restrain trade because it is rational—if socially harmful—for them to do so.

In assessing the antitrust status of reverse-payment agreements, moreover, it is important to understand *why* such agreements are attractive to the settling parties. When they select the date on which generic entry will be permitted under their settlement, the brand-name and generic manufacturers are not simply deciding how a fixed pool of profits will be divided between them. Rather, they are deciding how large the total pool will be, since the brand-name's profits during a year of market exclusivity will be greater than the combined profits of the brand-name and the generic manufacturers during a year when the two compete. See p. 19, *supra*. Thus, the later the date of generic entry, the greater the total profits of the brand-name and generic manufacturers taken together. Of course, if

the additional increment of profits were captured entirely by the brand-name manufacturer, the prospect of greater total revenues would provide no incentive for the generic to agree to later entry. In substance, the reverse payment is a mechanism for inducing the generic manufacturer to accept a reduction in its own drug sales in order to enhance the overall welfare of the combination. That co-option of potential competitors is at the very core of what the federal antitrust laws prohibit.

D. This Case Is A Superior Vehicle For Addressing the Question Presented

Also pending before this Court are petitions for writs of certiorari seeking review of the Third Circuit's judgment in *K-Dur*. See *Merck & Co.* v. *Louisiana Wholesale Drug Co.*, No. 12-245 (filed Aug. 24, 2012); *Upsher-Smith Labs., Inc.* v. *Louisiana Wholesale Drug Co*, No. 12-265 (filed Aug. 29, 2012). Although those petitions would be adequate vehicles for deciding the question presented, this petition offers a vehicle that is superior in several respects.[7]

First, *K-Dur* is a private class action, while this case is brought by a federal agency charged by Congress with challenging unfair methods of competition, see 15 U.S.C. 45, and responsible for reviewing agreements settling litigation under the Hatch-Waxman Amendments, see p. 20, *supra*. The FTC has challenged several reverse-payment agreements. See Health Care Division, FTC, *Overview of FTC Antitrust Actions in Pharmaceutical Services and Products* 13-19 (June 2012) (discussing activity), http://www.ftc.gov/bc/

[7] We are providing copies of this petition to counsel for the parties in Nos. 12-245 and 12-265.

healthcare/antitrust/rxupdate.pdf. And in suits between private parties, the United States and the FTC have often participated as amici curiae in this Court and in the courts of appeals.[8] The Court would benefit from the experienced presentation that the FTC, represented by the Solicitor General, would offer as a party.

Second, the court of appeals below affirmed the grant of a motion to dismiss the FTC's complaint, while the *K-Dur* court reversed the grant of motions for summary judgment. This case thus arrives with a simpler record and on a final judgment, while the *K-Dur* petitions are interlocutory and burdened by a complex record. The disadvantages of taking up *K-Dur* are not merely theoretical. The *K-Dur* record presents unresolved collateral or subsidiary issues that could complicate this Court's deliberations or limit the scope of its holding.

In particular, the parties in *K-Dur* dispute whether the monetary consideration there was paid in exchange for delayed entry by one of the potential generic competitors, or was instead compensation for a license to an unrelated drug product. *K-Dur*, 686 F.3d at 205-206. Although the Third Circuit (appropriately in our view) did not address that issue, the Eleventh Circuit in *Schering-Plough* thought there was "overwhelming evidence" that the payment in question was for an

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[8] See U.S. Br., *K-Dur*, *supra* (No. 10-2077) (filed May 18, 2011); FTC Br., *ibid.* (filed May 18, 2011); U.S. Br., *Arkansas Carpenters Health & Welfare Fund* v. *Bayer AG*, 604 F.3d 98 (2d Cir. 2010) (No. 05-2851) (filed July 7, 2009, at court's invitation); U.S. Br., *ibid.* (filed June 4, 2010, on petition for rehearing); FTC Br., *ibid.* (filed June 10, 2010, on petition for rehearing); U.S. Br., *Joblove* v. *Barr Labs., Inc.*, 551 U.S. 1144 (2007) (No. 06-830) (filed May 23, 2007); U.S. Br., *FTC* v. *Schering-Plough Corp.*, 548 U.S. 919 (2006) (No. 05-273) (filed May 17, 2006); U.S. Br., *Andrx Pharms., Inc.* v. *Kroger Co.*, 543 U.S. 939 (2004) (No. 03-779) (filed July 9, 2004).

unrelated product. 402 F.3d at 1070-1071. Under that view of the evidence, one of the manufacturers in *K-Dur* would be exonerated even under the legal standard that the Third Circuit adopted. See 686 F.3d at 218. No such concern is present in this case because, to the extent Solvay's generic competitors are providing services of value in exchange for Solvay's payment, they are doing so in support of the monopoly that their agreements not to compete helped to preserve. See Complaint ¶¶ 60-66, 72-77. In addition, the parties in *K-Dur* have addressed at length complex matters of chemistry and patent doctrine, in a dispute over whether Schering's generic competitors' products would have infringed its patent. See Appellants Br. 54-66, *K-Dur*, *supra* (No. 10-2077); Appellees Br. 55-80, *ibid.* No such complexity is present on the FTC's pleading here.

Third, the *K-Dur* plaintiffs seek only retrospective damages relief (because the underlying patent and reverse-payment agreements expired years ago, see *K-Dur*, 686 F.3d at 218-219), while here the FTC seeks only declaratory and prospective injunctive relief (principally against reverse-payment agreements that, by their terms, will remain in force until 2015, see App., *infra*, 12a). That makes this case the more attractive vehicle because whatever uncertainties may arise in fixing the damages caused by a reverse-payment agreement—a question no court of appeals has confronted or passed upon—the FTC unquestionably will be entitled to the remedy of an injunction if it proves that the reverse-payment agreements here are unfair methods of competition. Cf. *Blue Cross & Blue Shield United* v. *Marshfield Clinic*, 152 F.3d 588, 591 (7th Cir. 1998) ("Even though * * * [the antitrust plaintiff] has failed to come up with evidence that would authorize an award

of damages * * * , this does not justify withholding an injunction—rather the contrary."), cert. denied, 525 U.S. 1071 (1999).

Fourth, although both this case (see Complaint ¶¶ 86-87) and *K-Dur* (see 686 F.3d at 205) concern reverse-payment agreements made to settle patent litigation in which the generic competitors had strong arguments that their products did not infringe the brand-name manufacturer's patent, the antitrust plaintiffs in *K-Dur* have not relied on claims of patent invalidity in the underlying patent litigation, while the FTC has done so (see Complaint ¶¶ 88-89). The antitrust plaintiffs in *K-Dur* have argued, in part, for an antitrust analysis that distinguishes between invalidity and noninfringement defenses in the underlying patent litigation, in view of the fact that an issued patent is presumed valid, see p. 25, *supra*, but is not similarly presumed to be infringed. See Appellants Br. 35-38, *K-Dur*, *supra*. We do not endorse such a distinction (and no court of appeals has given dispositive effect to such a distinction). Granting certiorari in this case, however, would ensure that the Court can consider the proper antitrust analysis for cases in which the generic manufacturer has contested patent validity as well as for cases in which it has contested infringement.

As against these advantages, this case has no significant defects as a vehicle for addressing the question presented. The Court should therefore grant this petition for a writ of certiorari. The petitions for writs of certiorari in Nos. 12-245 and 12-265 could then be held pending resolution of this case. In the alternative, if the Court believes it would benefit from briefing on the factual record in *K-Dur*, it could grant all the pend-

ing petitions and consolidate the cases, allotting additional time for oral argument as appropriate.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted.

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OCTOBER 2012

APPENDIX A

UNITED STATES COURT OF APPEALS
FOR THE ELEVENTH CIRCUIT

NO. 10-12729

D.C. DOCKET NO. 1:09-CV-00955-TWT

FEDERAL TRADE COMMISSION,
PLAINTIFF-COUNTER DEFENDANT-APPELLANT

v.

WATSON PHARMACEUTICALS, INC., SOLVAY PHARMACEUTICALS, INC., DEFENDANTS-APPELLEES

PAR PHARMACEUTICAL COMPANIES, INC.,
PADDOCK LABORATORIES, INC.,
DEFENDANTS-COUNTER CLAIMANTS-APPELLEES

Apr. 25, 2012

Appeal From The United States District Court
For The Northern District Of Georgia

Before: CARNES, KRAVITCH, and FARRIS,* Circuit Judges.

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* Honorable Jerome Farris, United States Circuit Judge for the Ninth Circuit, sitting by designation.

CARNES, Circuit Judge:

The system of developing new drugs in this country exemplifies the maxims "no risk, no reward" and "more risk, more reward." Developing new drugs is a risky, lengthy, and costly endeavor, but it also can be highly lucrative. Only one in every 5,000 medicines tested for the potential to treat illness is eventually approved for patient use, and studies estimate that developing a new drug takes 10 to 15 years and costs more than $1.3 billion.[1] No rational actor would take that kind of a risk over that period of time without the prospect of a big reward. The reward, if any, comes when the drug is approved and patented, giving the pioneer or "brand name" company that developed it a monopoly over the sale of the new drug for the life of the patent. The pioneer company can then exploit the patent monopoly by charging higher prices than it could if competitors were allowed to sell bioequivalent or "generic" versions of the drug. In that manner, the pioneer company is usually able to recoup its investment and gain a profit, sometimes a super-sized one.

Another maxim might also apply to the patent monopoly of drug pioneers: "more money, more problems." The huge profits that new drugs can bring frequently attract competitors in the form of generic drug manufacturers that challenge or try to circum-

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[1] Bret Dickey, Jonathan Orszag & Laura Tyson, *An Economic Assessment of Patent Settlements in the Pharmaceutical Industry,* 19 Annals Health L. 367, 369 & n.10 (2010).

vent the pioneer's monopoly in the market. Patent litigation often results, threatening the pioneer's monopoly and profits. Instead of rolling the dice and risking their monopoly profits in the infamously costly and notoriously unpredictable process of patent litigation, many patent-holding companies choose to settle lawsuits in order to preserve their patents and keep the monopoly profits flowing.

This case involves a type of patent litigation settlement known as a "pay for delay" or "reverse payment" agreement. In this type of settlement, a patent holder pays the allegedly infringing generic drug company to delay entering the market until a specified date, thereby protecting the patent monopoly against a judgment that the patent is invalid or would not be infringed by the generic competitor. This case began when the Federal Trade Commission filed a complaint in district court alleging that the reverse payment settlements between the holder of a drug patent and two generic manufacturers of the drug are unfair restraints on trade that violate federal antitrust laws. The FTC claims that the settlements are simply tools that the three manufacturers used to avoid a judgment that the patent was invalid or would not be infringed by the generics, thereby protecting monopoly profits that the companies divvied up by means of payments from the patent holder to the generic manufacturers. The key allegation in the FTC's complaint is that the patent holder was "not likely to prevail" in the infringement actions that it brought against the generic manufacturers and then settled. According to the

FTC, the reverse payment settlements unlawfully protected or preserved a monopoly that likely was invalid and that should not be shielded from antitrust attack.

The drug companies counter that, far from being devices designed to dodge antitrust restrictions, reverse payment settlements are simply a way that patent holders protect and maintain the lawful exclusionary rights patent law grants them. *Cf. Walker Process Equip., Inc. v. Food Mach. & Chem. Corp.*, 382 U.S. 172, 177, 86 S. Ct. 347, 350 (1965) ("A patent . . . is an exception to the general rule against monopolies . . . ." (quotation marks omitted)); *Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co.*, 324 U.S. 806, 816, 65 S. Ct. 993, 998 (1945) (same). They say that punishing a patent holder for paying a potential competitor to stay out of the market as part of a settlement agreement would penalize precisely what patents are designed to permit: the exclusion of competition. That erosion of patent rights, the drug companies argue, would weaken incentives for investing in drug development, which would reduce the number of life-saving or life-enhancing innovations that benefit consumers.

The FTC would like us to hold that reverse payment settlements, like the ones in this case, are presumptively unlawful restraints of trade. It argues that such settlements allow brand name and generic drug companies to be partners in unlawful monopolies. Monopoly profits, the FTC says, will typically exceed the sum of the individual profits that the drug companies

could make by competing against each other. So even if the generic drug company is likely to win the infringement suit, it has a strong economic incentive to drop its lawsuit in exchange for a share of the brand name company's monopoly profits.[2] Viewed this way, a reverse payment settlement ending patent litigation is a "win-win" for both companies. The brand name drug company maintains its monopoly by enforcing a patent that may be invalid, and the generic drug company makes more money under the settlement than it could have earned by competing in a market free of the patent's restraints. While the drug companies are the big winners in this scenario, consumers are the big losers; they continue paying monopoly prices for the

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[2] The FTC's brief offers this explanation of the economic incentives involved:

> According to a study conducted by the FTC of the industry as a whole . . . , a branded manufacturer typically loses about 90 percent of its unit sales over the course of generic entry. While generic entrants gain that unit volume, they do not gain all the revenues lost by the branded manufacturer because, as generic competition sets in, the price falls, on average, to about 15 percent of what the branded manufacturer was charging. Thus, a branded manufacturer can expect that, if a drug is earning $1 billion a year before generic entry, the manufacturer will only earn about $100 million a year once generic competition has matured, and all the generic companies put together will only earn about $135 million a year (90% x 15% x $1 billion), thus leaving approximately $765 million a year for the public through the benefits of competition. The parties have a strong economic incentive to avoid that result.

Appellant Br. 33-34 (footnotes omitted).

drug even though the patent creating the monopoly is likely invalid or would not be infringed by generic competition. The FTC estimates that reverse payment settlements cost consumers about $3.5 billion per year in the form of higher drug prices.

I.

The usual protocol in opinions is to put the facts and procedural history of the case before a discussion of the applicable statutes, but in this case the facts make more sense after a discussion of the statutory process for introducing new drugs to the market.

No one can legally market or sell a new drug in the United States without first gaining the approval of the Food and Drug Administration. *See* 21 U.S.C. § 355(a). The particular pathway to approval depends largely on the type of drug involved. One pathway is for pioneer drugs, which are ones that have never before received FDA approval. To initiate that approval process, an applicant files a New Drug Application. *See id.* The NDA must contain detailed information about the drug, including its chemical composition, "full reports of investigations" about its safety and efficacy, descriptions of its production and packaging processes, and proposed labeling language. *Id.* § 355(b)(1). An NDA applicant must also provide the FDA with "the patent number and the expiration date of any patent" that a generic manufacturer would infringe by making or selling the applicant's drug. *Id.*; *see also* 21 C.F.R. § 314.53(b). If the FDA approves the NDA, it publishes the drug and patent information in a book called "Approved Drug Products

with Therapeutic Equivalence and Evaluations," commonly referred to as the "Orange Book." *See* 21 U.S.C. § 355(j)(7)(A); *see also Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, No. 10-844, 2012 WL 1288732, at *5 (U.S. Apr. 17, 2012). The pioneer company may then market and sell the drug.

A more streamlined pathway to approval is reserved for generic versions of pioneer drugs that the FDA has already approved and listed in the Orange Book. To begin the generic drug approval process, an applicant files an Abbreviated New Drug Application. *See* 21 U.S.C. § 355(j). The ANDA allows an applicant "to piggyback on the safety and efficacy studies conducted for the pioneer drug" and thereby gain FDA approval by establishing that the generic drug is chemically identical to a pioneer drug already listed in the Orange Book. *Valley Drug Co. v. Geneva Pharm., Inc.*, 344 F.3d 1294, 1296 (11th Cir. 2003); see 21 U.S.C. § 355(j)(2)(A); *Caraco Pharm. Labs.*, 2012 WL 1288732, at *5 ("Rather than providing independent evidence of safety and efficacy, the typical ANDA shows that the generic drug has the same active ingredients as, and is biologically equivalent to, the brand-name drug.").

An ANDA that piggybacks on a drug listed in the Orange Book must make one of four "paragraph certifications" with respect to any patents affiliated with the listed drug. It must certify that: (I) no patent information for the brand name drug has been filed with the FDA; (II) the patent has expired; (III) the patent will expire on a specifically identified date;

or (IV) the "patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted." 21 U.S.C. § 355(j)(2)(A)(vii).

It matters which certification is made. If the applicant certifies under paragraphs I or II, the FDA reviews the ANDA and may approve it. *See id.* § 355(j)(5)(B)(i). If the applicant certifies under paragraph III, however, the FDA will not approve the application until the patent for the listed drug has expired. *See id.* § 355(j)(5)(B)(ii).

If the applicant certifies under paragraph IV, things get complicated. The ANDA applicant must send notice to the patent holder of its position that the patent listed in the Orange Book is invalid or will not be infringed by the applicant's generic drug. *See id.* § 355(j)(2)(B). The patent holder then has 45 days to file an infringement lawsuit against the ANDA applicant. *Id.* § 355(j)(5)(B)(iii); *cf.* 35 U.S.C. § 271(e)(2)(A) (making it a constructive act of infringement to file a paragraph IV certification); *Caraco Pharm. Labs.*, 2012 WL 1288732, at *6 ("Filing a paragraph IV certification means provoking litigation."). If the patent holder does not sue within that time frame, the FDA proceeds with the ANDA approval process. 21 U.S.C. § 355(j)(5)(B)(iii). If a suit is timely filed, however, the FDA stays the ANDA approval process for 30 months to allow the parties or a court to resolve the infringement dispute. *Id.* If, during that 30-month stay, a court decides that the patent is invalid or not infringed, the FDA's

approval of the ANDA, if any, is effective on the date that the court enters its judgment. *Id.* § 355(j)(5)(B)(iii)(I)(aa).

Federal law encourages generic drug manufacturers to file paragraph IV certifications. The first ANDA applicant making a paragraph IV certification that receives FDA approval is granted a 180-day "exclusivity period" during which the FDA postpones its approval process for other ANDA applications for generic versions of the same Orange Book listed drug. *Id.* § 355(j)(5)(B)(iv). That exclusivity period begins to run "after the date of the first commercial marketing of the [generic] drug." *Id.* § 355(j)(5)(B)(iv)(I); *see also* 21 C.F.R. § 314.107(c)(1). As a result, the first generic manufacturer to make a paragraph IV certification could receive a 180-day head start to compete with the pioneer drug, which is "a significant incentive for generic manufacturers to challenge weak or narrow drug patents." *Valley Drug*, 344 F.3d at 1298.

