No. 12-416

In the Supreme Court of the United States

FEDERAL TRADE COMMISSION, PETITIONER

v.

WATSON PHARMACEUTICALS, INC., ET AL.

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

BRIEF FOR THE PETITIONER

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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) (per curiam). 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, or instead are presumptively anticompetitive and unlawful.

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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BRIEF FOR THE PETITIONER

OPINIONS BELOW

The opinion of the court of appeals (Pet. App. 1a-36a) is reported at 677 F.3d 1298. The order of the district court (Pet. App. 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 (Pet. App. 62a-63a). The petition for a writ of certiorari was filed on October 4, 2012, and was granted on December 7, 2012. The jurisdiction of this Court rests on 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 an appendix to this brief, App., *infra*, 1a-61a.

STATEMENT

This case presents a question of great economic importance to consumers of pharmaceuticals: 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 patentee (the brand-name manufacturer) agrees to pay an accused infringer (its would-be generic competitor), and the competitor agrees that it will not enter the market for a specified period of time. The court of appeals affirmed the dismissal of a complaint filed by the Federal Trade Commission (FTC) challenging two related reverse-payment agreements among respondents. Pet. App. 1a-36a. 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 the patentee does not obtain more protection from competition than would result from a successful infringement suit. *Id.* at 28a.

1. a. Under the Federal Food, Drug, and Cosmetic Act, as amended, 21 U.S.C. 301 *et seq.*, the manufacturer of a new drug must obtain approval from the Food and Drug Administration (FDA) of a new drug application (NDA) before marketing the drug. 21 U.S.C. 355(b).[1] The NDA must contain, *inter alia*, a statement of the

[1] All references in this brief to Title 21 are to the 2000 version of the United States Code. As used in this brief, "drug" refers to a drug, as defined in 21 U.S.C. 321(g)(1), regulated by FDA under 21 U.S.C. 355.

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, while maintaining and refining the patent laws' incentives for innovation. See H.R. Rep. No. 857, 98th Cong., 2d Sess. Pt. 1, at 14-17 (1984) (*House Report*); *id.* Pt. 2, at 5-6; see also *Eli Lilly & Co.* v. *Medtronic, Inc.*, 496 U.S. 661, 669-674 (1990) (explaining how the Hatch-Waxman Amendments address "unintended distortions of [a drug's] patent term produced by the requirement that certain products must receive premarket regulatory approval").

To simplify the approval process for generic drugs, 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)(D)), 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 and effectiveness. Instead, the typical ANDA must 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.

b. "Because," under most circumstances, "FDA cannot authorize a generic drug that would infringe a patent, the timing of an ANDA's approval depends on the scope and duration of the patents covering the brand-name drug." *Caraco*, 132 S. Ct. at 1676. 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 no infringement where the generic drug was designed to avoid a patent claiming an inactive ingredient); see generally *Caraco*, 132 S. Ct. at 1676 (noting that drug "patents come in different varieties"); 21 C.F.R. 314.53. In addition, a substantial fraction of fully litigated patent cases have resulted in a finding of patent invalidity. See John R. Allison & Mark A. 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 reported in *United States Patent Quarterly* between 1989 and 1996).

The Hatch-Waxman Amendments accordingly establish a litigation framework to facilitate the resolution of patent-related disputes between brand-name and generic manufacturers. Under that framework, a brand-name manufacturer must identify to FDA particular patents

that could reasonably be asserted against someone manufacturing, using, or selling its drug. 21 U.S.C. 355(b)(1); see *Caraco*, 132 S. Ct. at 1676. A generic firm submitting an ANDA must in turn explain how the generic drug can be marketed without infringing those 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 identified by the brand-name manufacturer "'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); p. 6, *infra*. 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.

c. Congress provided significant incentives for both brand-name and generic manufacturers to engage in paragraph IV litigation. On the generic side, the Hatch-Waxman Amendments reward the first filer of an ANDA containing a paragraph IV certification with a promise of 180 days of exclusivity on the market. See 21 U.S.C. 355(j)(5)(B)(iv) (providing that FDA will not approve an ANDA with a later-filed paragraph IV certification to the same patent as an earlier-filed ANDA for at least 180 days after either a court decision finding the patent invalid or not infringed, or the first commercial market-

ing of the drug under the first ANDA, whichever is earlier). That period of exclusivity ensures that the first filer does not face price competition from other generic entrants during the period of exclusivity, and it gives that manufacturer a head start in reaching commercial arrangements with large purchasers. According to the generic pharmaceutical industry's leading trade association, the "vast majority of potential profits for a generic drug manufacturer materialize during the 180-day exclusivity period." Comments of Generic Pharm. Ass'n to FTC on Authorized Generic Drug Study 2 (June 27, 2006), http://www.ftc.gov/os/comments/genericdrugstudy3/062806gpha.pdf.