II.

With that statutory approval process in mind, we turn to the facts of this case. Because this appeal arises from the district court's Rule 12(b)(6) dismissal of the FTC's complaint for failure to state a claim, we accept as true all of the factual allegations in that complaint. *Thaeter v. Palm Beach Cnty. Sheriff's Office*, 449 F.3d 1342, 1352 (11th Cir. 2006).

A.

Besins Healthcare, S.A., developed the prescription drug AndroGel, a topical gel that treats the symptoms

of low testosterone in men. Chemicals in the gel gradually penetrate the skin and enter the bloodstream, providing a sustained release of synthetic testosterone. In August 1995, Besins granted Solvay Pharmaceuticals, Inc., a license to sell AndroGel in the United States and agreed to provide a commercial supply of the drug if the FDA approved it for sale. Solvay filed an NDA for AndroGel in April 1999, which the FDA approved in February 2000. Solvay then began marketing and selling the drug with great success. Between 2000 and 2007, revenue from the sale of AndroGel in the United States exceeded $1.8 billion, far more than it cost to develop the drug.

Shortly after the FDA approved AndroGel, Solvay filed a patent application with the Patent and Trademark Office. A prior patent covering the synthetic testosterone used in AndroGel had expired decades earlier, but Solvay's application sought patent protection for a particular gel formulation of it. The Patent and Trademark Office granted Solvay's application on January 7, 2003, and jointly awarded Solvay and Besins Patent Number 6,503,894 ("the '894 patent"), which expires in August 2020. Within 30 days of being granted the patent, Solvay asked the FDA to include the '894 patent information in the Orange Book alongside the AndroGel listing. *Cf.* 21 U.S.C. § 355(c)(2) (requiring successful NDA applicants to inform the FDA within 30 days of receiving a new patent for a listed drug).

Other drug manufacturers soon developed generic versions of AndroGel. Two of those companies, Wat-

son Pharmaceuticals, Inc. and Paddock Laboratories, Inc., filed ANDAs with the FDA in May 2003. Watson was the first to file its ANDA, which made it eligible for the 180-day exclusivity period under 21 U.S.C. § 355(j)(5)(B)(iv). Both companies made paragraph IV certifications, claiming that their generic AndroGel products did not infringe on the '894 patent or that the patent was invalid. Within the relevant 45-day window, *id.* § 355(j)(5)(B)(iii), Solvay filed in federal district court a patent infringement lawsuit against Watson and Paddock.[3] That filing triggered the 30-month stay of the FDA's approval process for Watson's and Paddock's generic versions of AndroGel. *See id.* The stay was set to expire in January 2006.

The parties litigated the infringement action for the next few years. To spread the risks and costs of litigation, Paddock partnered with Par Pharmaceutical Companies, Inc., which agreed to share the costs of litigation with Paddock in exchange for part of the potential profits from Paddock's generic AndroGel product if that product gained FDA approval. After conducting discovery, Watson and Par/Paddock, the defendants in the patent infringement lawsuit, filed motions for summary judgment on the validity of the '894 patent. Those motions were fully briefed and ready for decision when the statutorily imposed 30-month stay on the FDA's approval process for Watson's ANDA ended in January 2006. The FDA approved Watson's generic AndroGel product that same month.

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[3] Besins filed a separate lawsuit against Watson and Paddock, but the outcome of that case is not relevant to this appeal.

As a result, Solvay was facing the possibility of losing its monopoly in the AndroGel market in early 2006. If the district court granted Watson's motion for summary judgment either on the ground that the '894 patent was invalid or that it would not be infringed by the generic drugs, Watson could immediately flood the market with generic versions of AndroGel without fear of being found to have violated Solvay's patent (unless the district court's decision was overturned on appeal). *See* 21 U.S.C. § 355(j)(5)(B)(iii)(I)(aa). Watson forecast that its generic version of AndroGel would sell for about 25% of the price of branded AndroGel, which could decrease the sales of branded AndroGel by 90% and cut Solvay's profits by $125 million per year. A lot was riding on the outcome of the patent litigation.

Before the district court ruled on Watson's and Par/Paddock's motions for summary judgment, and before any generic AndroGel was brought to market, the parties resolved their patent dispute with several settlement agreements. Under the terms of the settlements, Watson, Par, and Paddock agreed not to market generic versions of AndroGel until August 31, 2015, unless another manufacturer launched one before then. In addition, Watson agreed to promote branded AndroGel to urologists, and Par agreed to promote it to primary care doctors. Par also agreed to serve as a backup manufacturer for branded AndroGel but assigned that part of the agreement to Paddock.

For its part, Solvay agreed to pay Par/Paddock $10 million per year for six years and an additional $2 million per year for the backup manufacturing assistance.

Solvay also agreed to share some of its AndroGel profits with Watson through September 2015, projecting that those payments would be between $19 million and $30 million per year. After finalizing the agreements, all of the parties—Solvay, Watson, Par, and Paddock—filed in district court a stipulation of dismissal terminating the patent infringement lawsuit.

B.

After the settlement agreements ending the patent litigation were reported to the FTC as required by 21 U.S.C. § 355 note (2003) (Federal Trade Commission Review), the FTC filed an antitrust lawsuit against Solvay, Watson, Par, and Paddock. That lawsuit was then transferred to the Northern District of Georgia, which is where the parties had litigated the patent infringement claims. The FTC then filed an amended complaint against all four drug companies.[4]

The FTC's amended complaint claimed that the settlement agreements, in which Solvay promised to pay Watson and Par/Paddock in exchange for those companies not selling generic AndroGel until 2015, are unlawful agreements not to compete in violation of Section 5(a) of the Federal Trade Commission Act. 15 U.S.C. § 45(a)(1) (banning "[u]nfair methods of competition in or affecting commerce, and unfair or deceptive acts or practices in or affecting commerce").

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[4] Two other sets of plaintiffs—direct and indirect purchasers of AndroGel—joined the FTC in the district court and made a variety of state law claims. None of those plaintiffs joined the FTC in this appeal, and their claims are not before us.

It alleged that the settlement agreements were attempts to "defer" generic competition with branded AndroGel by postponing the entry date of the generic drugs, thereby maintaining Solvay's monopoly and allowing the parties to share monopoly profits "at the expense of the consumer savings that would result from price competition."

The lynchpin of the FTC's complaint is its allegation that Solvay probably would have lost the underlying patent infringement action—that is, Watson and Par/Paddock had a strong case that the '894 patent did not bar their entry into the generic AndroGel market. More specifically, the complaint alleges that "Solvay was *not likely to prevail*" in the patent litigation because "Watson and Par/Paddock developed persuasive arguments and amassed substantial evidence that their generic products did not infringe the ['894] patent and that the patent was invalid and/or unenforceable" (emphasis added). According to the FTC, because the '894 patent "was unlikely to prevent generic entry," Solvay's reverse payments to the generic drug producers continued and extended a monopoly that the patent laws did not authorize. By doing that, it argues, the reverse payment agreements unlawfully restrain competition.

The four defendants moved to dismiss the FTC's complaint under Rule 12(b)(6), arguing that this Court's precedent immunizes reverse payment settlements from antitrust attack unless a settlement "imposes an exclusion greater than that contained in the patent at issue." Because the FTC had not alleged

the settlements did that, the defendants argued, the complaint failed to state a claim on which relief could be granted. The district court agreed with the defendants, concluded that the FTC did "not allege that the settlements exceed the scope of the '894 patent," and granted the defendants' motion to dismiss. The FTC then filed this appeal, contending that it had sufficiently pleaded an antitrust claim by alleging that the parties had entered into the settlement agreements even though Solvay was "not likely to prevail" in the infringement actions against the generic producers.

III.

"We review *de novo* the district court's grant of a motion to dismiss under 12(b)(6) for failure to state a claim . . . ." *Ironworkers Local Union 68 v. AstraZeneca Pharm., LP*, 634 F.3d 1352, 1359 (11th Cir. 2011) (quotation marks omitted). In doing so, we accept the allegations in the complaint as true and construe them "in the light most favorable to the plaintiff." *Clark v. Riley*, 595 F.3d 1258, 1264 (11th Cir. 2010) (quotation marks omitted). "A complaint must state a plausible claim for relief, and '[a] claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.'" *Sinaltrainal v. Coca-Cola Co.*, 578 F.3d 1252, 1261 (11th Cir. 2009) (quoting *Ashcroft v. Iqbal*, 556 U.S. 662, —, 129 S. Ct. 1937, 1949 (2009)) (alteration in *Sinaltrainal*). "Stated differently, the factual allegations in a complaint must 'possess enough heft' to set forth 'a plausible entitlement to relief'

. . . ." *Fin. Sec. Assurance, Inc. v. Stephens, Inc.*, 500 F.3d 1276, 1282 (11th Cir. 2007) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 557, 559, 127 S. Ct. 1955, 1966-67 (2007)).

A.

The difficulty at the heart of this case is in deciding how to resolve the tension between the pro-exclusivity tenets of patent law and the pro-competition tenets of antitrust law. That difficulty is made less difficult, however, by the law's pro-precedent tenets. Our earlier decisions carry us much of the way to a resolution in this case.

This Court first confronted an antitrust challenge to a reverse payment settlement in *Valley Drug Co. v. Geneva Pharmaceuticals, Inc.*, 344 F.3d 1294 (11th Cir. 2003). The facts of that case parallel the facts of this one: Two generic manufacturers alleged that the patent for a drug listed in the Orange Book was invalid, the patent holder filed infringement claims against the generic manufacturers, and the parties settled before a court decided the merits of the claims. *Id.* at 1298-300. One generic manufacturer received millions of dollars in exchange for acknowledging the validity of the pioneer's patent and agreeing not to enter the market until another generic manufacturer did or until the patent expired, whichever came first. *Id.* at 1300. The other generic manufacturer, also in exchange for millions of dollars, agreed not to enter the market until one of those two events occurred or until a court held that the patent was invalid, whichever came first. *Id.*

Several private parties filed an antitrust lawsuit against the three manufacturers alleging that the settlement agreements were per se illegal contracts in restraint of trade in violation of Section 1 of the Sherman Act.[5] *See id.* at 1295-96; *see also* 15 U.S.C. § 1 ("Every contract . . . in restraint of trade or commerce among the several States, or with foreign nations, is declared to be illegal."). The district court agreed with the plaintiffs and granted their motion for partial summary judgment. *See Valley Drug*, 344 F.3d at 1295, 1301. After the court granted the drug companies' request for permission to take an interlocutory appeal, *see* 28 U.S.C. § 1292(b), we reversed. *Valley Drug*, 344 F.3d at 1295, 1313.

Our *Valley Drug* decision began by acknowledging that antitrust laws typically prohibit agreements where one company pays a potential competitor not to enter the market, but we reasoned that reverse payment settlements of patent litigation presented atypical cases because "one of the parties own[s] a patent." *Id.* at 1304. The patent made all the difference because it meant that the patent holder had a "lawful right to exclude others" from the market. *Id.*; *see also* 35 U.S.C. § 154(a)(1) ("Every patent shall

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[5] The analysis of whether a reverse payment agreement gives rise to antitrust liability is the same for claims brought under the Sherman Antitrust Act, which was involved in *Valley Drug*, and under the Federal Trade Commission Act, which is involved in this case. *See Schering-Plough Corp. v. FTC*, 402 F.3d 1056 (11th Cir. 2005) (applying the same antitrust analysis to Sherman Act and FTC Act claims).

. . . grant to the patentee . . . the right to exclude others from making, using, offering for sale, or selling the invention throughout the United States . . . ."); *Dawson Chem. Co. v. Rohm & Haas Co.*, 448 U.S. 176, 215, 100 S. Ct. 2601, 2623 (1980) ("[T]he essence of a patent grant is the right to exclude others from profiting by the patented invention."). The district court, we explained, "failed to consider" those exclusionary rights in its antitrust analysis when it held that the agreements were per se illegal. *Valley Drug*, 344 F.3d at 1306. Because one party to the reverse payment agreements held a patent, the agreements did not necessarily decrease the level of competition in the market. *Id.* at 1309. It followed that the district court had erred in using a per se test for determining the legality of the agreements. *See id.* ("If [the patent holder] had a lawful right to exclude competitors, it is not obvious that competition was limited more than that lawful degree by paying potential competitors for their exit."); *see also Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1065-66 (11th Cir. 2005) ("By their nature, patents create an environment of exclusion, and consequently, cripple competition. The anticompetitive effect is already present."); *cf. Asahi Glass Co. v. Pentech Pharm., Inc.*, 289 F. Supp. 2d 986, 994 (N.D. Ill. 2003) (Posner, J., sitting by designation) ("In a reverse-payment case, the settlement leaves the competitive situation unchanged from before the [generic manufacturer] tried to enter the market.").

After deciding to reverse the district court's partial grant of summary judgment in favor of the plaintiffs in *Valley Drug*, we went on to discuss several other matters "that promise[d] to be relevant on remand." *Valley Drug*, 344 F.3d at 1306. We first addressed the plaintiffs' argument that the analysis on remand should disregard the patent altogether because after the parties had entered into their settlement agreements a federal district court had invalidated the patent at issue. According to the plaintiffs in *Valley Drug*, that post-settlement invalidation meant the patent holder "never had any patent rights," which meant the settlements necessarily excluded more competition from the market than the patent holder was lawfully entitled to exclude (namely, none). *Id.* at 1306-07. Which meant, according to the plaintiffs, there were no patent rights to shield the settlements from antitrust attack, which meant the settlements were "subject to *per se* condemnation." *Id.* at 1306.

We rejected that argument, explaining that a court must judge the antitrust implications of a reverse payment settlement as of the time that the settlement was executed. *Id.* "[T]he mere subsequent invalidity of the patent does not render the patent irrelevant to the appropriate antitrust analysis." *Id.* at 1306-07. For that reason, even though the patent at issue in *Valley Drug* was in fact invalid, its terms had to be given full effect. *See id.* at 1305 (explaining that, at the time of settlement, the patent holder had "the right to exclude others from making, using, or selling

anhydrous terazosin hydrochloride until October of 2014, when [the patent] is due to expire").

Our decision to give full effect to the patent's terms in *Valley Drug* means that even a court judgment about a patent's *actual* exclusionary power, unless that judgment comes before settlement, does not count. What does count is the patent's "*potential* exclusionary power" as it appeared at the time of settlement. *Id.* at 1311 (emphasis added). The patent in *Valley Drug* had the potential to exclude competition at the time of settlement because, at that time, "no court had declared [the] patent invalid." *Id.* at 1306; *cf.* 35 U.S.C. § 282 ("A patent shall be presumed valid."). Because the patent had that potential at the time of settlement, we treated the holder as though it had an exclusionary right at that time. *See Valley Drug*, 344 F.3d at 1306.

Our discussion in *Valley Drug* about the "potential exclusionary power" of patents did not mean, however, that all reverse payment settlements of patent litigation are immune from antitrust attack. A patent holder and any of its challengers cannot enter into an agreement that excludes more competition than the patent has the potential to exclude. If a reverse payment settlement reduces generic competition to a greater extent than the patent grant potentially does, the holder of the patent has used the settlement to buy exclusionary rights that are not contained in the patent grant, and those additional rights are vulnerable to antitrust attack. *See id.* at 1312 ("[T]he patent exception to antitrust liability . . . is limited by the

terms of the patent and the statutory rights granted the patentee."); *cf. United States v. Masonite Corp.*, 316 U.S. 265, 277, 62 S. Ct. 1070, 1077 (1942) ("The owner of a patent cannot extend his statutory grant by contract or agreement. A patent affords no immunity for a monopoly not fairly or plainly within the grant."). Put another way, a patent gives its holder a "bundle of rights," *CMS Indus., Inc. v. L.P.S. Int'l, Ltd.*, 643 F.2d 289, 294 (5th Cir. 1981),[6] but any new exclusionary rights the holder buys to add to that bundle do not fall within the scope of the patent grant and for that reason do not fall within the scope of the patent's antitrust immunity.

In keeping with those principles, we said in *Valley Drug* that parties to a reverse payment settlement are immune from antitrust liability if the anticompetitive effects of their settlement fall "within the scope of the exclusionary potential of the patent." 344 F.3d at 1311. If any provisions of the settlement create restraints on competition beyond that scope, however, those excesses "may then be subject to traditional antitrust analysis to assess their probable anticompetitive effects in order to determine whether [they] violate § 1 of the Sherman Act."[7] *Id.* at 1312. What

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[6] In *Bonner v. City of Prichard*, 661 F.2d 1206, 1209 (11th Cir. 1981) (en banc), we adopted as binding precedent all decisions of the former Fifth Circuit handed down before October 1, 1981. The *CMS* decision was issued on April 22, 1981.

[7] The traditional antitrust analysis consists of two tests: the "per se" test and the "rule of reason" test. *See Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1064 (11th Cir. 2005). Under the per

was left for the district court to do on remand was to consider "the scope of the exclusionary potential of the patent [and] the extent to which the[] provisions of the Agreements exceed that scope." *Id.*

B.

Our next decision involving an antitrust challenge to a reverse payment settlement of patent litigation came in *Schering-Plough Corp. v. FTC*, 402 F.3d 1056 (11th Cir. 2005). Schering, which held the patent for a drug called K-Dur 20, settled lawsuits it had filed against two generic drug manufacturers, Upsher-Smith Laboratories, Inc. and ESI Lederle, Inc. *Id.* at 1058-60. Schering's settlement with Upsher had two main parts: (1) Upsher agreed not to enter the K-Dur 20 market until five years before Schering's patent expired, and (2) Schering paid Upsher more than $60 million to license some of Upsher's other drug products. *Id.* at 1059-60. Schering's settlement with the other generic manufacturer, ESI, also had two main parts: (1) ESI agreed not to enter the K-Dur 20 market until almost three years before Schering's patent expired; and (2) Schering paid ESI $5 million in legal fees and $15 million to license some of ESI's oth-

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se test, the challenged restraint categorically violates the antitrust laws because it is "so obviously anticompetitive, or so unlikely to be pro-competitive, that [it] can be deemed to violate [the antitrust laws] without much more than an examination of the agreement itself and the relationships of the parties to the agreement." *Valley Drug*, 344 F.3d at 1303. Under the rule of reason test, the legality of the challenged restraint hinges upon whether it promotes or suppresses competition. *See Schering-Plough*, 402 F.3d at 1064.

er drug products, plus another $10 million if ESI's generic drug received FDA approval. *Id.* at 1060-61 & n.8.

The FTC determined in an administrative proceeding that the settlement agreements violated the FTC Act and the Sherman Act. *Id.* at 1058. Although it did not expressly say that reverse payment agreements are per se illegal, the FTC's order nonetheless announced a rule prohibiting all reverse payment settlements in which the generic company receives anything of value in exchange for deferring its research, development, or entry to market. *Id.* at 1062. The defendant drug companies petitioned this Court to review the order, we did so, and we vacated it. *Id.* at 1076.

We began our review of the FTC's order by reiterating what we had said in *Valley Drug*: neither the rule of reason nor the per se test is an appropriate way to analyze the antitrust implications of a reverse payment settlement of patent litigation. *Id.* at 1065. That traditional analysis is inappropriate because one of the signatories to the settlement holds a patent, and a patent conveys the right to "cripple competition." *Id.* at 1066. The proper analysis, we explained, "requires an examination of: (1) the scope of the exclusionary potential of the patent; (2) the extent to which the agreements exceed that scope; and (3) the resulting anticompetitive effects." *Id.* (citing *Valley Drug*, 344 F.3d at 1312). The essence of this three-prong analysis is an evaluation of whether the settlement agreements contain provisions that restrict competi-

tion beyond the scope of the exclusionary potential of the patent. Cf. United States v. Singer Mfg. Co., 374 U.S. 174, 196-97, 83 S. Ct. 1773, 1785 (1963) ("[I]t is . . . well settled that the possession of a valid patent or patents does not give the patentee any exemption from the provisions of the Sherman Act beyond the limits of the patent monopoly."); In re Tamoxifen Citrate Antitrust Litig., 466 F.3d 187, 213 (2d Cir. 2006) ("[T]here is no injury to the market cognizable under existing antitrust law, as long as competition is restrained only within the scope of the patent.").

After describing that analysis in *Schering-Plough*, we defined the potential exclusionary scope of the K-Dur 20 patent, giving full force to the exclusionary rights it potentially conveyed. Under the patent, Schering could exclude both of the generic companies from the K-Dur 20 market. *Schering-Plough*, 402 F.3d at 1066. The patent also gave Schering the "right to grant licenses, if it so chooses." *Id.* at 1067. Those exclusionary and licensing rights existed until the patent expired on September 5, 2006, or until the generic manufacturers "proved either that the . . . patent was invalid or that their products . . . did not infringe Schering's patent." *Id.* at 1066-67.

With the potential exclusionary scope of the patent defined in *Schering-Plough*, we then evaluated whether the settlements extended Schering's exclusionary rights beyond that scope. That was simple to do. The settlement with Upsher permitted that company to market its generic K-Dur 20 product more than five years before the expiration of Schering's patent, and

the settlement with ESI allowed it to market its generic product almost three years before the patent expired. *Id.* at 1068-71. The settlements excluded competition for a shorter period of time (five years less and three years less) than the face of the patent allowed. For that reason, we held that the reverse payment settlements did not impermissibly extend Schering's patent monopoly.

Our *Schering-Plough* decision also rejected the FTC's argument that Schering had agreed to pay too much money to settle the case and that the generic companies had agreed to stay off the market for too long. *See id.* at 1073. If that were true, the FTC asserted, it meant that Schering must have paid the generic companies not only to settle the infringement lawsuit but also to obtain increased exclusionary rights in the K-Dur 20 market. *See id.* In other words, the FTC claimed that Schering used the reverse payment settlements not just to protect its legitimate bundle of patent rights, but also to mask a "naked payment" to horizontal competitors in order to expand the scope of its monopoly. *Id.* at 1070, 1072.

We rejected the FTC's contention in part because it did not take into account the underlying patent litigation, which was "certain[ ] to be a bitter and prolonged process." *Id.* at 1072; *see also id.* at 1075 ("[T]he size of the payment . . . should not dictate the availability of a settlement remedy."). We emphasized that "[t]he general policy of the law is to favor the settlement of litigation," *id.* at 1072, and reiterated that patent litigation is costly and complex, *see id.* at

1073-74. All three drug companies in *Schering-Plough* were facing high risks and costs if they continued to litigate the infringement action. *See id.* at 1075 (discussing the costs of attorney fees, expert fees, and discovery expenses, and noting the "caustic environment of patent litigation" that may increase the "period of uncertainty" for patenting and marketing new drugs). The agreements among the parties reflected that high-stakes reality, so their settlements "fell well within the protections of the [K-Dur 20] patent, and were therefore not illegal." *Id.* at 1076.[8]

C.

Our third and most recent decision involving the antitrust implications of reverse payment settlements is *Andrx Pharmaceuticals, Inc. v. Elan Corp.*, 421 F.3d 1227 (11th Cir. 2005). The district court in that case granted a patent holder's motion for judgment on

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[8] The FTC's brief in this case places great weight on our statement in *Schering-Plough* that a proper antitrust analysis of reverse payment agreements needs to "evaluate the *strength of the patent.*" 402 F.3d at 1076 (emphasis added). The FTC argues that evaluating the "strength of the patent" means evaluating "the strength of the patent holder's claims of validity and infringement, as objectively viewed at the time of settlement." We disagree. When read in the context of the facts and the reasoning of *Schering-Plough*, the phrase "strength of the patent" refers to the potential exclusionary scope of the patent—that is, the exclusionary rights appearing on the patent's face and not the underlying merits of the infringement claim. Nowhere in the *Schering-Plough* opinion did we actually evaluate the merits of the infringement claim when defining how much competition the patent could potentially exclude from the market.

the pleadings, but we reversed the judgment because the plaintiff had sufficiently pleaded an antitrust claim. It had done so in two ways. First, the complaint in *Andrx* alleged that the generic manufacturer had agreed "to refrain from *ever* marketing a generic" version of the patented drug. *Id.* at 1235 (emphasis added). If true, that meant the settlement agreement blocked generic competition *after* the patent expired, and in that way excluded competition beyond "the scope of exclusion intended by the . . . patent." *Id.*

The other way the complaint in *Andrx* stated a plausible antitrust claim was by alleging that the settlement agreement allowed the generic company to retain its 180-day exclusivity period of 21 U.S.C. § 355(j)(5)(B)(iv) even though that company had "no intention of marketing its generic drug." *Andrx*, 421 F.3d at 1231. If true, that meant the 180-day period, which begins to run "after the date of first commercial marketing," 21 U.S.C. § 355(j)(5)(B)(iv)(I), would never be "trigger[ed]," *Andrx*, 421 F.3d at 1231. As a result, the exclusivity period would have acted like a cork in a bottle, blocking *other* generic competition from pouring into the market.[9] By doing that, the settlement created anti-

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[9] In 2003 Congress amended the statutory provisions governing the 180-day exclusivity period to keep corks out of bottles by providing that the first paragraph IV ANDA filer forfeits its right of exclusivity if it fails to market a generic drug within certain time periods. *See* 21 U.S.C. § 355(j)(5)(D). A grandfather provision of that amendment specified that the changes would not apply to

competitive effects beyond the scope of the patent. *Id.* at 1235; *see also id.* at 1231 ("[T]he settlement agreement had the effect of preventing *any* generic competition in the . . . market and constituted a conspiracy to restrain trade." (emphasis added)). For those reasons, we held that the complaint in *Andrx* stated a plausible antitrust claim. *Id.* at 1236.

IV.

Our *Valley Drug*, *Schering-Plough*, and *Andrx* decisions establish the rule that, absent sham litigation or fraud in obtaining the patent, a reverse payment settlement is immune from antitrust attack so long as its anticompetitive effects fall within the scope of the exclusionary potential of the patent.[10] The issue in

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paragraph IV ANDAs filed before the date of enactment. Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-713, § 1102(b)(1), 117 Stat. 2066. *See generally Caraco Pharm. Labs., Ltd. v. Forest Labs., Inc.*, 527 F.3d 1278, 1284 n.2 (Fed. Cir. 2008) (discussing the amendment).

[10] There was no allegation in our first two decisions that the patents were fraudulently obtained or that the litigation giving rise to the settlement was a sham. *See Valley Drug*, 344 F.3d at 1307-09 & nn.19, 21; *Schering-Plough*, 402 F.3d at 1068. The plaintiff in our third decision did contend that there had been sham litigation, but we rejected that contention as unfounded. *See Andrx*, 421 F.3d at 1233-34.

We stated in *Valley Drug* that: "[A]ppellees have neither alleged nor asserted that the patent was procured by fraud, that appellants knew the patent was invalid, that there was no objective basis to believe that the patent was valid, or any such similar allegations. We therefore are not called upon to decide what the antitrust consequences of such circumstances might be." 344 F.3d at

this case is whether, under that test, the FTC's complaint states an antitrust claim by alleging that Solvay was "not likely to prevail" in the underlying infringement action against Watson, Par, and Paddock.

The FTC argues that its "not likely to prevail" allegation sufficiently states an antitrust claim because a patent has *no* exclusionary potential if its holder was not likely to win the underlying infringement suit. And if the patent has no exclusionary potential, the FTC continues, then any reverse payment settlement that excludes any competition from the market necessarily exceeds the potential exclusionary scope of the patent and must be seen as the patent holder's illegal "'buying off' of a serious threat to competition." Consistent with that reasoning, the FTC urges us to adopt "a rule that an exclusion payment is unlawful if, viewing the situation objectively as of the time of the settlement, it is more likely than not that the patent would not have blocked generic entry earlier than the agreed-upon entry date." Under that rule, the FTC's allegation that Solvay was "not likely to prevail" in the patent litigation would state a plausible antitrust claim.

1307 n.19. We make the same observations about this case and limit our decision in the same way. Although the FTC's complaint alleges that Solvay was "not likely to prevail" in its infringement actions against Watson and Par/Paddock, it does not contend that any of the three companies knew that the patent was invalid or not infringed or that there was no objective basis to believe the patent was valid and infringed. Accordingly, we do not rule out the possibility that sufficient allegations of any of those facts would state a valid antitrust claim.

We decline the FTC's invitation and reject its argument. The FTC's position equates a likely result (failure of an infringement claim) with an actual result, but it is simply not true that an infringement claim that is "likely" to fail actually will fail. "Likely" means more likely than not, and that includes a 51% chance of a result one way against a 49% chance of a result the other way. *Cf. United States v. Frazier*, 387 F.3d 1244, 1280-81 (11th Cir. 2004) ("[I]t is more likely than not—that is, there is more than a fifty-percent chance—that [the event] would have occurred."). Giving the word its plain meaning, as many as 49 out of 100 times that an infringement claim is "likely" to fail it actually will succeed and keep the competitor out of the market. Our decisions focus on the potential exclusionary effect of the patent, not the likely exclusionary effect. *See*, *e.g.*, *Valley Drug*, 344 F.3d at 1305; *Schering-Plough*, 402 F.3d at 1066; *Andrx*, 421 F.3d at 1235.

In few cases that are settled is the probability needle pointing straight up. One side or the other almost always has a better chance of prevailing, but a chance is only a chance, not a certainty. Rational parties settle to cap the cost of litigation and to avoid the chance of losing. Those motives exist not only for the side that is likely to lose but also for the side that is likely, but only likely, to win. A party likely to win might not want to play the odds for the same reason that one likely to survive a game of Russian roulette might not want to take a turn. With four chambers of a seven-chamber revolver unloaded, a party pulling the trigger

is likely (57% to 43%) to survive, but the undertaking is still one that can lead to undertaking.

Patent litigation can also be a high stakes, spin-the-chambers, all or nothing undertaking. *See Valley Drug*, 344 F.3d at 1308; *Schering-Plough*, 402 F.3d at 1075-76. For the company with a patented drug, it obviously makes sense to settle the infringement action if it is "not likely to prevail," even though that company may have a substantial (up to 49%) chance of winning. On the other side of the settlement equation is the generic drug company that is only "likely to prevail" in the action; with a substantial (up to 49%) chance of losing, that company also has a legitimate motive for settling. When both sides of a dispute have a substantial chance of winning and losing, especially when their chances may be 49% to 51%, it is reasonable for them to settle. That companies with conflicting claims settle drug patent litigation in these circumstances is not a violation of the antitrust laws.

The FTC argues in its brief that "Solvay's patent was vulnerable," that it "knew that its patent was in trouble," and that "its claims of infringement were very much in doubt." Those arguments not only go beyond the allegations of the complaint, which is all that we can consider in this appeal from a Rule 12(b)(6) dismissal, but they also do little more than reflect the reality of patent litigation and the risks it presents to the patent holder. That reality and those risks are precisely why a party is likely to choose to settle a patent dispute even if it might well prevail. When hundreds of millions of dollars of lost profits are at stake,

"even a patentee confident in the validity of its patent might pay a potential infringer a substantial sum in settlement." *Valley Drug*, 344 F.3d at 1310; *cf. In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 261 F. Supp. 2d 188, 208 (E.D.N.Y. 2003) ("No matter how valid a patent is—no matter how often it has been upheld in other litigation or successfully reexamined—it is still a gamble to place a technology case in the hands of a lay judge or jury. Even the confident patent owner knows that the chances of prevailing in patent litigation rarely exceed seventy percent. Thus, there are risks involved even in that rare case with great prospects." (alterations and quotation marks omitted)).

There are other reasons to reject the FTC's approach. It would require an after-the-fact calculation of how "likely" a patent holder was to succeed in a settled lawsuit if it had not been settled. Predicting the future is precarious at best; retroactively predicting from a past perspective a future that never occurred is even more perilous. And it is too perilous an enterprise to serve as a basis for antitrust liability and treble damages. *See Valley Drug*, 344 F.3d at 1308 ("Patent litigation is too complex and the results too uncertain for parties to accurately forecast whether enforcing the exclusionary right through settlement will expose them to treble damages if the patent immunity were destroyed by the mere invalidity of the patent."); *cf. Whitmore v. Arkansas*, 495 U.S. 149, 159-60, 110 S. Ct. 1717, 1725 (1990) ("It is just not possible for a litigant to prove in advance that the judicial system will lead to any particular result in his case.").

The FTC's retrospective predict-the-likely-outcome-that-never-came approach would also impose heavy burdens on the parties and courts. It would require, in the FTC's words, "viewing the situation objectively as of the time of the settlement." In this case, assaying the infringement claim "as of the time of settlement" would have required mining through mountains of evidence—when the lawsuit settled, more than 40 depositions had been taken and one side alone had produced more than 350,000 pages of documents. The settlement made that unnecessary, but the FTC's approach would put that burden back on the parties and the court, undo much of the benefit of settling patent litigation, and discourage settlements. Our legal system can ill afford that. *See Schering-Plough*, 402 F.3d at 1075 ("There is no question that settlements provide a number of private and social benefits as opposed to the inveterate and costly effects of litigation."); *see also Valley Drug*, 344 F.3d at 1309 (noting "the important role played by settlement in the enforcement of patent rights"); *cf. In re Tamoxifen Citrate*, 466 F.3d at 202 ("Where a case is complex and expensive, and resolution of the case will benefit the public, the public has a strong interest in settlement." (quotation marks omitted)); *Flex-Foot, Inc. v. CRP, Inc.*, 238 F.3d 1362, 1368 (Fed. Cir. 2001) (noting "the important policy of enforcing settlement agreements").

There is also the fact that retrospective prediction, at least in this type of case, is unlikely to be reliable. The FTC itself has recognized as much in the past. In its order in the *Schering-Plough* case, the full

Commission explained that:

> An after-the-fact inquiry by the Commission into the merits of the underlying litigation is not only unlikely to be particularly helpful, but also likely to be unreliable. As a general matter, tribunals decide patent issues in the context of a true adversary proceeding, and their opinions are informed by the arguments of opposing counsel. Once a case settles, however, the interests of the formerly contending parties are aligned. A generic competitor that has agreed to delay its entry no longer has an incentive to attack vigorously the validity of the patent in issue or a claim of infringement.

In re Schering-Plough Corp., No. 9297, 2003 WL 22989651, at *22 (F.T.C. Dec. 8, 2003), *vacated by Schering-Plough*, 402 F.3d 1056. For those reasons, the FTC concluded that "it would not be necessary, practical, or particularly useful . . . to embark on an inquiry into the merits of the underlying patent dispute when resolving antitrust issues in patent settlements." *Id.* at *23. The FTC was right then for the same reasons it is wrong now.

There is another reason to reject the FTC's new approach. Congress has given the United States Court of Appeals for the Federal Circuit exclusive appellate jurisdiction over patent cases. *See* 28 U.S.C. § 1295(a)(1); *see also Cardinal Chem. Co. v. Morton Int'l, Inc.*, 508 U.S. 83, 89, 113 S. Ct. 1967, 1971 (1993); *Christianson v. Colt Indus. Operating Corp.*, 486 U.S. 800, 807, 108 S. Ct. 2166, 2173 (1988). This Court and the other non-specialized circuit courts have no exper-

tise or experience in the area. We are ill-equipped to make a judgment about the merits of a patent infringement claim, which is what we would have to do in order to decide how likely the claim was to prevail if it had been pursued to the end. The FTC's approach is in tension with Congress' decision to have appeals involving patent issues decided by the Federal Circuit.

As we discussed at the beginning of this opinion, the FTC warns that the alternative to its approach of looking back to decide what the likely outcome of settled infringement claims would have been is unacceptable. The alternative, according to the FTC, will allow patent holders and potential competitors "to forgo litigation over patent infringement and split up an ongoing stream of monopoly profits, even in situations in which it is evident that it is more likely than not that the patent would be found invalid or not infringed." The FTC believes that, because drug prices will be higher in the absence of competition, the profits generated by a patent holder's monopoly will typically exceed the aggregated profits that all companies individually would earn through competition. As a result, a potential competitor can make more money by dropping its patent challenge in return for a share of the holder's monopoly profits than it can by continuing to attack an invalid patent and bringing a less expensive version of the drug to market before the patent expires.