The Hatch-Waxman Amendments also encourage (though they do not require) the brand-name manufacturer to respond to a paragraph IV certification by promptly suing the generic applicant for patent infringement. Such a suit triggers an automatic stay of FDA approval of the ANDA for 30 months. 21 U.S.C. 355(j)(5)(B)(iii). That stay is extremely valuable to the brand-name manufacturer because it provides the rough practical equivalent of an automatic preliminary injunction against generic competition during the first 30 months of any infringement litigation.

d. In cases litigated to decision, would-be generic competitors have prevailed nearly three quarters of the time in paragraph IV litigation against brand-name manufacturers. See FTC, *Generic Drug Entry Prior to Patent Expiration* 10, 19-20 (July 2002), http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf (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 in paragraph IV litigation initiated between 1992 and 2000); see also Paul

M. Janicke & LiLan Ren, *Who Wins Patent Infringement Cases?*, 34 AIPLA Q.J. 1, 20 chart 1 (2006) (finding that, between 2002 and 2004, accused infringers had a 70% success rate in Federal Circuit decisions with a final ruling on drug-patent claims).

Paragraph IV litigation continues to be an important route for the entry of generic competition. The patent portfolios of brand-name drug manufacturers have grown in recent years with the addition of "secondary" patents, such as "patents on chemical variants, alternative formulations, methods of use, and relatively minor aspects of the drug." C. Scott Hemphill & Bhaven N. Sampat, *When Do Generics Challenge Drug Patents?,* 8 J. Empirical Legal Stud. 613, 615, 619-623 (2011); see Amy Kapczynski et al., *Polymorphs and Prodrugs and Salts (Oh My!): An Empirical Analysis of "Secondary" Pharmaceutical Patents*, PLOS ONE, e49470, at 6 (Dec. 2012) (analyzing 432 new drugs with patent protection approved by FDA between 1988 and 2005, and concluding that "patents with secondary claims are extremely common" and that such patents "on average add substantial time to the nominal patent terms enjoyed by drugs"); cf. *Caraco*, 132 S. Ct. at 1676 (noting that patents held by brand-name manufacturers "come in different varieties" and are not limited to patents that "protect[] the drug compound itself"). Those secondary patents may be particularly susceptible to being avoided, in whole or in part, by generic competitors.

e. 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/

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As generic competition sets in, prices for generic drugs fall, on average to about 15% of what the branded manufacturer was charging. See FTC, *Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions* 8 (2010), http://www.ftc.gov/os/2010/01/100112payfordelayrpt.pdf (*Pay-for-Delay Report*). At the same time, the brand-name manufacturer loses about 90 percent of its market share (by unit sales) to its generic competitors. *Ibid.* Those substantially lower prices benefit a wide range of participants in the market, including individuals (who may pay for drugs out-of-pocket), health-insurance companies (which reimburse the cost of prescription drugs), employers (which pay health-insurance premiums), and taxpayers (who support programs such as Medicare and Medicaid). The savings generated by market competition from generic pharmaceuticals amount to many tens of billions of dollars annually. See U.S. Gov't Accountability Off., *Report No. GAO-12-371R*, *Savings from Generic Drug Use* 9-11 (2012), http://www.gao.gov/assets/590/588064.pdf (discussing studies).

Given the significant difference between monopoly and competitive drug prices, a brand-name manufacturer has a strong economic incentive to induce its would-be generic competitor to forgo competition. And while the generic manufacturer will profit if it prevails in paragraph IV litigation and enters the market, its profits will be much less than the brand-name manufacturer

stands to lose. As a result, both the brand-name and generic manufacturers may benefit (at the expense of consumers) if the brand-name manufacturer agrees to share its monopoly profits in exchange for the generic manufacturer's agreement to defer its own entry into the market. See, *e.g.*, C. Scott Hemphill, *An Aggregate Approach to Antitrust: Using New Data and Rulemaking to Preserve Drug Competition*, 109 Colum. L. Rev. 629, 635-636 (2009) (*Aggregate Approach to Antitrust*).

2. The agreements at issue in this case 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, J.A. 37. Besins Healthcare, S.A., developed AndroGel® and licensed the marketing rights in the United States to respondent Solvay Pharmaceuticals, Inc. in 1995. *Id.* ¶ 32, J.A. 36-37. FDA approved AndroGel® in February 2000, and in 2007 the product had sales of more than $400 million. *Id.* ¶¶ 33, 34, J.A. 37.

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, J.A. 36-38. In January 2003, the Patent and Trademark Office (PTO) issued a patent to Solvay. *Id.* ¶ 42, J.A. 39. 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, J.A. 39-40. 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, J.A. 40.

In August 2003, Solvay sued Watson and Paddock for patent infringement, Complaint ¶ 47, J.A. 40, triggering the 30-month stay of ANDA approval provided in 21 U.S.C. 355(j)(5)(B)(iii). 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. Complaint ¶¶ 86-89, J.A. 53-55. By late 2005, Watson and Paddock had filed motions for summary judgment detailing much of this evidence. *Id.* ¶ 90, J.A. 55.

In January 2006—at the expiration of the 30-month stay of FDA approval, and while the patent litigation was still pending—FDA approved Watson's ANDA. Complaint ¶ 52, J.A. 41. Watson and Paddock/Par expected to begin selling their products no later than 2007. *Id.* ¶ 54, J.A. 42. They predicted that prices for generic versions of AndroGel® would fall to as little as 15-25% of the price of Solvay's branded AndroGel®. *Id.* ¶¶ 50-51, J.A. 41. Solvay anticipated losing approximately 90% of its AndroGel® sales within a year after the launch of a generic version, cutting its profits by $125 million a year. *Id.* ¶ 49, J.A. 41. Solvay's U.S. CEO advised his European superiors that Watson might launch generic AndroGel® sometime in 2006. *Id.* ¶ 53, J.A. 42.

Solvay therefore internally evaluated the prospects for a settlement that would avoid that outcome. Com-

plaint ¶ 57, J.A. 43.[2] Solvay concluded that Watson and Paddock/Par might prefer agreeing to defer entry into the market rather than face an uncertain outcome in litigation, *ibid.*, but that they would not accede to a generic entry date in 2015 (which was significant to Solvay because it anticipated shifting its customers by that date to a new product with no generic equivalent, *id.* ¶ 63, J.A. 45-46). Payments, however, changed the equation. Solvay calculated that if it were to share AndroGel® monopoly profits with Watson and Paddock/Par, a settlement with a generic entry date in 2015 would be more profitable for each respondent than continued litigation. *Id.* ¶ 58, J.A. 43-44.

As Solvay had anticipated, Watson and Paddock/Par each insisted on receiving a payment in exchange for assenting to Solvay's preferred 2015 generic entry date. Complaint ¶¶ 61, 67, 70-71, 79, J.A. 44-45, 46-47, 50. Solvay ultimately agreed to pay Watson an estimated $19-30 million annually, ostensibly for Watson to market AndroGel® to urologists. *Id.* ¶¶ 65-67, J.A. 46. 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,

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[2] Solvay's internal analysis is attached to the Complaint as Exhibit A and reprinted, under seal, at J.A. 103-116. On December 19, 2012, the district court agreed with the FTC that the exhibit should be made public, in view of the passage of time, evolution of the AndroGel® market, and the heightened public interest attending this Court's grant of certiorari. Dkt. 202. Solvay then sought and obtained a stay from the Eleventh Circuit pending its appeal of the unsealing order. No. 12-16488 Docket entry (Jan. 10, 2013). We therefore limit our discussion to the matters alleged in the public complaint.

J.A. 48-49.[3] Those 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, J.A. 50-53. The reverse-payment agreements eliminated potential competition that could have saved consumers hundreds of millions of dollars a year. *Id.* ¶¶ 96, 98, J.A. 57-58.

3. The FTC filed suit under Section 5 of the Federal Trade Commission Act (FTC 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, J.A. 60-61. The FTC further alleged that Solvay had unlawfully extended its monopoly on AndroGel®, not on the basis of its formulation patent, but by compensating its potential competitors. *Id.* ¶¶ 110-111, J.A. 61-62. 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). J.A. 62-63 (Complaint Prayer for Relief).

4. The district court dismissed the FTC's complaint for failure to state a claim. Pet. App. 37a-61a. Relying

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[3] While this case was pending in the court of appeals, Par reported that it had terminated its co-promotion agreement with Solvay before that agreement's scheduled expiration in exchange for a $2 million payment. See Par Pharm. Cos., Inc., Annual Report (Form 10-K), at 38 (Feb. 24, 2011). The FTC has not had investigation or discovery into matters surrounding that development, such as the content of Par's continuing agreements with Solvay respecting AndroGel®. In any event, subsequent developments would not bear on the FTC's allegation that Par and Solvay's agreement not to compete is unlawful.