The FTC's ominous forecast discounts the reality that there usually are many potential challengers to a patent, at least to drug patents. If the patent actually

is vulnerable, then presumably other generic companies, which are not bound by the first challenger's reverse payment settlement, will attempt to enter the market and make their own challenges to the patent. Blood in the water can lead to a feeding frenzy. Although a patent holder may be able to escape the jaws of competition by sharing monopoly profits with the first one or two generic challengers, those profits will be eaten away as more and more generic companies enter the waters by filing their own paragraph IV certifications attacking the patent. *Cf.* Herbert Hovenkamp, *Sensible Antitrust Rules for Pharmaceutical Competition*, 39 U.S.F. L. Rev. 11, 25 (2004) ("In a world in which there are numerous firms willing and able to enter the market, an exit payment to one particular infringement defendant need not have significant anticompetitive effects. If there is good reason for believing the patent [is] invalid others will try the same thing.").

In closing, it is worth emphasizing that what the FTC proposes is that we attempt to decide how some other court in some other case at some other time was likely to have resolved some other claim if it had been pursued to judgment. If we did that we would be deciding a patent case within an antitrust case about the settlement of the patent case, a turducken task. Even if we found that prospect palatable, we would be bound to follow the simpler recipe for deciding these cases that is laid out in our existing precedent. As we interpret that precedent, the FTC loses this appeal.

AFFIRMED.

APPENDIX B

UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION

MDL Docket No. 2084
ALL CASES

1:09-MD-2084-TWT

IN RE: ANDROGEL ANTITRUST LITIGATION (NO. II)

Filed: Feb. 22, 2010

ORDER

This is a Multidistrict Litigation proceeding involving antitrust actions that are consolidated for pretrial proceedings. It is before the Court on the Defendants' Motions to Dismiss the Indirect Purchaser Plaintiffs' Complaints [MDL Doc. 8, 9]; the Defendants' Motions to Dismiss the Second Amended Complaint [MDL Doc. 22, 23, 24, 26 and 28]; and the Defendants' Motions to Dismiss the Private Plaintiffs' Second Amended Complaints [MDL Doc. 25, 27 and 29]. For the reasons set forth below, the Defendants' motions are GRANTED in part and DENIED in part.

I. Background

AndroGel is a prescription gel used to treat male hypogonadism. Male hypogonadism is a medical condition where the body does not produce normal levels of testosterone. Symptoms include depression, fatigue, loss of muscle mass, and decreased libido. Physicians prescribe AndroGel to increase levels of testosterone in their patients. Patients apply the gel directly onto their skin. The testosterone penetrates the skin and gradually enters the bloodstream, providing for a sustained release of testosterone. AndroGel is not the only available method of testosterone replacement therapy. Physicians also prescribe testosterone injections or skin patches. But these other methods have not been as effective or as popular as AndroGel. AndroGel has quickly become the most popular form of testosterone replacement therapy. From 2000 to 2007, sales of AndroGel in the United States were over $1.8 billion.

Besins Healthcare, S.A. developed the pharmaceutical formulation for AndroGel. In August 1995, Besins granted Solvay Pharmaceuticals, Inc., a license to sell AndroGel in the United States. Besins also agreed to produce AndroGel and supply it to Solvay once Solvay received approval to sell the drug. To sell any new drug in the United States, a person must file a New Drug Application (NDA) with the Food and Drug Administration (FDA). 21 U.S.C. § 355(a). The NDA must contain a complete report about the drug, including safety and efficacy studies, the composition of the drug, description of how the drug is produced,

and proposed labeling. 21 U.S.C. § 355(b). In April 1999, Solvay filed a NDA for AndroGel with the FDA. In February 2000, the FDA approved Solvay's NDA, and soon after Solvay began selling AndroGel.

Like most pharmaceutical companies that sell new drugs, Solvay sought legal protection against generic versions of AndroGel. Solvay first sought protection under federal drug laws. In April 1999, when Solvay filed its NDA for AndroGel, Solvay also asked the FDA for new drug product exclusivity. This exclusivity prevents the FDA from approving any other application to sell the same drug until the exclusivity period ends. The FDA will grant five years of exclusivity for any NDA that contains active ingredients never previously approved by the FDA. *See* 21 U.S.C. § 355(c)(3)(F)(ii). The FDA will grant three years of exclusivity for any NDA that contains an active ingredient that has previously been approved by the FDA but still includes new clinical investigations essential to approval of the NDA. *See* 21 U.S.C. § 355(c)(3)(F)(iii). AndroGel fell into the latter category, and so in February 2000, the FDA granted Solvay three years of exclusivity.

Solvay also sought protection under federal patent laws. In August 2000, employees from Solvay and Besins filed a patent application with the Patent and Trademark Office (PTO). The application claimed the gel formulation used in AndroGel. It did not claim testosterone itself or testosterone replacement therapy. In January 2003, the PTO granted the application and issued U.S. Patent No. 6,503,894 ('894 pa-

tent).[1] In June 2003, Solvay requested that the PTO correct certain mistakes that it made in the patent. In December 2003, the PTO granted the request and issued a certificate of correction. *See* 35 U.S.C. § 255. Solvay and Besins jointly own the '894 patent. It expires in August 2020. Within thirty days after the PTO issued the '894 patent, Solvay submitted the '894 patent to the FDA for listing in the Orange Book. The Orange Book is a publication by the FDA containing information about each approved drug. 21 U.S.C. § 355(j)(7)(A). For any NDA, a person must also submit any patent that the person believes would be infringed by a generic drug. 21 U.S.C. § 355(b)(1). This requirement applies even if the PTO issues the patent after the person filed a NDA. 21 U.S.C. § 355(c)(2). The FDA accepted Solvay's submission and listed the '894 patent in the Orange Book.

Other pharmaceutical companies soon developed a generic version of AndroGel. To sell a generic drug, a person may file an Abbreviated New Drug Application (ANDA) with the FDA. 21 U.S.C. § 355(j). The Hatch-Waxman Act created the ANDA procedure. Pub. L. No. 98-417, 98 Stat. 1585 (1984). One goal of the Hatch-Waxman Act was to streamline the process for approving generic drugs. *See id.* As a result, an ANDA does not need to contain a complete report about the drug. It can show that the generic drug

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[1] The Court takes judicial notice of the '894 patent. *See Day v. Taylor*, 400 F.3d 1272, 1276 (11th Cir. 2005) (taking notice of a document that was "(1) central to the plaintiff's claim and (2) undisputed").

is bioequivalent to a previously approved drug and then rely on that drug's NDA. *See* 21 U.S.C. § 355(j)(2)(A)(iv). But if there is a patent that claims the previously approved drug, the ANDA must contain an additional certification. The ANDA must certify that (1) the patent has not been listed in the Orange Book, or (2) the patent has expired, or (3) the patent will expire on a certain date, or (4) the patent is invalid or will not be infringed by the generic drug. *See* 21 U.S.C. § 355(j)(2)(A)(vii). When the ANDA certifies that the patent is invalid or will not be infringed, it is known as a Paragraph IV certification. For any ANDA with a Paragraph IV certification, the applicant must also notify the patent holder of the ANDA. 21 U.S.C. § 355(j)(2)(B).

Once Solvay's new drug product exclusivity expired in February 2003, the FDA was authorized to approve generic versions of AndroGel. In May 2003, two companies each submitted ANDAs with Paragraph IV certifications for generic AndroGel. Watson Pharmaceuticals, Inc. submitted the first ANDA, and Paddock Laboratories, Inc. submitted the second ANDA. Both companies also sent notice of their ANDAs to Solvay and Besins. In July 2003, Paddock reached an agreement with Par Pharmaceuticals, Inc. Par agreed to share any litigation costs with Paddock and to sell Paddock's generic AndroGel. In return, Paddock agreed to share profits with Par.

Solvay responded to the ANDAs by asserting its rights under the '894 patent. In August 2003, Solvay's subsidiary, Unimed Pharmaceuticals, Inc., filed patent

infringement actions against Watson and Paddock in this Court. *See Unimed Pharm., Inc. v. Watson Pharm., Inc.*, No. 1:03-CV-2501-TWT (N.D. Ga. Aug. 21, 2003); *Unimed Pharm., Inc. v. Paddock Labs., Inc.*, No. 1:03-CV-2503-TWT (N.D. Ga. Aug. 21, 2003). Solvay alleged infringement based on the filing of the ANDAs. *See* 35 U.S.C. § 271(e)(2)(A). This is not an ordinary infringement action. It is an "artificial" one based solely on the filing of an ANDA. *See Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1569 (Fed. Cir. 1997). If a patent holder files such infringement action within forty-five days of receiving notice of an ANDA with a Paragraph IV certification, the FDA will stay approval of that ANDA for thirty months. 21 U.S.C. § 355(j)(5)(B)(iii). But if before the thirty month period ends a district court decides that the patent is invalid or not infringed, the FDA may approve the ANDA effective on the date of such judgment. *Id.*; *see In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 192 n.4 (2d Cir. 2006). Because Solvay filed infringement actions against Watson and Paddock within forty-five days of receiving notice, the FDA stayed approval of their ANDAs for thirty months.

For the next few years, Solvay, Watson, and Paddock litigated the infringement actions. The two infringement actions followed a similar schedule. From late 2003 to the middle of 2005, the parties engaged in discovery, scheduling, and other initial litigation matters. By August 2005, the parties had filed motions for claim construction. By December 2005, Watson

and Paddock had filed motions for summary judgment on the validity of the '894 patent. All of the motions were fully briefed and ready for decision. While the motions were pending, Watson and Paddock moved towards entering the market with generic AndroGel. In January 2006, the thirty month stay ended, and the FDA approved Watson's ANDA. The FDA, however, continued to stay approval of Paddock's ANDA. The first person to file an ANDA with a Paragraph IV certification receives generic exclusivity. This exclusivity prevents the FDA from approving any subsequent person's ANDA for the same drug until 180 days after the earlier of (1) the date the first person begins commercial marketing of its generic drug or (2) the date a district court enters judgment that the patent is invalid or not infringed, whichever date is earlier. 21 U.S.C. § 355(j)(5)(B)(iv); *see In re Tamoxifen*, 466 F.3d at 193 n.5. Because Watson was the first to file an ANDA for generic AndroGel, it received generic exclusivity over Paddock. In February 2006, Watson prepared a report predicting that it would sell generic AndroGel by January 2007 and that the price would be 75 percent less than brand name AndroGel. In the same month, Par prepared a report predicting that Watson would sell generic AndroGel as early as March 2006 and that Par and Paddock would follow in September 2006.

Before the Court decided any motions in the infringement actions, and before anyone sold generic AndroGel, Solvay, Watson, and Paddock settled. The parties began settlement negotiations in early 2006,

and on September 13, 2006, Solvay entered into settlements with Watson and Paddock. Under the settlement between Solvay and Watson, Solvay agreed to voluntarily dismiss the infringement action, and Watson agreed not to market generic AndroGel until the earlier of August 31, 2015 or the date another company marketed generic AndroGel. Under the settlement between Solvay and Paddock, Solvay agreed to a consent judgment dismissing the infringement action, and Paddock agreed not to market generic AndroGel until the earliest of August 31, 2015, but only if Watson did not assert its 180-day generic exclusivity period, or the date another company launched generic AndroGel, or February 28, 2016.

On the same day as the settlements, Solvay also entered into business promotion agreements with Watson, Par, and Paddock. Under the agreement between Solvay and Watson, Solvay agreed to share profits of AndroGel with Watson, and Watson agreed to promote AndroGel to urologists. Solvay estimated that its annual payments to Watson would be between $15 and $30 million. Under the agreement between Solvay and Par, Solvay agreed to share profits of AndroGel with Par, and Par agreed to promote AndroGel to primary care physicians. Solvay estimated that its annual payments to Par would be about $6 million. Under the agreement between Solvay and Paddock, Solvay agreed to share profits of AndroGel with Paddock, and Paddock agreed to serve as backup supplier of AndroGel. Solvay estimated that

its annual payments to Paddock would be about $2 million.

The settlements prompted an investigation by the Federal Trade Commission (FTC) for violations of antitrust laws. In 2008, the FTC completed its investigation. In 2009, the FTC and a number of private parties filed these antitrust actions against Solvay, Watson, Par, and Paddock. All of the actions were filed in other federal district courts and then transferred to this Court either by change of venue or by order of the United States Judicial Panel on Multidistrict Litigation. There are three groups of Plaintiffs: the FTC, the Direct Purchasers, and the Indirect Purchasers. All of the Plaintiffs allege that the Defendants violated various federal antitrust laws. *See* Sherman Antitrust Act §§ 1-2, 15 U.S.C. §§ 1-2; Federal Trade Commission Act § 5(a), 15 U.S.C. § 45(a). The Indirect Purchasers also allege that the Defendants violated the common law and antitrust laws of about forty states. All of the Plaintiffs assert antitrust claims based on the settlements. They say that Solvay paid Watson, Par, and Paddock millions of dollars for agreeing not to sell generic AndroGel before August 31, 2015. The Direct Purchasers, but not the other Plaintiffs, also assert antitrust claims based on the Defendants' conduct before the settlements. They say that Solvay filed sham infringement actions against Watson and Paddock; Solvay improperly listed the '894 patent in the Orange Book; all of the Defendants participated in a scheme to monopolize the market for generic AndroGel; and Watson, Par, and Pad-

dock agreed not to compete with each other in the market for generic AndroGel. The Defendants now move to dismiss all of the Plaintiffs' claims for failure to state a claim upon which relief can be granted.

II. Motion to Dismiss Standard

A complaint should be dismissed under Rule 12(b)(6) only where it appears that the facts alleged fail to state a "plausible" claim for relief. *Ashcroft v. Iqbal*, 129 S. Ct. 1937, 1949 (2009); Fed. R. Civ. P. 12(b)(6). A complaint may survive a motion to dismiss for failure to state a claim, however, even if it is "improbable" that a plaintiff would be able to prove those facts; even if the possibility of recovery is extremely "remote and unlikely." *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 556 (2007) (citations and quotations omitted). In ruling on a motion to dismiss, the court must accept factual allegations as true and construe them in the light most favorable to the plaintiff. *See Quality Foods de Centro America, S.A. v. Latin American Agribusiness Dev. Corp., S.A.*, 711 F.2d 989, 994-95 (11th Cir. 1983). Generally, notice pleading is all that is required for a valid complaint. *See Lombard's, Inc. v. Prince Mfg., Inc.*, 753 F.2d 974, 975 (11th Cir. 1985), *cert. denied*, 474 U.S. 1082 (1986). Under notice pleading, the plaintiff need only give the defendant fair notice of the plaintiff's claim and the grounds upon which it rests. *See Erickson v. Pardus*, 551 U.S. 89, 93 (2007) (*citing Twombly*, 550 U.S. at 555).

III. Discussion

A. Patent Infringement Settlements

All of the Plaintiffs assert antitrust claims based on the settlements. They say that the business promotion agreements were really just a way for Solvay to pay Watson, Par, and Paddock for agreeing not to sell generic AndroGel before August 31, 2015. They say that this was an antitrust violation because, without these "reverse payments," Solvay would have either lost its infringement actions or settled on a date for sale of generic AndroGel earlier than August 31, 2015. In either situation, Watson, Par, and Paddock would have sold generic AndroGel before August 31, 2015, and market competition would have substantially reduced the price of AndroGel.

To state an antitrust claim based on the settlements, the Plaintiffs must allege facts that show the settlements were unreasonable restraints of trade. *See Valley Drug Co. v. Geneva Pharms., Inc.*, 344 F.3d 1294, 1303 (11th Cir. 2003). Ordinarily, courts decide whether a restraint is unreasonable by applying either a rule of reason or per se analysis. *Schering-Plough Corp. v. Federal Trade Comm'n*, 402 F.3d 1056, 1064 (11th Cir. 2005). Generally, when one company agrees to pay a competitor not to compete, the agreement is a per se antitrust violation. *Valley Drug*, 344 F.3d at 1304. But "neither the rule of reason nor the per se analysis is appropriate" when a patent settlement is involved. *Schering-Plough*, 402 F.3d at 1065. This is because the general approaches look at "whether the challenged conduct had an anticompetitive effect on

the market. By their nature, patents create an environment of exclusion, and consequently, cripple competition. The anticompetitive effect is already present." *Id.* at 1065-66. Instead of applying a rule of reason or per se analysis, the Eleventh Circuit has established a separate approach for antitrust actions involving a patent settlement. "[T]he proper analysis of antitrust liability requires an examination of: (1) the scope of the exclusionary potential of the patent; (2) the extent to which the agreements exceed that scope; and (3) the resulting anticompetitive effects." *Id.* at 1066.