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." Pet. App. 48a. The district court emphasized that the settlements 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.[4] The court also rejected, as inconsistent with circuit precedent, the FTC's contention that reverse-payment agreements should be treated as presumptively unlawful. *Id.* at 51a-52a.

5. The court of appeals affirmed. Pet. App. 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 agree-

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[4] The district court has since held as a matter of law, in private antitrust litigation challenging the reverse-payment agreements at issue here, that Solvay's infringement suits were not objectively baseless. *In re Androgel Antitrust Litig. (No. II)*, No. 09-MD-2084, 2012 WL 5352986 (N.D. Ga. Oct. 30, 2012). The plaintiffs have appealed that ruling, and the Eleventh Circuit has stayed proceedings in those appeals pending this Court's decision in this case. *E.g.*, *Rochester Drug Co-Op, Inc.* v. *Unimed Pharms. Inc.*, No. 12-15562, Docket entry (11th Cir. Nov. 26, 2012).

ments were subject to very limited antitrust scrutiny. The court of appeals rejected the FTC's efforts to limit or distinguish those decisions, see Gov't C.A. Br. 22-43, explaining that, under its prior rulings, the brand-name manufacturer's patent made "traditional [antitrust] analysis * * * inappropriate." Pet. App. 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 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 unlawful 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." Gov't C.A. Br. 52; see *id.* at 43-56. The court of appeals acknowledged the FTC's fundamental position, Pet. App. 4a, but adhered to its precedent.

6. In a decision rendered shortly after the Eleventh Circuit's decision in this case, the Third Circuit rejected

the so-called scope-of-the-patent approach applied by the Eleventh Circuit below, explaining that in practice, that test "does not subject reverse payment agreements to any antitrust scrutiny." See *In re K-Dur Antitrust Litig.*, 686 F.3d 197, 214 (2012), petitions for cert. pending, No. 12-245 (filed Aug. 24, 2012) and No. 12-265 (filed Aug. 29, 2012). The Third Circuit found "no significant support" for the scope-of-the-patent approach's "almost unrebuttable presumption of patent validity." *Ibid.* The court further explained that "the effectively conclusive presumption that a patent holder is entitled to exclude competitors is particularly misguided" in cases where infringement is at issue and there is no presumption favoring the patent holder's claim. *Ibid.* The Third Circuit 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.

7. The Eleventh Circuit 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. Pet. App. 62a-63a.

SUMMARY OF ARGUMENT

I. Reverse-payment agreements should be treated as presumptively unlawful because they closely resemble the sorts of horizontal agreements to suppress competition that have previously been condemned under the antitrust laws. Such agreements have been treated as per se unlawful even if the would-be competitor's prospects of market entry were uncertain at the time the agreement was formed. When parties to paragraph IV litigation settle a case by simply agreeing on a compro-

mise date of generic entry, the generic manufacturer's incentive is to negotiate the earliest possible entry date in order to maximize its own profits. That incentive ensures that consumer interests will receive significant protection in the negotiating process, and it provides reason for confidence that the agreed-upon entry date reflects the parties' own assessment of the likely litigation outcome. By contrast, a Hatch-Waxman settlement that includes a reverse payment allows the brand-name manufacturer to co-opt its rival by sharing the monopoly profits that result from an artificially prolonged period of market exclusivity.

Nothing in the Patent Act legitimizes the use of reverse payments as a settlement term. Although a patentee's good-faith effort to enforce its patent through litigation cannot subject it to antitrust liability, a patentee who chooses that course accepts the risk that it might lose. And while a Hatch-Waxman settlement without a reverse payment should ordinarily raise no antitrust concern, there are sound reasons to treat reverse-payment settlements differently. Such agreements depart from usual settlement practices by giving the generic manufacturer a monetary payment that it could not have hoped to obtain from the brand-name manufacturer even by winning the lawsuit. The reverse payment also severs the alignment of interests that would otherwise exist between the generic manufacturer and consumers when the parties to paragraph IV litigation negotiate a compromise date of generic entry.

Reverse-payment agreements also subvert the balance of competing policies struck in the Hatch-Waxman Amendments. Congress established the paragraph IV patent litigation framework to facilitate early and definitive resolution of patent disputes, and nothing in the

Amendments contemplates that a patentee will pay an accused infringer to escape that framework. Moreover, the Amendments reflect a balance of benefits for generic manufacturers and protections from competition for brand-name manufacturers, a balance that would be upset by giving a brand-name manufacturer the added opportunity to purchase still more protection by sharing its monopoly profits.

Reverse-payment agreements should accordingly be treated as presumptively anticompetitive under a "quick look" rule of reason analysis. The defendants in the antitrust suit should in turn be given an opportunity to rebut the presumption. The principal means of rebuttal would be through proof that the payment was instead consideration for unrelated property or services, or that the payment was commensurate with the litigation costs that the brand-name manufacturer would otherwise have borne. In rare circumstances, other unusual business or litigation justifications may also supply a rebuttal. Absent such a rebuttal, however, a reverse-payment agreement should be held unlawful. Such a "quick look" approach of treating reverse-payment agreements as presumptively anticompetitive would preserve the salutary incentives Congress has provided for brand-name and generic manufacturers to resolve paragraph IV litigation in alternative ways that do not undo the manufacturers' competitive relationship.

II. The "quick look" approach, which treats reverse-payment agreements as presumptively unlawful, is superior to the other modes of analysis that have emerged in the case law. In particular, the scope-of-the-patent approach applied by the court below gives no meaningful antitrust scrutiny to reverse-payment agreements, notwithstanding their manifest anticompetitive potential.

That approach effectively assumes that the relevant patent is valid and infringed, even though generic manufacturers often prevail in paragraph IV litigation, and even though one party to every reverse-payment agreement is a generic manufacturer who has previously certified that the patent is invalid or will not be infringed. Given the profitability of reverse-payment agreements, if this Court were to adopt the scope-of-the-patent approach as the applicable nationwide rule, brand-name manufacturers would have little reason *not* to offer their potential generic competitors payments not to compete, and the generic manufacturers would have little reason to refuse. The increased frequency and severity of reverse-payment agreements would, in turn, substantially increase prescription drug costs for consumers.

The public policy in favor of voluntary settlement does not justify the scope-of-the-patent rule. The "quick look" approach leaves manufacturers substantial latitude to settle their disputes so long as they do not utilize reverse payments. The financial incentives created by the Hatch-Waxman Amendments likewise provide no justification for the scope-of-the-patent approach. Those incentives are not different in kind from the incentives of patentees in other infringement suits, yet reverse payments appear to be essentially unknown outside the Hatch-Waxman context. In any event, to the extent that some brand-name manufacturers face especially strong pressure to settle particular Hatch-Waxman suits, generic manufacturers can exploit that pressure either by negotiating an especially early entry date or by accepting a reverse payment in exchange for delaying competition. Although the scope-of-the-patent approach treats those as equally legitimate negotiating

tactics, requiring the generic manufacturer to pursue the former accords with the consumer-protective purposes of the antitrust laws.

III. The FTC's complaint states a claim for relief under the "quick look" approach. It alleges that, in settling paragraph IV litigation, respondents entered into agreements under which the brand-name manufacturer promised substantial monetary payments and the generic manufacturers agreed to refrain from marketing competing products for the next nine years.

ARGUMENT

I. TREATING REVERSE-PAYMENT AGREEMENTS AS PRESUMPTIVELY UNLAWFUL SERVES THE PURPOSES OF COMPETITION LAW, PATENT LAW, AND THE HATCH-WAXMAN AMENDMENTS

Reverse-payment agreements exist at the intersection of competition law, patent law, and the Hatch-Waxman Amendments' framework for regulating generic drugs. Because reverse-payment agreements closely resemble other horizontal agreements between competitors that this Court has categorically condemned, respondents' defense of the practice necessarily depends on the contention that either the Patent Act or the Hatch-Waxman Amendments implicitly legitimize conduct that would ordinarily be viewed as a paradigmatic antitrust violation. That argument is misconceived. Absent unusual circumstances, reverse-payment agreements disserve rather than further the purposes of patent law and the Hatch-Waxman Amendments, and they should accordingly be treated as presumptively unlawful.

A. Reverse-Payment Agreements Closely Resemble Other Horizontal Agreements Between Competitors That Are Per Se Unlawful Under Federal Competition Law

1. An incumbent firm's agreement to pay a potential competitor to stay out of the market is 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) (per curiam). "Under the Sherman Act a combination formed for the purpose and with the effect of raising, depressing, fixing, pegging, or stabilizing the price of a commodity in interstate or foreign commerce is illegal *per se*." *United States* v. *Socony-Vacuum Oil Co.*, 310 U.S. 150, 223 (1940). In general, "raising price, reducing output, and dividing markets have the same anticompetitive effects." *California Dental Ass'n* v. *FTC*, 526 U.S. 756, 777 (1999) (citation omitted). Such agreements therefore are ordinarily condemned as unlawful per se. See *Catalano, Inc.* v. *Target Sales, Inc.*, 446 U.S. 643, 647 (1980) (per curiam) (reviewing a wide range of horizontal agreements between competitors that this Court has condemned as unlawful per se). From an economic perspective, such agreements between rivals are 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).