The Plaintiffs do not allege that the settlements between the Defendants exceed the scope of the '894 patent. First, the settlements only exclude generic AndroGel from the market. The '894 patent claims the gel formulation used in AndroGel and that gel formulation is "necessary to the manufacture and sale of" generic AndroGel. *See Andrx Pharms., Inc. v. Elan Corp., PLC*, 421 F.3d 1227, 1235 (11th Cir. 2005). The settlements do not exclude any product other than generic AndroGel. *Cf. In re Tamoxifen*, 466 F.3d at 213 (listing cases where the settlement did exclude "unrelated or non-infringed products"). Second, the settlements only exclude generic AndroGel from the market until August 31, 2015. This provides for five years less exclusion than the '894 patent, which does not expire until August 2020. Third, the settlements only prevent Watson, Par, and Paddock from selling generic AndroGel. The Plaintiffs do not allege, for example, any agreement to use Watson's 180-day ge-

neric exclusivity period to prevent other companies from selling generic AndroGel. *See id.* at 200. Indeed, Watson says that it relinquished its exclusivity as part of the settlement. (Mem. of Law in Supp. of Defs.' Mot. to Dismiss the FTC's Second Am. Compl., at 18.)[2]

In response, the FTC and the Private Plaintiffs say that the scope of a patent includes more than just the patent's claims and duration. They say that it also includes the likelihood that a patent holder could assert its claims in court and win. But this argument is inconsistent with the Eleventh Circuit's reasoning in *Valley Drug*. In *Valley Drug*, a brand name manufacturer settled its infringement actions against two generic drug manufacturers. One of the generic manufacturers agreed to a final settlement, while the other only agreed to an interim settlement. Under the interim settlement, the generic manufacturer agreed not to sell its product until it got a final judgment in its favor. The brand name and generic manufacturer continued to litigate the infringement action, and eventually the district court held that the brand name manufacturer's patent was invalid. Later, some purchasers of the brand name drug filed antitrust actions against the brand name manufacturer and the two generic manufacturers. They said that per se analysis should apply because the brand name manu-

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[2] Because the Plaintiffs do not allege that the settlements exceed the '894 patent, the Court does not need to go to the third step and examine "the resulting anticompetitive effect." *See Valley Drug*, 344 F.3d at 1312.

facturer's patent was invalid, and so it never really had any patent rights. The Eleventh Circuit disagreed. It held that "the mere subsequent invalidity of the patent does not render the patent irrelevant to the appropriate antitrust analysis." *Valley Drug*, 344 F.3d at 1306-07. It explained that:

> Patent litigation is too complex and the results too uncertain for parties to accurately forecast whether enforcing the exclusionary right through settlement will expose them to treble damages if the patent immunity were destroyed by the mere invalidity of the patent. This uncertainty, coupled with a treble damages penalty, would tend to discourage settlement of any validity challenges except those that the patentee is certain to win at trial and the infringer certain to lose. By restricting settlement options, which would effectively increase the cost of patent enforcement, the proposed rule would impair the incentives for disclosure and innovation.

Id. at 1308; *see also Schering-Plough*, 402 F.3d at 1075; *In re Tamoxifen*, 466 F.3d at 204; *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323, 1337 (Fed. Cir. 2008). Those same concerns apply equally here. Considering whether Solvay would have won its infringement actions creates the same uncertainty that the court in *Valley Drug* believed would severely limit settlements.[3]

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[3] This does not, however, preclude the Plaintiffs from alleging that Solvay filed sham infringement actions against Watson and Paddock. Those allegations will be addressed later in this Order.

The Plaintiffs also say that it should be presumptively unlawful for companies to settle a patent dispute with reverse payments. But this argument is also inconsistent with the Eleventh Circuit's reasoning in *Valley Drug*. In *Valley Drug*, both settlements included substantial payments from the brand name manufacturer to the generic manufacturers. The plaintiffs said that per se analysis should apply because a patent does not include the right to pay for exclusion. The Eleventh Circuit disagreed. It held that per se analysis does not apply to reverse payments. *Valley Drug*, 344 F.3d at 1309. The court explained that:

> The failure to produce the competing . . . drug, rather than the payment of money, is the exclusionary effect, and litigation is a much more costly mechanism to achieve exclusion, both to the parties and to the public, than is settlement. To hold that an ostensibly reasonable settlement of patent litigation gives rise to per se antitrust liability if it involves any payment by the patentee would obviously chill such settlements, thereby increasing the cost of patent enforcement and decreasing the value of patent protection generally. We are not persuaded that such a per se rule would be an appropriate accommodation of the competing policies of the patent and antitrust laws.

Id. (citation omitted). In *Schering-Plough*, the Eleventh Circuit reiterated its holding in *Valley Drug* and explained that reverse payments should not matter to an analysis of antitrust liability:

> We have said before, and we say it again, that the size of the payment, or the mere presence of a payment, should not dictate the availability of a settlement remedy. Due to the 'asymmetrics of risk and large profits at stake, even a patentee confident in the validity of its patent might pay a potential infringer a substantial sum in settlement.' . . . What we must focus on is the extent to which the exclusionary effects of the agreement fall within the scope of the patent's protection.

Schering-Plough, 402 F.3d at 1075-76 (*quoting Valley Drug*, 344 F.3d at 1310); *see also In re Tamoxifen*, 466 F.3d at 206; *In re Ciprofloxacin*, 544 F.3d at 1329. Because the Plaintiffs do not allege that the settlements exceed the scope of the '894 patent, it does not matter if the Defendants settled their patent disputes with reverse payments. The Plaintiffs' reverse payment settlement claims must be dismissed.

B. Sham Litigation

Although it is not entirely clear, it appears that the Eleventh Circuit's Hatch-Waxman cases allow antitrust Plaintiffs to assert a claim of "sham litigation" in the context of reverse payment patent infringement settlements. *See Schering-Plough*, 402 F.3d at 1072. The Direct Purchasers allege that Solvay engaged in sham litigation in filing and prosecuting the patent infringement actions against the generic Defendants. They allege that the generic Defendants conspired to restrain trade by entering into settlements of the sham litigation in exchange for a portion of Solvay's monopoly profits.

Solvay, Par and Paddock assert immunity under the Noerr-Pennington doctrine. The Noerr-Pennington doctrine provides that there is no antitrust liability for petitioning the government for an anticompetitive outcome. *Andrx*, 421 F.3d at 1235. It prevents federal antitrust laws from interfering with the First Amendment right to "petition the Government for a redress of grievances." U.S. Const. amend. I; *see also Professional Real Estate Investors v. Columbia Pictures Indus., Inc.*, 508 U.S. 49, 56 (1993). Courts have defined petitioning activity to include lobbying for government legislation and seeking redress through administrative or judicial proceedings. *See Eastern R.R. Presidents Conf. v. Noerr Motor Freight, Inc.*, 365 U.S. 127, 136 (1961); *United Mine Workers v. Pennington*, 381 U.S. 657, 670 (1965); *California Motor Transport Co. v. Trucking Unlimited*, 404 U.S. 508, 510 (1972).

It is well established that there is a sham litigation exception to Noerr-Pennington immunity. *See Noerr*, 365 U.S. at 144 (noting that there is no protection for petitioning activity that is "a mere sham to cover what is actually nothing more than an attempt to interfere directly with the business relationships of a competitor"). In this context, the Eleventh Circuit has said that sham litigation has two elements: "(1) the lawsuit is objectively baseless in the sense that no reasonable litigant could realistically expect success on the merits; and (2) the party bringing the allegedly baseless suit did so with a subjective motivation to interfere directly with the business relationships of a

competitor." *Andrx*, 421 F.3d at 1234 (internal quotation marks and emphasis omitted).

The Direct Purchasers say that Solvay's infringement actions were objectively baseless because generic AndroGel clearly did not infringe the original '894 patent.[4] The '894 patent claims a testosterone gel formulation. The formulation is made up of various ingredients; and the relevant ingredient for purposes of the patent litigation is sodium hydroxide. As originally issued, four of the five independent claims in the '894 patent describe a pharmaceutical composition containing 1% to 5% of sodium hydroxide. *See* '894 patent cls. 1, 9, 10, 18. The fifth independent claim does not describe any amount of sodium hydroxide. *See* '894 patent cl. 31. The Direct Purchasers say that neither brand name AndroGel nor generic AndroGel contains anywhere near 1% sodium hydroxide. Indeed, they say that any skilled chemist would recognize that a gel containing even 1% sodium hydroxide is harmful and would burn a patient's skin. The Direct Purchasers say that AndroGel actually contains a diluted sodium hydroxide solution that is 50 to 250 times less concentrated than the compositions described in the '894 patent. In other words, Solvay made a mistake in drafting the '894 patent. Because of this mis-

[4] The original '894 patent matters because "[antitrust] analysis should focus on what the litigant knew or reasonably could have known at the time the suits were filed." *In re Wellbutrin SR Antitrust Litig.*, No. Civ.A. 04-5525, 2006 WL 616292, *11 (E.D. Pa. Mar. 9, 2006). At the time Solvay filed its infringement actions, the PTO had not yet issued a certificate of correction.

take, the Direct Purchasers say that generic AndroGel clearly did not infringe the original '894 patent.

Solvay says that the error could be corrected by the Court. A district court can correct a patent error "if (1) the correction is not subject to reasonable debate based on consideration of the claim language and the specification and (2) the prosecution history does not suggest a different interpretation of the claims." *Novo Indus., L.P. v. Micro Molds Corp.*, 350 F.3d 1348, 1354 (Fed. Cir. 2003). These "determinations must be made from the point of view of one skilled in the art." *Ultimax Cement Mfg. Corp. v. CTS Cement Mfg. Corp.*, 587 F.3d 1339, 1353 (Fed. Cir. 2009). Solvay says that the Court would have corrected its drafting mistake. First, Solvay says that there is no dispute that the claims should have referred to diluted sodium hydroxide. Agreeing with the Direct Purchasers, Solvay says that any skilled chemist would recognize that a gel containing even 1% sodium hydroxide is harmful and would burn a patient's skin. It also says that the specification includes a table listing the specific composition for brand name AndroGel. This table correctly lists sodium hydroxide as a diluted solution. *See* '894 patent cl.13 table 5 (listing sodium hydroxide as "0.1 N NaOH at 4.72g per 100g of gel [or 4.72%]"). Second, Solvay says that there is nothing in the prosecution history which suggests that it meant for the gel to contain a harmful amount of sodium hydroxide. Based on these arguments, which were made during the patent litigation, Solvay says that it had "a reasonable belief that there [was] a chance" the

Court would judicially correct Solvay's drafting mistake. *See Professional Real Estate Investors*, 508 U.S. at 63 (internal quotation marks omitted). The Direct Purchasers have alleged facts that may support a sham litigation theory of recovery. Therefore, the motions to dismiss should be denied.

The Direct Purchasers also say that Solvay's infringement actions were objectively baseless because the '894 patent clearly did not meet the written description requirement. The written description requirement provides that:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

35 U.S.C. § 112. The Direct Purchasers say that there is no written description in the specification to support the ranges of sodium hydroxide described in the claims. Those claims describe a pharmaceutical composition containing 1% to 5% of sodium hydroxide. *See* '894 patent cls. 1, 9, 10, 18. The Direct Purchasers say that nothing in the specification mentions any range of sodium hydroxide. The only mention of sodium hydroxide in the specification is the table listing the composition for brand name AndroGel:

Table 5

Composition of AndroGel®

Substance	Amount (w/w) Per 100 g of Gel
Testosterone	1.0 g
Carbopol 980	0.90 g
Isopropyl myristate	0.50 g
0.1 N NaOH	4.72 g
Ethanol (95% w/w)	72.5 g (corresponding to 67 g of ethanol)
Purified water (qaf)	100 g

'894 patent cl.13 table 5. This table refers to a specific amount of sodium hydroxide—4.72% of diluted sodium hydroxide—and does not refer to any range. *Id.*

The Direct Purchasers' allegations regarding the written description requirement are sufficient to state a plausible antitrust claim. "The written description does not have to describe the invention exactly." *Nelson v. K2 Inc.*, No. C07-1660, 2008 WL 4603409, at *1 (W.D. Wash. Oct. 15, 2008). For claims involving ranges, "[t]he question is whether the disclosure provides adequate direction which reasonably would lead one skilled in the art to the particular item or range claimed as the invention." *Id.*; *see also Union Oil Co. v. Atlantic Richfield Co.*, 208 F.3d 989, 1000 (Fed Cir. 2000). This raises questions of fact that cannot be resolved at the pleading stage.

D. Overall Scheme

The Direct Purchasers also assert an antitrust claim that all of the Defendants participated in a scheme to monopolize the market for generic AndroGel. The components of this scheme include improper listing in the Orange Book, filing sham infringement actions, and reverse payment settlements. As discussed above, only the sham litigation claim survives. The Direct Purchasers say that, even so, the Court may still consider their overall scheme claim because it would "be [im]proper to focus on specific individual acts . . . while refusing to consider their overall combined effect." *Anaheim v. Southern Cal. Edison Co.*, 955 F.2d 1373, 1376 (9th Cir. 1992). But, while this principle is true, the Direct Purchasers do not actually identify any improper "combined effect" to the Defendants' actions. They simply repeat their allegations about the individual components and then conclude that the overall combined effect of the Defendants' actions was unlawful. *See id.* ("[I]f all we are shown is a number of perfectly legal acts, it becomes much more difficult to find overall wrongdoing."). Such legal conclusions "are not entitled to the assumption of truth." *Iqbal*, 129 S. Ct. at 1950.

E. Agreements Between Watson, Par, and Paddock

The Direct Purchasers also assert an antitrust claim that Watson, Par, and Paddock agreed not to compete with each other in the market for generic AndroGel. They say that this claim does not involve any patent rights, and so it should be subject to either

a rule of reason or per se antitrust analysis. But the Direct Purchasers did not assert this claim or provide any supporting factual allegations in their complaints. The first time they mentioned an agreement between Watson, Par, and Paddock was in their response brief to the Defendants' motions to dismiss. (Pls.' Mem. of Law in Opp'n of Defs.' Mots. to Dismiss the Second Am. Compl., at 55.) This was too late. "[A] plaintiff cannot amend the complaint by arguments of counsel made in opposition to a motion to dismiss." *Kuhn v. Thompson*, 304 F. Supp. 2d 1313, 1321 (M.D. Ala. 2004). In the post-*Twombly* world, the complaint is judged as it is and not on whether a set of facts could be imagined that would support the claim.

F. State Law Claims

In addition to violating federal antitrust laws, the Indirect Purchasers also allege that the Defendants violated the common law and antitrust laws of about forty states. But the factual allegations for both types of claims are the same. The Indirect Purchasers also do not identify any differences between federal antitrust laws and the relevant state laws. Because the Plaintiffs' allegations do not state a plausible antitrust claim under federal law, the Indirect Purchasers also do not state a plausible antitrust claim under state law. *See In re Tamoxifen*, 466 F.3d at 198 (noting that the district court "dismissed the plaintiffs' state law claims, which had alleged violations of the antitrust laws of seventeen states . . . , because those claims were based on the same allegations as the plaintiffs' federal antitrust claims"); *R.J.*

Reynolds Tobacco Co. v. Phillip Morris, Inc., 199 F. Supp. 2d 362, 396 (M.D.N.C. 2002) ("Because [p]laintiffs do not allege any facts that suggest that [d]efendant's conduct is unlawful beyond the conduct that is the basis for their federal claims, [p]laintiffs' state common law and statutory claims fail as well.").

G. Leave to Amend

The Indirect Purchasers ask for leave to file a consolidated amended complaint. But they made this request in a footnote within their response brief to the Defendants' motions to dismiss. "In the event that the Court grants Defendants any relief requested . . . , we request leave to file a Consolidated Amended Complaint." (End-Payor Pls.' Opp'n to Defs.' Mots. to Dismiss, at 6 n.5.) This is not an appropriate request for leave to amend. The request must be made by motion. *See* Fed. R. Civ. P. 7(b)(1); *Posner v. Essex Ins. Co.*, 178 F.3d 1209, 1222 (11th Cir. 1999) ("Where a request for leave to file an amended complaint simply is imbedded within an opposition memorandum, the issue has not been raised properly."). The request must also either include "the substance of the proposed amendment or attach a copy of the proposed amendment." *Long v. Satz*, 181 F.3d 1275, 1279 (11th Cir. 1999).

IV. Conclusion

For the reasons set forth above, the Defendants' Motions to Dismiss [MDL Doc. 8, 9, 22 and 23] are GRANTED as to the claims of the FTC and the Indirect Purchasers. The Defendants' Motions to Dis-

miss [MDL Doc. 24, 25, 26, 27, 28 and 29] are GRANTED in part and DENIED in part as to the claims of the Direct Purchasers.

SO ORDERED, this 22 day of Feb., 2010.

/s/ THOMAS W. THRASH
THOMAS W. THRASH, JR.
United States District Judge

APPENDIX C

UNITED STATES COURT OF APPEALS
FOR THE ELEVENTH CIRCUIT

No. 10-12729-DD

FEDERAL TRADE COMMISSION,
PLAINTIFF-COUNTER DEFENDANT-APPELLANT

v.

WATSON PHARMACEUTICALS, INC., SOLVAY PHARMACEUTICALS, INC., DEFENDANTS-APPELLEES
PAR PHARMACEUTICAL COMPANIES, INC.,
PADDOCK LABORATORIES, INC.,
DEFENDANTS-COUNTER CLAIMANTS-APPELLEES

[Filed: July 18, 2002]

Appeal From The United States District Court
For The Northern District Of Georgia

ON PETITION(S) FOR REHEARING AND
PETITION(S) FOR REHEARING EN BANC

Before: CARNES, KRAVITCH and FARRIS,* Circuit Judges.

* Honorable Jerome Farris, United States Circuit Judge for the Ninth Circuit, sitting by designation.

PER CURIAM:

The Petition(s) for Rehearing are DENIED and no Judge in regular active service on the Court having requested that the Court be polled on rehearing en banc (Rule 35, Federal Rules of Appellate Procedure), the Petition(s) for Rehearing En Banc are DENIED.
ENTERED FOR THE COURT:

/s/ ED CARNES
ED CARNES
United States Circuit Judge

ORD-42

APPENDIX D

1. 15 U.S.C. 1 provides in relevant part:

Trusts, etc., in restraint of trade illegal, penalty

Every contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce among the several States, or with foreign nations, is declared to be illegal. * * *

2. 15 U.S.C. 2 provides in relevant part:

Monopolizing trade a felony; penalty

Every person who shall monopolize, or attempt to monopolize, or combine or conspire with any other person or persons, to monopolize any part of the trade or commerce among the several States, or with foreign nations, shall be deemed guilty of a felony, * * * .

3. 15 U.S.C. 45(a)(1)-(2) provides in relevant part:

Unfair methods of competition unlawful; prevention by Commission

(a) Declaration of unlawfulness; power to prohibit u fair practices; inapplicability to foreign trade

(1) Unfair methods of competition in or affecting commerce, and unfair or deceptive acts or practices in or affecting commerce, are hereby declared unlawful.

(2) The Commission is hereby empowered and directed to prevent persons, partnerships, or corporations * * * from using unfair methods of competition in or affecting commerce and unfair or deceptive acts or practices in or affecting commerce.