Those bedrock principles of competition law apply even if the would-be competitor's prospects of successful market entry were uncertain when the agreement was formed. See *United States* v. *Griffith*, 334 U.S 100, 107 (1948) ("The anti-trust laws are as much violated by the prevention of competition as by its destruction."); 12 Herbert Hovenkamp, *Antitrust Law* ¶ 2030b, at 220 (3d ed. 2012) (*Antitrust Law*) ("[T]he law does not con-

done the purchase of protection from uncertain competition any more than it condones the elimination of actual competition."); *Engine Specialties, Inc.* v. *Bombardier Ltd.*, 605 F.2d 1, 9 (1st Cir. 1979) ("Agreements not to compete among potential competitors as well as among actual competitors are forbidden."), cert. denied, 446 U.S. 983, and 449 U.S. 890 (1980); cf. *United States* v. *Microsoft Corp.*, 253 F.3d 34, 79 (D.C. Cir.) (en banc) (per curiam) (exclusionary conduct is unlawful when it "is aimed at producers of nascent competitive technologies as well as when it is aimed at producers of established substitutes"), cert. denied, 534 U.S. 952 (2001).

2. Competitors often have a strong economic self-interest in entering into such horizontal agreements. In the pharmaceutical industry, for example, 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. The brand-name manufacturer's monopoly profits are large enough to pay its would-be generic competitors more than they could hope to earn if they entered the market, while still 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*). If no legal impediment to such agreements existed, both the brand-name and generic manufacturers could benefit financially if the generic company agreed to defer competition in exchange for a share of the resulting monopoly profits. See 12 *Antitrust Law* ¶ 2046c1, at 338 ("In such cases [an] agreement effec-

tively 'preserves' the patent, thus giving the [brand-name and generic manufacturers] the joint-maximizing, or monopoly, output.").

These incentives are particularly apparent when the brand-name manufacturer and its potential generic competitor are settling paragraph IV litigation. When they select a date on which generic entry will be permitted under their settlement, the two manufacturers are not simply deciding how a fixed pool of profits will be divided between them (as might be the case in the settlement of an ordinary commercial dispute), but are also controlling how large the combined pool will be. Even though the generic manufacturer earns no profits during a year of brand-name exclusivity, the total profits of the two firms taken together (*i.e.*, the brand-name manufacturer's monopoly profits plus zero profits for the generic manufacturer) will be greater than the brand-name and generic manufacturers' combined profits during a year when the firms compete. Those extra profits will come at the expense of consumers, who pay more for drugs during a period of brand-name exclusivity and consequent monopoly pricing. By agreeing to a later date of generic entry, the brand-name and generic manufacturers can extend the period of monopoly pricing and thereby increase total profits, while harming consumers. See, *e.g.*, *Aggregate Approach to Antitrust*, 109 Colum. L. Rev. at 635-636.

Of course, the potential maximization of "total" profits for a year of brand-name monopoly will have no practical benefit for a generic manufacturer whose share of that total is zero. Thus, when brand-name and generic drug manufacturers simply negotiate a compromise date of generic entry, the generic manufacturer's incentive is to negotiate the earliest entry date it can, consistent

with the parties' respective assessments of the likely outcome of the suit. Like the competing supplier of bar-exam review courses in *Palmer*, see 498 U.S. at 47, the generic manufacturer will have no reason to gratuitously agree to withdraw from competition simply to enable the brand-name manufacturer to obtain greater revenues than the two companies together could earn in a competitive environment. In that circumstance, the financial interest of the generic manufacturer in maximizing its own profits is aligned with the interest of consumers in hastening the advent of generic competition and consequent lower prices.

The generic manufacturer's incentives are different, however, if it is offered a share of the profits the brand-name manufacturer could earn during an extended period of monopoly conditions. That was the function of the revenue-sharing arrangement in *Palmer*, 498 U.S. at 47, 49-50, and it is the usual function of a reverse payment in the pharmaceutical context. In substance, a reverse-payment agreement is a mechanism for inducing the generic manufacturer to forgo its own output, as a way to increase the manufacturers' combined profits, at the expense of competition and consumer welfare. Such "treaties with * * * competitors," *United States* v. *Citizens & S. Nat'l Bank*, 422 U.S. 86, 116 (1975), are "the supreme evil of antitrust: collusion," *Verizon Commc'ns, Inc.* v. *Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398, 408 (2004) (*Trinko*).