4. 15 U.S.C. 53 provides in relevant part:

False advertisements; injunctions and restraining orders

* * * * *

(b) Temporary restraining orders; preliminary injunctions

Whenever the Commission has reason to believe—

(1) that any person, partnership, or corporation is violating, or is about to violate, any provision of law enforced by the Federal Trade Commission, and

(2) that the enjoining thereof pending the issuance of a complaint by the Commission and until such complaint is dismissed by the Commission or set aside by the court on review, or until the order of the Commission made, there-on has become final, would be in the interest of the public—

the Commission by any of its attorneys designated by it for such purpose may bring suit in a district court of the United States to enjoin any such act or practice. Upon a proper showing that, weighing the equities and considering the Commission's likelihood of ultimate

success, such action would be in the public interest, and after notice to the defendant, a temporary restraining order or a preliminary injunction may be granted without bond: *Provided, however,* That if a complaint is not filed within such period (not exceeding 20 days) as may be specified by the court after issuance of the temporary restraining order or preliminary injunction, the order or injunction shall be dissolved by the court and be of no further force and effect: *Provided further,* That in proper cases the Commission may seek, and after proper proof, the court may issue, a permanent injunction. Any suit may be brought where such person, partnership, or corporation resides or transacts business, or wherever venue is- proper under section 1391 of title 28. In addition, the court may, if the court determines that the interests of justice require that any other person, partnership, or corporation should be a party in such suit, cause such other person, partnership, or corporation to be added as a party without regard to whether venue is otherwise proper in the district in which the suit is brought. In any suit under this section, process may be served on any person, partnership, or corporation wherever it may be found.

* * * * *

5. 21 U.S.C. 355(j) (2006 & Supp. V 2011) provides:

New drugs

(j) Abbreviated new drug applications

(1) Any person may file with the Secretary an abbreviated application for the approval of a new drug.

(2)(A) An abbreviated application for a new drug shall contain—

(i) information to show that the conditions of use prescribed, recommended, or suggested in the labeling proposed for the new drug have been previously approved for a drug listed under paragraph (7) (hereinafter in this subsection referred to as a "listed drug");

(ii)(I) if the listed drug referred to in clause (i) has only one active ingredient, information to show that the active ingredient of the new drug is the same as that of the listed drug;

(II) if the listed drug referred to in clause (i) has more than one active ingredient, information to show that the active ingredients of the new drug are the same as those of the listed drug, or

(III) if the listed drug referred to in clause (i) has more than one active ingredient and if one of the active ingredients of the new drug is different and the application is filed pursuant to the approval of a petition filed under subparagraph (C), information to show that the other active ingredients of the new drug are the same as the active ingredients

of the listed drug, information to show that the different active ingredient is an active ingredient of a listed drug or of a drug which does not meet the requirements of section 321(p) of this title, and such other information respecting the different active ingredient with respect to which the petition was filed as the Secretary may require;

(iii) information to show that the route of administration, the dosage form, and the strength of the new drug are the same as those of the listed drug referred to in clause (i) or, if the route of administration, the dosage form, or the strength of the new drug is different and the application is filed pursuant to the approval of a petition filed under subparagraph (C), such information respecting the route of administration, dosage form, or strength with respect to which the petition was filed as the Secretary may require;

(iv) information to show that the new drug is bioequivalent to the listed drug referred to in clause (i), except that if the application is filed pursuant to the approval of a petition filed under subparagraph (C), information to show that the active ingredients of the new drug are of the same pharmacological or therapeutic class as those of the listed drug referred to in clause (i) and the new drug can be expected to have the same therapeutic effect as the listed drug when administered to patients for a condition of use referred to in clause (i);

(v) information to show that the labeling proposed for the new drug is the same as the labeling

approved for the listed drug referred to in clause (i) except for changes required because of differences approved under a petition filed under subparagraph (C) or because the new drug and the listed drug are produced or distributed by different manufacturers;

(vi) the items specified in clauses (B) through (F) of subsection (b)(1) of this section;

(vii) a certification, in the opinion of the applicant and to the best of his knowledge, with respect to each patent which claims the listed drug referred to in clause (i) or which claims a use for such listed drug for which the applicant is seeking approval under this subsection and for which information is required to be filed under subsection (b) or (c) of this section—

(I) that such patent information has not been filed,

(II) that such patent has expired,

(III) of the date on which such patent will expire, or

(IV) that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted; and

(viii) if with respect to the listed drug referred to in clause (i) information was filed under subsection (b) or (c) of this section for a method of use patent which does not claim a use for which the applicant is seeking approval under this subsection, a statement that the method of use patent does not claim such a use.

The Secretary may not require that an abbreviated application contain information in addition to that required by clauses (i) through (viii).

(B) NOTICE OF OPINION THAT PATENT IS INVALID OR WILL NOT BE INFRINGED.—

(i) AGREEMENT TO GIVE NOTICE.—An applicant that makes a certification described in subparagraph (A)(vii)(IV) shall include in the application a statement that the applicant will give notice as required by this subparagraph.

(ii) TIMING OF NOTICE.—An applicant that makes a certification described in subparagraph (A)(vii)(IV) shall give notice as required under this subparagraph—

(I) if the certification is in the application, not later than 20 days after. the date of the postmark on the notice with which the Secretary informs the applicant that the application has been filed; or

(II) if the certification is in an amendment or supplement to the application, at the time at which the applicant submits the amendment or supplement, regardless of whether the applicant has already given notice with respect to another such certification contained in the application or in an amendment or supplement to the application.

(iii) RECIPIENTS OF NOTICE.—An applicant required under this subparagraph to give notice shall give notice to—

(I) each owner of the patent that is the subject of the certification (or a representative of the owner designated to receive such a notice); and

(II) the holder of the approved application under subsection (b) of this section for the drug that is claimed by the patent or a use of which is claimed by the patent (or a representative of the holder designated to receive such a notice).

(iv) CONTENTS OF NOTICE.—A notice required under this subparagraph shall—

(I) state that an application that contains data from bioavailability or bioequivalence studies has been submitted under this subsection for the drug with respect to which the certification is made to obtain approval to engage in the commercial manufacture, use, or sale of the drug before the expiration of the patent referred to in the certification; and

(II) include a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed.

(C) If a person wants to submit an abbreviated application for a new drug which has a different active ingredient or whose route of administration, dosage

form, or strength differ from that of a listed drug, such person shall submit a petition to the Secretary seeking permission to file such an application. The Secretary shall approve or disapprove a petition submitted under this subparagraph within ninety days of the date the petition is submitted. The Secretary shall approve such a petition unless the Secretary finds-

(i) that investigations must be conducted to show the safety and effectiveness of the drug or of any of its active ingredients, the route of administration, the dosage form, or strength which differ from the listed drug; or

(ii) that any drug with a different active ingredient may not be adequately evaluated for approval as safe and effective on the basis of the information required to be submitted in an abbreviated application.

(D)(i) An applicant may not amend or supplement an application to seek approval of a drug referring to a different listed drug from the listed drug identified in the application as submitted to the Secretary.

(ii) With respect to the drug for which an application is submitted, nothing in this subsection prohibits an applicant from amending or supplementing the application to seek approval of a different strength.

(iii) Within 60 days after December 8, 2003, the Secretary shall issue guidance defining the term "listed drug" for purposes of this subparagraph.

(3)(A) The Secretary shall issue guidance for the individuals who review applications submitted under paragraph (1), which shall relate to promptness in conducting the review, technical excellence, lack of bias and conflict of interest, and knowledge of regulatory and scientific standards, and which shall apply equally to all individuals who review such applications.

(B) The Secretary shall meet with a sponsor of an investigation or an applicant for approval for a drug under this subsection if the sponsor or applicant makes a reasonable written request for a meeting for the purpose of reaching agreement on the design and size of bioavailability and bioequivalence studies needed for approval of such application. The sponsor or applicant shall provide information necessary for discussion and agreement on the design and size of such studies. Minutes of any such meeting shall be prepared by the Secretary and made available to the sponsor or applicant.

(C) Any agreement regarding the parameters of design and size of bioavailability and bioequivalence studies of a drug under this paragraph that is reached between the Secretary and a sponsor or applicant shall be reduced to writing and made part of the administrative record by the Secretary. Such agreement shall not be changed after the testing begins, except-

(i) with the written agreement of the sponsor or applicant; or

(ii) pursuant to a decision, made in accordance with subparagraph (D) by the director of the re-

viewing division, that a substantial scientific issue essential to determining the safety or effectiveness of the drug has been identified after the testing has begun.

(D) A decision under subparagraph (O)(ii) by the director shall be in writing and the Secretary shall provide to the sponsor or applicant an opportunity for a meeting at which the director and the sponsor or applicant will be present and at which the director will document the scientific issue involved.

(E) The written decisions of the reviewing division shall be binding upon, and may not directly or indirectly be changed by, the field or compliance office personnel unless such field or compliance office personnel demonstrate to the reviewing division why such decision should be modified.

(F) No action by the reviewing division may be delayed because of the unavailability of information from or action by field personnel unless the reviewing division determines that a delay is necessary to assure the marketing of a safe and effective drug.

(G) For purposes of this paragraph, the reviewing division is the division responsible for the review of an application for approval of a drug under this subsection (including scientific matters, chemistry, manufacturing, and controls).

(4) Subject to paragraph (5), the Secretary shall approve an application for a drug unless the Secretary finds—

(A) the methods used in, or the facilities and controls used for, the manufacture, processing, and packing of the drug are inadequate to assure and preserve its identity, strength, quality, and purity;

(B) information submitted with the application is insufficient to show that each of the proposed conditions of use have been previously approved for the listed drug referred to in the application;

(C)(i) if the listed drug has only one active ingredient, information submitted with the application is insufficient to show that the active ingredient is the same as that of the listed drug;

(ii) if the listed drug has more than one active ingredient, information submitted with the application is insufficient to show that the active ingredients are the same as the active ingredients of the listed drug, or

(iii) if the listed drug has more than one active ingredient and if the application is for a drug which has an active ingredient different from the listed drug, information submitted with the application is insufficient to show—

(I) that the other active ingredients are the same as the active ingredients of the listed drug, or

(II) that the different active ingredient is an active ingredient of a listed drug or a drug which does not meet the requirements of section 321(p) of this title,

or no petition to file an application for the drug with the different ingredient was approved under paragraph (2)(C);

(D)(i) if the application is for a drug whose route of administration, dosage form, or strength of the drug is the same as the route of administration, dosage form, or strength of the listed drug referred to in the application, information submitted in the application is insufficient to show that the route of administration, dosage form, or strength is the same as that of the listed drug, or

(ii) if the application is for a drug whose route of administration, dosage form, or strength of the drug is different from that of the listed drug referred to in the application, no petition to file an application for the drug with the different route of administration, dosage form, or strength was approved under paragraph (2)(C);

(E) if the application was filed pursuant to the approval of a petition under paragraph (2)(C), the application did not contain the information required by the Secretary respecting the active ingredient, route of administration, dosage form, or strength which is not the same;

(F) information submitted in the application is insufficient to show that the drug is bioequivalent to the listed drug referred to in the application or, if the application was filed pursuant to a petition approved under paragraph (2)(C), information submitted in the application is insufficient to show that

the active ingredients of the new drug are of the same pharmacological or therapeutic class as those of the listed drug referred to in paragraph (2)(A)(i) and that the new drug can be expected to have the same therapeutic effect as the listed drug when administered to patients for a condition of use referred to in such paragraph;

(G) information submitted in the application is insufficient to show that the labeling proposed for the drug is the same as the labeling approved for the listed drug referred to in the application except for changes required because of differences approved under a petition filed under paragraph (2)(0) or because the drug and the listed drug are produced or distributed by different manufacturers;

(H) information submitted in the application or any other information available to the Secretary shows that (i) the inactive ingredients of the drug are unsafe for use under the conditions prescribed, recommended, or suggested in the labeling proposed for the drug, or (ii) the composition of the drug is unsafe under such conditions because of the type or quantity of inactive ingredients included or the manner in which the inactive ingredients are included;

(I) the approval under subsection (c) of this section of the listed drug referred to in the application under this subsection has been withdrawn or suspended for grounds described in the first sentence of subsection (e) of this section, the Secretary has published a notice of opportunity for hearing to

withdraw approval of the listed drug under subsection (c) of this section for grounds described in the first sentence of subsection (e) of this section, the approval under this subsection of the listed drug referred to in the application under this subsection has been withdrawn or suspended under paragraph (6), or the Secretary has determined that the listed drug has been withdrawn from sale for safety or effectiveness reasons;

(J) the application does not meet any other requirement of paragraph (2)(A); or

(K) the application contains an untrue statement of material fact.

(5)(A) Within one hundred and eighty days of the initial receipt of an application under paragraph (2) or within such additional period as may be agreed upon by the Secretary and the applicant, the Secretary shall approve or disapprove the application.

(B) The approval of an application submitted under paragraph (2) shall be made effective on the last applicable date determined by applying the following to each certification made under paragraph (2)(A)(vii):

(i) If the applicant only made a certification described in subclause (I) or (II) of paragraph (2)(A)(vii) or in both such subclauses, the approval may be made effective immediately.

(ii) If the applicant made a certification described in subclause (III) of paragraph (2)(A)(vii), the approval may be made effective on the date certified under subclause (III).

(iii) If the applicant made a certification described in subclause (IV) of paragraph (2)(A)(vii), the approval shall be made effective immediately unless, before the expiration of 45 days after the date on which the notice described in paragraph (2)(B) is received, an action is brought for infringement of the patent that is the subject of the certification and for which information was submitted to the Secretary under subsection (b)(1) or (c)(2) of this section before the date on which the application (excluding an amendment or supplement to the application), which the Secretary later determines to be substantially complete, was submitted. If such an action is brought before the expiration of such days, the approval shall be made effective upon the expiration of the thirty-month period beginning on the date of the receipt of the notice provided under paragraph (2)(B)(i) or such shorter or longer period as the court may order because either party to the action failed to reasonably cooperate in expediting the action, except that—

(I) if before the expiration of such period the district court decides that the patent is invalid or not infringed (including any substantive determination that there is no cause of action for patent infringement or invalidity), the approval shall be made effective on—

(aa) the date on which the court enters judgment reflecting the decision; or

(bb) the date of a settlement order or consent decree signed and entered by the court stating that the patent that is the subject of the certification is invalid or not infringed;

(II) if before the expiration of such period the district court decides that the patent has been infringed—

(aa) if the judgment of the district court is appealed, the approval shall be made effective on—

(AA) the date on which the court of appeals decides that the patent is invalid or not infringed (including any substantive determination that there is no cause of action for patent infringement or invalidity); or

(BB) the date of a settlement order or consent decree signed and entered by the court of appeals stating that the patent that is the subject of the certification is invalid or not infringed; or

(bb) if the judgment of the district court is not appealed or is affirmed, the approval shall be made effective on the date specified by the district court in a court order under section 271(e)(4)(A) of title 35;

(III) if before the expiration of such period the court grants a preliminary injunction prohibiting the applicant from engaging in the commercial manufacture or sale of the drug until the court decides the issues of patent validity and infringement and if the court decides that such patent is invalid or not infringed, the approval shall be made effective as provided in subclause (I); or

(IV) if before the expiration of such period the court grants a preliminary injunction prohibiting the applicant from engaging in the commercial manufacture or sale of the drug until the court decides the issues of patent validity and infringement and if the court decides that such patent has been infringed, the approval shall be made effective as provided in subclause (II).

In such an action, each of the parties shall reasonably cooperate in expediting the action.

(iv) 180-DAY EXCLUSIVITY PERIOD.—

(I) EFFECTIVENESS OF APPLICATION.— Subject to subparagraph (D), if the application contains a certification described in paragraph (2)(A)(vii)(IV) and is for a drug for which a first applicant has submitted an application containing such a certification, the application shall be made effective on the date that is 180 days after the date of the first commercial marketing of the drug (including the commer-

cial marketing of the listed drug) by any first applicant.

(II) DEFINITIONS.—In this paragraph:

(aa) 180-DAY EXCLUSIVITY PERIOD.—The term "180-day exclusivity period" means the 180-day period ending on the day before the date on which an application submitted by an applicant other than a first applicant could become effective under this clause.

(bb) FIRST APPLICANT.—As used in this subsection, the term "first applicant" means an applicant that, on the first day on which a substantially complete application containing a certification described in paragraph (2)(A)(vii)(IV) is submitted for approval of a drug, submits a substantially complete application that contains and lawfully maintains a certification described in paragraph (2)(A)(vii)(IV) for the drug.

(cc) SUBSTANTIALLY COMPLETE APPLICATION.—As used in this subsection, the term "substantially complete application" means an application under this subsection that on its face is sufficiently complete to permit a substantive review and contains all the information required by paragraph (2)(A).

(dd) TENTATIVE APPROVAL.—

(AA) IN GENERAL.—The term "tentative approval" means notification to an ap-

plicant by the Secretary that an application under this subsection meets the requirements of paragraph (2)(A), but cannot receive effective approval because the application does not meet the requirements of this subparagraph, there is a period of exclusivity for the listed drug under subparagraph (F) or section 355a of this title, or there is a 7-year period of exclusivity for the listed drug under section 360cc of this title.

(BB) LIMITATION.—A drug that is granted tentative approval by the Secretary is not an approved drug and shall not have an effective approval until the Secretary issues an approval after any necessary additional review of the application.

(C) CIVIL ACTION TO OBTAIN PATENT CERTAINTY.—

(i) DECLARATORY JUDGMENT ABSENT INFRINGEMENT ACTION.—

(I) IN GENERAL.—No action may be brought under section 2201 of title 28 by an applicant under paragraph (2) for a declaratory judgment with respect to a patent which is the subject of the certification referred to in subparagraph (B)(iii) unless—

(aa) the 45-day period referred to in such subparagraph has expired;

(bb) neither the owner of such patent nor the holder of the approved application under subsection (b) of this section for the drug that is claimed by the patent or a use of which is claimed by the patent brought a civil action against the applicant for infringement of the patent before the expiration of such period; and

(cc) in any case in which the notice provided under paragraph (2)(B) relates to noninfringement, the notice was accompanied by a document described in subclause (III).