3. Solvay's analysis of the settlement of paragraph IV litigation with Watson and Paddock/Par vividly illustrates the economic analysis outlined above. In general, Solvay's analysis revealed that, absent a reverse payment, the parties had the opposing interests that one expects competitors to have: An earlier agreed-upon

generic entry date would have been acceptable to the generic manufacturers, because that would yield profits that equaled or exceeded the profits the generic manufacturers would expect from continuing to litigate. See Complaint ¶¶ 57, J.A. 43. By contrast, a later agreed-upon entry date made settlement more profitable for Solvay, because that would preserve its monopoly profits. *Id.* ¶ 58, J.A. 43-44. But Solvay recognized that if it could pay its potential competitors, then all parties would earn more profit by delaying competition. *Ibid.* Solvay therefore pursued a strategy of paying its potential generic competitors to agree to a later entry date, which in turn increased the combined pool of profits available to all the manufacturers, at the expense of consumers.

B. Reverse-Payment Agreements Do Not Further, And In Important Respects Disserve, The Purposes Of The Patent Act

The FTC brought suit in this case under Section 5 of the FTC Act, 15 U.S.C. 45, which prohibits "[u]nfair methods of competition in or affecting commerce." 15 U.S.C. 45(a)(1). Just as an agreement not to compete among potential competitors ordinarily is a prohibited "contract * * * in restraint of trade" under Section 1 of the Sherman Act, 15 U.S.C. 1, such an agreement is ordinarily an "[u]nfair method[] of competition" proscribed by the FTC Act. See, *e.g.*, *California Dental*, 526 U.S. at 762 n.3 ("The FTC Act's prohibition of unfair competition and deceptive acts or practices overlaps the scope of § 1 of the Sherman Act aimed at prohibiting restraint of trade.") (citation omitted). The question presented in this case is whether, and under what circumstances, an agreement not to compete ceases to be

"unfair" because it is encompassed within the settlement of ongoing patent litigation.

Under the Patent Act and this Court's precedents, a brand-name manufacturer's good-faith effort to enforce its patent through litigation cannot subject it to liability under the antitrust laws, even though the purpose of such litigation is to forestall competition. Nor should antitrust liability ordinarily attach to a settlement by which the parties to paragraph IV litigation simply agree on a compromise date of generic entry. Although such an agreement entails a restriction of competition, that is the natural subject of compromise in a suit whose very aim is to restrict competition. Significantly, the extent of that restriction is kept in check by the generic manufacturer's financial incentive to negotiate the earliest possible entry date that the strength of its bargaining position enables it to obtain, in turn affording some assurance that the agreed-upon entry date reflects the strength of the patentee's infringement claim. That justification evaporates, however, when the parties' agreement provides for a substantial reverse payment, because such a payment can be expected to redirect the generic manufacturer's financial incentive into preserving the brand-name manufacturer's monopoly for as long as that monopoly will be profitable.

1. A valid patent confers a right to exclude others from practicing the invention it claims. 35 U.S.C. 154(a)(1). But simply holding a patent does not result in the automatic exclusion of potential rivals who choose to test the patent's validity or scope in court. See *In re K-Dur Antitrust Litig.*, 686 F.3d 197, 214-215 (3d Cir. 2012), petitions for cert. pending, No. 12-245 (filed Aug. 24, 2012) and No. 12-265 (filed Aug. 29, 2012). To enforce a contested patent, a patentee must prove 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). And while 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 held invalid despite it, see *Validity of Litigated Patents*, 26 AIPLA Q.J. at 205.

A patentee 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 Indus., Inc.*, 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. The consequences of that possibility are magnified by the rule of *Blonder-Tongue Laboratories, Inc.* v. *University of Illinois Foundation*, 402 U.S. 313, 350 (1971), that a determination of patent invalidity may be given collateral estoppel effect against the patentee in a subsequent infringement suit against a different party. The risks attendant to patent enforcement are part of the balance struck by the patent laws.

2. Although the Patent Act does not expressly authorize the use of voluntary settlements to resolve patent-infringement suits, it is well-established that such agreements do not generally violate the antitrust laws. See *Standard Oil Co. (Ind.)* v. *United States*, 283 U.S. 163, 171 (1931) (stating, in the patent context, that "[w]here there are legitimately conflicting claims or threatened interferences, a settlement by agreement,

rather than litigation, is not precluded by the [Sherman] Act"). At the same time, private agreements that settle patent litigation do not enjoy the antitrust immunity afforded to litigation itself. Cf. *United States* v. *Masonite Corp.*, 316 U.S. 265, 277 (1942) ("Beyond the limited monopoly which is granted, the arrangements by which the patent is utilized are subject to the general law.").