(II) FILING OF CIVIL ACTION.—If the conditions described in items (aa), (bb), and as applicable, (cc) of subclause (I) have been met, the applicant referred to in such subclause may, in accordance with section 2201 of title 28, bring a civil action under such section against the owner or holder referred to in such subclause (but not against any owner or holder that has brought such a civil action against the applicant, unless that civil action was dismissed without prejudice) for a declaratory judgment that the patent is invalid or will not be infringed by the drug for which the applicant seeks approval, except that such civil action may be brought for a declaratory judgment that the patent will not be infringed only in a case in which the condition described in subclause (I)(cc) is applicable. A civil action referred to in this subclause shall be brought in the judicial district where the defendant has its

principal place of business or a regular and established place of business.

(III) OFFER OF CONFIDENTIAL ACCESS TO APPLICATION.—For purposes of subclause (I)(cc),the document described in this subclause is a document providing an offer of confidential access to the application that is in the custody of the applicant under paragraph (2) for the purpose of determining whether an action referred to in subparagraph (B)(iii) should be brought. The document providing the offer of confidential access shall contain such restrictions as to persons entitled to access, and on the use and disposition of any information accessed, as would apply had a protective order been entered for the purpose of protecting trade secrets and other confidential business information. A request for access to an application under an offer of confidential access shall be considered acceptance of the offer of confidential access with the restrictions as to persons entitled to access, and on the use and disposition of any information accessed, contained in the offer of confidential access, and those restrictions and other terms of the offer of confidential access shall be considered terms of an enforceable contract. Any person provided an offer of confidential access shall review the application for the sole and limited purpose of evaluating possible infringement of the patent that is the subject of the certification under paragraph (2)(A)(vii)(IV) and for no

other purpose, and may not disclose information of no relevance to any issue of patent infringement to any person other than a person provided an offer of confidential access. Further, the application may be redacted by the applicant to remove any information of no relevance to any issue of patent infringement.

(ii) COUNTERCLAIM TO INFRINGEMENT ACTION.—

(I) IN GENERAL.—If an owner of the patent or the holder of the approved application under subsection (b) of this section for the drug that is claimed by the patent or a use of which is claimed by the patent brings a patent infringement action against the applicant, the applicant may assert a counterclaim seeking an order requiring the holder to correct or delete the patent information submitted by the holder under subsection (b) or (c) of this section on the ground that the patent does not claim either—

(aa) the drug for which the application was approved; or

(bb) an approved method of using the drug.

(II) NO INDEPENDENT CAUSE OF ACTION. Subclause (I) does not authorize the assertion of a claim described in subclause (I) in any civil action or proceeding other than a counterclaim described in subclause (I).

(iii) NO DAMAGES.—An applicant shall not be entitled to damages in a civil action under clause (i) or a counterclaim under clause (ii).

(D) FORFEITURE OF 180-DAY EXCLUSIVITY PERIOD.—

(i) DEFINITION OF FORFEITURE EVENT.—In this subparagraph, the term "forfeiture event", with respect to an application under this subsection, means the occurrence of any of the following:

(I) FAILURE TO MARKET.—The first applicant fails to market the drug by the later of—

(aa) the earlier of the date that is—

(AA) 75 days after the date on which the approval of the application of the first applicant is made effective under subparagraph (B)(iii); or

(BB) 30 months after the date of submission of the application of the first applicant; or

(bb) with respect to the first applicant or any other applicant (which other applicant has received tentative approval), the date that is 75 days after the date as of which, as to each of the patents with respect to which the first applicant submitted and lawfully maintained a certification qualifying the first applicant for the 180-day exclusivity period under subparagraph (B)(iv), at least 1 of the following has occurred:

(AA) In an infringement action brought against that applicant with respect to the patent or in a declaratory judgment action brought by that applicant with respect to the patent, a court enters a final decision from which no appeal (other than a petition to the Supreme Court for a writ of certiorari) has been or can be taken that the patent is invalid or not infringed.

(BB) In an infringement action or a declaratory judgment action described in subitem (AA), a court signs a settlement order or consent decree that enters a final judgment that includes a finding that the patent is invalid or not infringed.

(CC) The patent information submitted under subsection (b) or (c) of this section is withdrawn by the holder of the application approved under subsection (b) of this section.

(II) WITHDRAWAL OF APPLICATION.—The first applicant withdraws the application or the Secretary considers the application to have been withdrawn as a result of a determination by the Secretary that the application does not meet the requirements for approval under paragraph (4).

(III) AMENDMENT OF CERTIFICATION.—The first applicant amends or withdraws the certification for all of the patents with respect to which that applicant submitted a certification qualify-

ing the applicant for the 180-day exclusivity period.

(IV) FAILURE TO OBTAIN TENTATIVE APPROVAL.—The first applicant fails to obtain tentative approval of the application within 30 months after the date on which the application is filed, unless the failure is caused by a change in or a review of the requirements for approval of the application imposed after the date on which the application is filed.

(V) AGREEMENT WITH ANOTHER APPLICANT, THE LISTED DRUG APPLICATION HOLDER, OR A PATENT OWNER.—The first applicant enters into an agreement with another applicant under this subsection for the drug, the holder of the application for the listed drug, or an owner of the patent that is the subject of the certification under paragraph (2)(A)(vii)(IV), the Federal Trade Commission or the Attorney General files a complaint, and there is a final decision of the Federal Trade Commission or the court with regard to the complaint from which no appeal (other than a petition to the Supreme Court for a writ of certiorari) has been or can be taken that the agreement has violated the antitrust laws (as defined in section 12 of title 15, except that the term includes section 45 of title 15 to the extent that that section applies to unfair methods of competition).

(VI) EXPIRATION OF ALL PATENTS.—All of the patents as to which the applicant submitted a

certification qualifying it for the 180-day exclusivity period have expired.

(ii) FORFEITURE.—The 180-day exclusivity period described in subparagraph (B)(iv) shall be forfeited by a first applicant if a forfeiture event occurs with respect to that first applicant.

(iii) SUBSEQUENT APPLICANT.—If all first applicants forfeit the 180-day exclusivity period under clause (ii)—

(I) approval of any application containing a certification described in paragraph (2)(A)(vii)(IV) shall be made effective in accordance with subparagraph (B)(iii); and

(II) no applicant shall be eligible for a 180-day exclusivity period.

(E) If the Secretary decides to disapprove an application, the Secretary shall give the applicant notice of an opportunity for a hearing before the Secretary on the question of whether such application is approvable. If the applicant elects to accept the opportunity for hearing by written request within thirty days after such notice, such hearing shall commence not more than ninety days after the expiration of such thirty days unless the Secretary and the applicant otherwise agree. Any such hearing shall thereafter be conducted on an expedited basis and the Secretary's order thereon shall be issued within ninety days after the date fixed by the Secretary for filing final briefs.

(F)(i) If an application (other than an abbreviated new drug application) submitted under subsection (b) of this section for a drug, no active ingredient (including any ester or salt of the active ingredient) of which has been approved in any other application under subsection (b) of this section, was approved during the period beginning January 1, 1982, and ending on September 24, 1984, the Secretary may not make the approval of an application submitted under this subsection which refers to the drug for which the subsection (b) application was submitted effective before the expiration of ten years from the date of the approval of the application under subsection (b) of this section.

(ii) If an application submitted under subsection (b) of this section for a drug, no active ingredient (including any ester or salt of the active ingredient) of which has been approved in any other application under subsection (b) of this section, is approved after September 24, 1984, no application may be submitted under this subsection which refers to the drug for which the subsection (b) application was submitted before the expiration of five years from the date of the approval of the application under subsection (b) of this section, except that such an application may be submitted under this subsection after the expiration of four years from the date of the approval of the subsection (b) application if it contains a certification of patent invalidity or noninfringement described in subclause (IV) of paragraph (2)(A)(vii). The approval of such an application shall be made effective in accordance

with subparagraph (B) except that, if an action for patent infringement is commenced during the one-year period beginning forty-eight months after the date of the approval of the subsection (b) application, the thirty-month period referred to in subparagraph (B)(iii) shall be extended by such amount of time (if any) which is required for seven and one-half years to have elapsed from the date of approval of the subsection (b) application.

(iii) If an application submitted under subsection (b) of this section for a drug, which includes an active ingredient (including any ester or salt of the active ingredient) that has been approved in another application approved under subsection (b) of this section, is approved after September 24, 1984, and if such application contains reports of new clinical investigations (other than bioavailability studies) essential to the approval of the application and conducted or sponsored by the applicant, the Secretary may not make the approval of an application submitted under this subsection for the conditions of approval of such drug in the subsection (b) application effective before the expiration of three years from the date of the approval of the application under subsection (b) of this section for such drug.

(iv) If a supplement to an application approved under subsection (b) of this section is approved after September 24, 1984, and the supplement contains reports of new clinical investigations (other than bioavailability studies) essential to the approv-

al of the supplement and conducted or sponsored by the person submitting the supplement, the Secretary may not make the approval of an application submitted under this subsection for a change approved in the supplement effective before the expiration of three years from the date of the approval of the supplement under subsection (b) of this section.

(v) If an application (or supplement to an application) submitted under subsection (b) of this section for a drug, which includes an active ingredient (including any ester or salt of the active ingredient) that has been approved in another application under subsection (b) of this section, was approved during the period beginning January 1, 1982, and ending on September 24, 1984, the Secretary may not make the approval of an application submitted under this subsection which refers to the drug for which the subsection (b) application was submitted or which refers to a change approved in a supplement to the subsection (b) application effective before the expiration of two years from September 24, 1984.

(6) If a drug approved under this subsection refers in its approved application to a drug the approval of which was withdrawn or suspended for grounds described in the first sentence of subsection (e) of this section or was withdrawn or suspended under this paragraph or which, as determined by the Secretary, has been withdrawn from sale for safety or effectiveness reasons, the approv-

al of the drug under this subsection shall be withdrawn or suspended—

(A) for the same period as the withdrawal or suspension under subsection (e) of this section or this paragraph, or

(B) if the listed drug has been withdrawn from sale, for the period of withdrawal from sale or, if earlier, the period ending on the date the Secretary determines that the withdrawal from sale is not for safety or effectiveness reasons.

(7)(A)(i) Within sixty days of September 24, 1984, the Secretary shall publish and make available to the public—

(I) a list in alphabetical order of the official and proprietary name of each drug which has been approved for safety and effectiveness under subsection (c) of this section before September 24, 1984;

(II) the date of approval if the drug is approved after 1981 and the number of the application which was approved; and

(III) whether in vitro or in vivo bioequivalence studies, or both such studies, are required for applications filed under this subsection which will refer to the drug published.

(ii) Every thirty days after the publication of the first list under clause (i) the Secretary shall revise the list to include each drug which has been approved for safety and effectiveness under subsec-

tion (c) of this section or approved under this subsection during the thirty-day period.

(iii) When patent information submitted under subsection (b) or (c) of this section respecting a drug included on the list is to be published by the Secretary, the Secretary shall, in revisions made under clause (ii), include such information for such drug.

(B) A drug approved for safety and effectiveness under subsection (c) of this section or approved under this subsection shall, for purposes of this subsection, be considered to have been published under subparagraph (A) on the date of its approval or September 24, 1984, whichever is later.

(C) If the approval of a drug was withdrawn or suspended for grounds described in the first sentence of subsection (e) of this section or was withdrawn or suspended under paragraph (6) or if the Secretary determines that a drug has been withdrawn from sale for safety or effectiveness reasons, it may not be published in the list under subparagraph (A) or, if the withdrawal or suspension occurred after its publication in such list, it shall be immediately removed from such list—

(i) for the same period as the withdrawal or suspension under subsection (e) of this section or paragraph (6), or

(ii) if the listed drug has been withdrawn from sale, for the period of withdrawal from sale or, if earlier, the period ending on the date the Secre-

tary determines that the withdrawal from sale is not for safety or effectiveness reasons.

A notice of the removal shall be published in the Federal Register.

(8) For purposes of this subsection:

(A)(i) The term "bioavailability" means the rate and extent to which the active ingredient or therapeutic ingredient is absorbed from a drug and becomes available at the site of drug action.

(ii) For a drug that is not intended to be absorbed into the bloodstream, the Secretary may assess bioavailability by scientifically valid measurements intended to reflect the rate and extent to which the active ingredient or therapeutic ingredient becomes available at the site of drug action.

(B) A drug shall be considered to be bioequivalent to a listed drug if—

(i) the rate and extent of absorption of the drug do not show a significant difference from the rate and extent of absorption of the listed drug when administered at the same molar dose of the therapeutic ingredient under similar experimental conditions in either a single dose or multiple doses; or

(ii) the extent of absorption of the drug does not show a significant difference from the extent of absorption of the listed drug when administered at the same molar dose of the therapeutic ingredient under similar ex-

perimental conditions in either a single dose or multiple doses and the difference from the listed drug in the rate of absorption of the drug is intentional, is reflected in its proposed labeling, is not essential to the attainment of effective body drug concentrations on chronic use, and is considered medically insignificant for the drug.

(C) For a drug that is not intended to be absorbed into the bloodstream, the Secretary may establish alternative, scientifically valid methods to show bioequivalence if the alternative methods are expected to detect a significant difference between the drug and the listed drug in safety and therapeutic effect.

(9) The Secretary shall, with respect to each application submitted under this subsection, maintain a record of—

(A) the name of the applicant,

(B) the name of the drug covered by the application,

(C) the name of each person to whom the review of the chemistry of the application was assigned and the date of such assignment, and

(D) the name of each person to whom the bioequivalence review for such application was assigned and the date of such assignment.

The information the Secretary is required to maintain under this paragraph with respect to an application

submitted under this subsection shall be made available to the public after the approval of such application.

(10)(A) If the proposed labeling of a drug that is the subject of an application under this subsection differs from the listed drug due to a labeling revision described under clause (i), the drug that is the subject of such application shall, notwithstanding any other provision of this chapter, be eligible for approval and shall not be considered misbranded under section 352 of this title if—

(i) the application is otherwise eligible for approval under this subsection but for expiration of patent, an exclusivity period, or of a delay in approval described in paragraph (5)(B)(iii), and a revision to the labeling of the listed drug has been approved by the Secretary within 60 days of such expiration;

(ii) the labeling revision described under clause (i) does not include a change to the "Warnings" section of the labeling;

(iii) the sponsor of the application under this subsection agrees to submit revised labeling of the drug that is the subject of such application not later than 60 days after the notification of any changes to such labeling required by the Secretary; and

(iv) such application otherwise meets the applicable requirements for approval under this subsection.

(B) If, after a labeling revision described in subparagraph (A)(i), the Secretary determines that the continued presence in interstate commerce of the labeling of the listed drug (as in effect before the revision described in subparagraph (A)(i)) adversely impacts the safe use of the drug, no application under this subsection shall be eligible for approval with such labeling.

6. 21 U.S.C. 355(j) (2000) provides:

New drugs

(j) Abbreviated new drug applications

(1) Any person may file with the Secretary an abbreviated application for the approval of a new drug.

(2)(A) An abbreviated application for a new drug shall contain—

(i) information to show that the conditions of use prescribed, recommended, or suggested in the labeling proposed for the new drug have been previously approved for a drug listed under paragraph (7) (hereinafter in this subsection referred to as a "listed drug");

(ii)(I) if the listed drug referred to in clause (i) has only one active ingredient, information to show that the active ingredient of the new drug is the same as that of the listed drug;

(II) if the listed drug referred to in clause (i)

has more than one active ingredient, information to show that the active ingredients of the new drug are the same as those of the listed drug, or

(III) if the listed drug referred to in clause (i) has more than one active ingredient and if one of the active ingredients of the new drug is different and the application is filed pursuant to the approval of a petition filed under subparagraph (C), information to show that the other active ingredients of the new drug are the same as the active ingredients of the listed drug, information to show that the different active ingredient is an active ingredient of a listed drug or of a drug which does not meet the requirements of section 321(p) of this title, and such other information respecting the different active ingredient with respect to which the petition was filed as the Secretary may require;

(iii) information to show that the route of administration, the dosage form, and the strength of the new drug are the same as those of the listed drug referred to in clause (i) or, if the route of administration, the dosage form, or the strength of the new drug is different and the application is filed pursuant to the approval of a petition filed under subparagraph (C), such information respecting the route of administration, dosage form, or strength with respect to which the petition was filed as the Secretary may require;

(iv) information to show that the new drug is bioequivalent to the listed drug referred to in clause (i), except that if the application is filed pur-

suant to the approval of a petition filed under subparagraph (C), information to show that the active ingredients of the new drug are of the same pharmacological or therapeutic class as those of the listed drug referred to in clause (i) and the new drug can be expected to have the same therapeutic effect as the listed drug when administered to patients for a condition of use referred to in clause (i);

(v) information to show that the labeling proposed for the new drug is the same as the labeling approved for the listed drug referred to in clause (i) except for changes required because of differences approved under a petition filed under subparagraph (C) or because the new drug and the listed drug are produced or distributed by different manufacturers;

(vi) the items specified in clauses (B) through (F) of subsection (b)(1) of this section;

(vii) a certification, in the opinion of the applicant and to the best of his knowledge, with respect to each patent which claims the listed drug referred to in clause (i) or which claims a use for such listed drug for which the applicant is seeking approval under this subsection and for which information is required to be filed under subsection (b) or (c) of this section—

(I) that such patent information has not been filed,

(II) that such patent has expired,

(III) of the date on which such patent will expire, or

(IV) that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted; and

(viii) if with respect to the listed drug referred to in clause (i) information was filed under subsection (b) or (c) of this section for a method of use patent which does not claim a use for which the applicant is seeking approval under this subsection, a statement that the method of use patent does not claim such a use.

The Secretary may not require that an abbreviated application contain information in addition to that required by clauses (i) through (viii).

(B)(i) An applicant who makes a certification described in subparagraph (A)(vii)(IV) shall include in the application a statement that the applicant will give the notice required by clause (ii) to—

(I) each owner of the patent which is the subject of the certification or the representative of such owner designated to receive such notice, and

(II) the holder of the approved application under subsection (b) of this section for the drug which is claimed by the patent or a use of which is claimed by the patent or the representative of such holder designated to receive such notice.

(ii) The notice referred to in clause (i) shall state that an application, which contains data from bioavailability or bioequivalence studies, has been submitted under this subsection for the drug with respect to which the certification is made to obtain approval to engage in the commercial manufacture, use, or sale of such drug before the expiration of the patent referred to in the certification. Such notice shall include a detailed statement of the factual and legal basis of the applicant's opinion that the patent is not valid or will not be infringed.

(iii) If an application is amended to include a certification described in subparagraph (A)(vii)(IV), the notice required by clause (ii) shall be given when the amended application is submitted.

(C) If a person wants to submit an abbreviated application for a new drug which has a different active ingredient or whose route of administration, dosage form, or strength differ from that of a listed drug, such person shall submit a petition to the Secretary seeking permission to file such an application. The Secretary shall approve or disapprove a petition submitted under this subparagraph within ninety days of the date the petition is submitted. The Secretary shall approve such a petition unless the Secretary finds—

(i) that investigations must be conducted to show the safety and effectiveness of the drug or of any of its active ingredients, the route of administration, the dosage form, or strength which differ from the listed drug; or

(ii) that any drug with a different active ingredient may not be adequately evaluated for approval as safe and effective on the basis of the information required to be submitted in an abbreviated application.

(3)(A) The Secretary shall issue guidance for the individuals who review applications submitted under paragraph (1), which shall relate to promptness in conducting the review, technical excellence, lack of bias and conflict of interest, and knowledge of regulatory and scientific standards, and which shall apply equally to all individuals who review such applications.

(B) The Secretary shall meet with a sponsor of an investigation or an applicant for approval for a drug under this subsection if the sponsor or applicant makes a reasonable written request for a meeting for the purpose of reaching agreement on the design and size of bioavailability and bioequivalence studies needed for approval of such application. The sponsor or applicant shall provide information necessary for discussion and agreement on the design and size of such studies. Minutes of any such meeting shall be prepared by the Secretary and made available to the sponsor or applicant.

(C) Any agreement regarding the parameters of design and size of bioavailability and bioequivalence studies of a drug under this paragraph that is reached between the Secretary and a sponsor or applicant shall be reduced to writing and made part of the administrative record by the Secretary. Such

agreement shall not be changed after the testing begins, except—

(i) with the written agreement of the sponsor or applicant; or

(ii) pursuant to a decision, made in accordance with subparagraph (D) by the director of the reviewing division, that a substantial scientific issue essential to determining the safety or effectiveness of the drug has been identified after the testing has begun.

(D) A decision under subparagraph (C)(ii) by the director shall be in writing and the Secretary shall provide to the sponsor or applicant an opportunity for a meeting at which the director and the sponsor or applicant will be present and at which the director will document the scientific issue involved.

(E) The written decisions of the reviewing division shall be binding upon, and may not directly or indirectly be changed by, the field or compliance office personnel unless such field or compliance office personnel demonstrate to the reviewing division why such decision should be modified.

(F) No action by the reviewing division may be delayed because of the unavailability of information from or action by field personnel unless the reviewing division determines that a delay is necessary to assure the marketing of a safe and effective drug.

(G) For purposes of this paragraph, the reviewing division is the division responsible for the review

of an application for approval of a drug under this subsection (including scientific matters, chemistry, manufacturing, and controls).

(4) Subject to paragraph (5), the Secretary shall approve an application for a drug unless the Secretary finds—

(A) the methods used in, or the facilities and controls used for, the manufacture, processing, and packing of the drug are inadequate to assure and preserve its identity, strength, quality, and purity;

(B) information submitted with the application is insufficient to show that each of the proposed conditions of use have been previously approved for the listed drug referred to in the application;

(C)(i) if the listed drug has only one active ingredient, information submitted with the application is insufficient to show that the active ingredient is the same as that of the listed drug;

(ii) if the listed drug has more than one active ingredient, information submitted with the application is insufficient to show that the active ingredients are the same as the active ingredients of the listed drug, or

(iii) if the listed drug has more than one active ingredient and if the application is for a drug which has an active ingredient different from the listed drug, information submitted with the application is insufficient to show—

(I) that the other active ingredients are the same as the active ingredients of the listed drug, or

(II) that the different active ingredient is an active ingredient of a listed drug or a drug which does not meet the requirements of section 321(p) of this title,

or no petition to file an application for the drug with the different ingredient was approved under paragraph (2)(C);

(D)(i) if the application is for a drug whose route of administration, dosage form, or strength of the drug is the same as the route of administration, dosage form, or strength of the listed drug referred to in the application, information submitted in the application is insufficient to show that the route of administration, dosage form, or strength is the same as that of the listed drug, or

(ii) if the application is for a drug whose route of administration, dosage form, or strength of the drug is different from that of the listed drug referred to in the application, no petition to file an application for the drug with the different route of administration, dosage form, or strength was approved under paragraph (2)(C);

(E) if the application was filed pursuant to the approval of a petition under paragraph (2)(C), the application did not contain the information required by the Secretary respecting the active ingredient, route of administration, dosage form, or strength which is not the same;

(F) information submitted in the application is insufficient to show that the drug is bioequivalent to the listed drug referred to in the application or, if the application was filed pursuant to a petition approved under paragraph (2)(C), information submitted in the application is insufficient to show that the active ingredients of the new drug are of the same pharmacological or therapeutic class as those of the listed drug referred to in paragraph (2)(A)(i) and that the new drug can be expected to have the same therapeutic effect as the listed drug when administered to patients for a condition of use referred to in such paragraph;

(G) information submitted in the application is insufficient to show that the labeling proposed for the drug is the same as the labeling approved for the listed drug referred to in the application except for changes required because of differences approved under a petition filed under paragraph (2)(C) or because the drug and the listed drug are produced or distributed by different manufacturers;

(H) information submitted in the application or any other information available to the Secretary shows that (i) the inactive ingredients of the drug

are unsafe for use under the conditions prescribed, recommended, or suggested in the labeling proposed for the drug, or (ii) the composition of the drug is unsafe under such conditions because of the type or quantity of inactive ingredients included or the manner in which the inactive ingredients are included;

(I) the approval under subsection (c) of this section of the listed drug referred to in the application under this subsection has been withdrawn or suspended for grounds described in the first sentence of subsection (e) of this section, the Secretary has published a notice of opportunity for hearing to withdraw approval of the listed drug under subsection (c) of this section for grounds described in the first sentence of subsection (e) of this section, the approval under this subsection of the listed drug referred to in the application under this subsection has been withdrawn or suspended under paragraph (6), or the Secretary has determined that the listed drug has been withdrawn from sale for safety or effectiveness reasons;

(J) the application does not meet any other requirement of paragraph (2)(A); or

(K) the application contains an untrue statement of material fact.

(5)(A) Within one hundred and eighty days of the initial receipt of an application under paragraph (2) or within such additional period as may be agreed upon by the Secretary and the appli-

cant, the Secretary shall approve or disapprove the application.

(B) The approval of an application submitted under paragraph (2) shall be made effective on the last applicable date determined under the following:

(i) If the applicant only made a certification described in subclause (I) or (II) of paragraph (2)(A)(vii) or in both such subclauses, the approval may be made effective immediately.

(ii) If the applicant made a certification described in subclause (III) of paragraph (2)(A)(vii), the approval may be made effective on the date certified under subclause (III).

(iii) If the applicant made a certification described in subclause (IV) of paragraph (2)(A)(vii), the approval shall be made effective immediately unless an action is brought for infringement of a patent which is the subject of the certification before the expiration of forty-five days from the date the notice provided under paragraph (2)(B)(i) is received. If such an action is brought before the expiration of such days, the approval shall be made effective upon the expiration of the thirty-month period beginning on the date of the receipt of the notice provided under paragraph (2)(B)(i) or such shorter or longer period

as the court may order because either party to the action failed to reasonably cooperate in expediting the action, except that—

(I) if before the expiration of such period the court decides that such patent is invalid or not infringed, the approval shall be made effective on the date of the court decision,

(II) if before the expiration of such period the court decides that such patent has been infringed, the approval shall be made effective on such date as the court orders under section 271(e)(4)(A) of Title 35, or

(III) if before the expiration of such period the court grants a preliminary injunction prohibiting the applicant from engaging in the commercial manufacture or sale of the drug until the court decides the issues of patent validity and infringement and if the court decides that such patent is invalid or not infringed, the approval shall be made effective on the date of such court decision.

In such an action, each of the parties shall reasonably cooperate in expediting the action. Until the expiration of forty-five days from the date the notice made under paragraph (2)(B)(i) is received, no action may be brought under section 2201 of title 28, for a declaratory judgment with respect to the patent. Any action brought under section 2201 shall be brought in the judicial district where the defendant has its principal place of business or a regular and established place of business.

(iv) If the application contains a certification described in subclause (IV) of paragraph (2)(A)(vii) and is for a drug for which a previous application has been

submitted under this subsection continuing such a certification, the application shall be made effective not earlier than one hundred and eighty days after—

(I) the date the Secretary receives notice from the applicant under the previous application of the first commercial marketing of the drug under the previous application, or

(II) the date of a decision of a court in an action described in clause (iii) holding the patent which is the subject of the certification to be invalid or not infringed,

whichever is earlier.

(C) If the Secretary decides to disapprove an application, the Secretary shall give the applicant notice of an opportunity for a hearing before the Secretary on the question of whether such application is approvable. If the applicant elects to accept the opportunity for hearing by written request within thirty days after such notice, such hearing shall commence not more than ninety days after the expiration of such thirty days unless the Secretary and the applicant otherwise agree. Any such hearing shall thereafter be conducted on an expedited basis and the Secretary's order thereon shall be issued within ninety days after the date fixed by the Secretary for filing final briefs.

(D)(i) If an application (other than an abbreviated new drug application) submitted under subsection (b) of this section for a drug, no active ingredient (including any ester or salt of the active ingredient) of

which has been approved in any other application under subsection (b) of this section, was approved during the period beginning January 1, 1982, and ending on September 24, 1984, the Secretary may not make the approval of an application submitted under this subsection which refers to the drug for which the subsection (b) application was submitted effective before the expiration of ten years from the date of the approval of the application under subsection (b) of this section.

(ii) If an application submitted under subsection (b) of this section for a drug, no active ingredient (including any ester or salt of the active ingredient) of which has been approved in any other application under subsection (b) of this section, is approved after September 24, 1984, no application may be submitted under this subsection which refers to the drug for which the subsection (b) application was submitted before the expiration of five years from the date of the approval of the application under subsection (b) of this section, except that such an application may be submitted under this subsection after the expiration of four years from the date of the approval of the subsection (b) application if it contains a certification of patent invalidity or noninfringement described in subclause (IV) of paragraph (2)(A)(vii). The approval of such an application shall be made effective in accordance with subparagraph (B) except that, if an action for patent infringement is commenced during the one-year period beginning forty-eight months after the date of the approval of the subsection (b) applica-

tion, the thirty-month period referred to in subparagraph (B)(iii) shall be extended by such amount of time (if any) which is required for seven and one-half years to have elapsed from the date of approval of the subsection (b) application.

(iii) If an application submitted under subsection (b) of this section for a drug, which includes an active ingredient (including any ester or salt of the active ingredient) that has been approved in another application approved under subsection (b) of this section, is approved after September 24, 1984, and if such application contains reports of new clinical investigations (other than bioavailability studies) essential to the approval of the application and conducted or sponsored by the applicant, the Secretary may not make the approval of an application submitted under this subsection for the conditions of approval of such drug in the subsection (b) application effective before the expiration of three years from the date of the approval of the application under subsection (b) of this section for such drug.

(iv) If a supplement to an application approved under subsection (b) of this section is approved after September 24, 1984, and the supplement contains reports of new clinical investigations (other than bioavailability studies) essential to the approval of the supplement and conducted or sponsored by the person submitting the supplement, the Secretary may not make the approval of an application submitted under this subsection for a change approved in the supplement effective before the expiration of three

years from the date of the approval of the supplement under subsection (b) of this section.

(v) If an application (or supplement to an application) submitted under subsection (b) of this section for a drug, which includes an active ingredient (including any ester or salt of the active ingredient) that has been approved in another application under subsection (b) of this section, was approved during the period beginning January 1, 1982, and ending on September 24, 1984, the Secretary may not make the approval of an application submitted under this subsection which refers to the drug for which the subsection (b) application was submitted or which refers to a change approved in a supplement to the subsection (b) application effective before the expiration of two years from September 24, 1984.

(6) If a drug approved under this subsection refers in its approved application to a drug the approval of which was withdrawn or suspended for grounds described in the first sentence of subsection (e) of this section or was withdrawn or suspended under this paragraph or which, as determined by the Secretary, has been withdrawn from sale for safety or effectiveness reasons, the approval of the drug under this subsection shall be withdrawn or suspended—

(A) for the same period as the withdrawal or suspension under subsection (e) of this section or this paragraph, or

(B) if the listed drug has been withdrawn from sale, for the period of withdrawal from sale

or, if earlier, the period ending on the date the Secretary determines that the withdrawal from sale is not for safety or effectiveness reasons.

(7)(A)(i) Within sixty days of September 24, 1984, the Secretary shall publish and make available to the public—

(I) a list in alphabetical order of the official and proprietary name of each drug which has been approved for safety and effectiveness under subsection (c) of this section before September 24, 1984;

(II) the date of approval if the drug is approved after 1981 and the number of the application which was approved; and

(III) whether in vitro or in vivo bioequivalence studies, or both such studies, are required for applications filed under this subsection which will refer to the drug published.

(ii) Every thirty days after the publication of the first list under clause (i) the Secretary shall revise the list to include each drug which has been approved for safety and effectiveness under subsection (c) of this section or approved under this subsection during the thirty-day period.

(iii) When patent information submitted under subsection (b) or (c) of this section respecting a drug included on the list is to be published by the Secretary, the Secretary shall, in revisions made under clause (ii), include such information for such drug.

(B) A drug approved for safety and effectiveness under subsection (c) of this section or approved under this subsection shall, for purposes of this subsection, be considered to have been published under subparagraph (A) on the date of its approval or September 24, 1984, whichever is later.

(C) If the approval of a drug was withdrawn or suspended for grounds described in the first sentence of subsection (e) of this section or was withdrawn or suspended under paragraph (6) or if the Secretary determines that a drug has been withdrawn from sale for safety or effectiveness reasons, it may not be published in the list under subparagraph (A) or, if the withdrawal or suspension occurred after its publication in such list, it shall be immediately removed from such list—

(i) for the same period as the withdrawal or suspension under subsection (e) of this section or paragraph (6), or

(ii) if the listed drug has been withdrawn from sale, for the period of withdrawal from sale or, if earlier, the period ending on the date the Secretary determines that the withdrawal from sale is not for safety or effectiveness reasons.

A notice of the removal shall be published in the Federal Register.

(8) For purposes of this subsection:

(A) The term "bioavailability" means the rate and extent to which the active ingredient or thera-

peutic ingredient is absorbed from a drug and becomes available at the site of drug action.

(B) A drug shall be considered to be bioequivalent to a listed drug if—

(i) the rate and extent of absorption of the drug do not show a significant difference from the rate and extent of absorption of the listed drug when administered at the same molar dose of the therapeutic ingredient under similar experimental conditions in either a single dose or multiple doses; or

(ii) the extent of absorption of the drug does not show a significant difference from the extent of absorption of the listed drug when administered at the same molar dose of the therapeutic ingredient under similar experimental conditions in either a single dose or multiple doses and the difference from the listed drug in the rate of absorption of the drug is intentional, is reflected in its proposed labeling, is not essential to the attainment of effective body drug concentrations on chronic use, and is considered medically insignificant for the drug.

(9) The Secretary shall, with respect to each application submitted under this subsection, maintain a record of—

(A) the name of the applicant,

(B) the name of the drug covered by the application,

(C) the name of each person to whom the review of the chemistry of the application was assigned and the date of such assignment, and

(D) the name of each person to whom the bioequivalence review for such application was assigned and the date of such assignment.

The information the Secretary is required to maintain under this paragraph with respect to an application submitted under this subsection shall be made available to the public after the approval of such application.

7. 35 U.S.C. 271 provides in relevant part:

Infringement of patent

* * * * *

(e)(1) It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention (other than a new animal drug or veterinary biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Act of March 4, 1913) which is primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site specific genetic manipulation techniques) solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products.

(2) It shall be an act of infringement to submit—

(A) an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act or described in section 505(b)(2) of such Act for a drug claimed in a patent or the use of which is claimed in a patent, or

(B) an application under section 512 of such Act or under the Act of March 4, 1913 (21 U.S.C. 151-158) for a drug or veterinary biological product which is not primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site specific genetic manipulation techniques and which is claimed in a patent or the use of which is claimed in a patent,

if the purpose of such submission is to obtain approval under such Act to engage in the commercial manufacture, use, or sale of a drug or veterinary biological product claimed in a patent or the use of which is claimed in a patent before the expiration of such patent.

(3) In any action for patent infringement brought under this section, no injunctive or other relief may be granted which would prohibit the making, using, offering to sell, or selling within the United States or importing into the United States of a patented invention under paragraph (1).

(4) For an act of infringement described in paragraph (2)—

(A) the court shall order the effective date of any approval of the drug or veterinary biological product involved in the infringement to be a date which is not earlier than the date of the expiration of the patent which has been infringed,

(B) injunctive relief may be granted against an infringer to prevent the commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States of an approved drug or veterinary biological product, and

(C) damages or other monetary relief may be awarded against an infringer only if there has been commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States of an approved drug or veterinary biological product.

The remedies prescribed by subparagraphs (A), (B), and (C) are the only remedies which may be granted by a court for an act of infringement described in paragraph (2), except that a court may award attorney fees under section 285.

(5) Where a person has filed an application described in paragraph (2) that includes a certification under subsection (b)(2)(A)(iv) or (j)(2)(A)(vii)(IV) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355), and neither the owner of the patent that is the subject of the certification nor the holder of the approved application under subsection (b) of such section for the drug that is claimed by the patent or a use of which is claimed by the patent

brought an action for infringement of such patent before the expiration of 45 days after the date on which the notice given under subsection (b)(3) or (j)(2)(B) of such section was received, the courts of the United States shall, to the extent consistent with the Constitution, have subject matter jurisdiction in any action brought by such person under section 2201 of title 28 for a declaratory judgment that such patent is invalid or not infringed.

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