Thus, while the parties to patent-infringement litigation have substantial latitude to settle their differences in accordance with the settlement practices commonly used in private lawsuits, the antitrust analysis requires a nuanced examination of the specific terms of the parties' agreement. When the parties to a Hatch-Waxman settlement simply agree upon a compromise date of generic entry, with no money or similar consideration flowing from the brand-name to the generic manufacturer, the settlement is unlikely to raise antitrust concerns. That is so for two basic reasons.

First, an agreement of that nature fits comfortably within traditional understandings of the way in which private litigation is generally settled. The typical settlement provides for a compromise outcome that falls between the dispositions that would result from judgments in favor of the plaintiff and defendant respectively. In paragraph IV litigation, a judgment in favor of the brand-name manufacturer would allow continued exclusion of generic competition until the patent expires, while a judgment for the generic manufacturer would facilitate immediate generic entry. An agreed-upon date of generic entry in between those endpoints is closely analogous to the typical settlement of a suit for money damages, under which the defendant agrees to pay some portion of what it would be required to pay if it litigated and lost. And although such a compromise settlement of

paragraph IV litigation will entail the parties' agreement not to compete, that feature alone is not a reason for skepticism in the patent litigation context, where the underlying dispute concerns the patentee's claimed legal right to prevent competition.

Second, in negotiating a compromise date of generic entry, the generic manufacturer has a substantial financial incentive to press for the earliest possible entry date, keeping the competitive consequences of the settlement agreement in check. For example, a generic manufacturer that believes it has a strong chance of success typically will not accept a settlement that delays its entry for most of the patent life. See, *e.g.*, Michael J. Meurer, *The Settlement of Patent Litigation*, 20 RAND J. Econ. 77, 77-79 (1989); Carl Shapiro, *Antitrust Analysis of Patent Settlements Between Rivals*, Antitrust, Summer 2003, at 70, 75. The generic manufacturer's desire to maximize its own profits therefore has the practical effect of aligning its interests in paragraph IV litigation with those of consumers, who benefit from the lower prices that generic competition provides. Cf. *Premier Elec. Constr. Co.* v. *National Elec. Contractors Ass'n*, 814 F.2d 358, 369 (7th Cir. 1987) (Easterbrook, J.) ("Th[e] rationale [for approving particular restraints of trade] depends on the alignment of interests between consumers and manufacturers. Destroy that alignment and you destroy the power of the argument."). For that reason, a generic manufacturer's acceptance of a particular deferred entry date provides significant assurance that the agreed-upon date roughly corresponds to the parties' assessments of their likelihood of success in the litigation.

3. Those rationales are inapplicable, however, to settlements that include reverse payments from brand-

name to generic manufacturers. Payments from patentees to accused infringers (or from defendants to plaintiffs more generally) are not a traditional settlement term; to the contrary, they appear to be essentially unknown outside the Hatch-Waxman context. And this Court has never suggested that the bundle of rights a patent provides to its holder includes the right to share the patentee's monopoly profits to induce potential competitors to abandon their efforts to compete or stay out of the market altogether. See *Masonite*, 316 U.S. at 278-282; *United States* v. *Line Material Co.*, 333 U.S. 287, 314-315 (1948); *United States* v. *United States Gypsum Co.*, 333 U.S. 364, 400 (1948); *United States* v. *New Wrinkle, Inc.*, 342 U.S. 371, 378-380 (1952); *United States* v. *Singer Mfg. Co.*, 374 U.S. 174, 196-197 (1963).

Lacking support in the Patent Act and traditional settlement practice, the presence of a reverse payment raises concerns about the integrity of the competition-restricting features of the settlement. The effect of a reverse payment is to sever the alignment of interests that would otherwise exist between the generic manufacturer and consumers when the parties to paragraph IV litigation negotiate a compromise date of generic entry. If the brand-name manufacturer can share its monopoly profits with its potential competitor, both manufacturers will maximize their profits by delaying generic entry, regardless of the parties' assessments of the suit's likely outcome. Where that incentive exists, the generic manufacturer's assent to a particular date of entry provides no assurance that the interests of consumers have been adequately protected in the settlement process. As a leading commentator explains, under a reverse-payment agreement, "the exclusion [of a generic competitor] 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.

One court has nonetheless suggested that reverse-payment agreements are no different in principle from the typical settlement because "*any* settlement agreement can be characterized as involving 'compensation' to the defendant, who would not settle unless he had something to show for the settlement," *Asahi Glass Co.* v. *Pentech Pharms., Inc.*, 289 F. Supp. 2d 986, 994 (N.D. Ill. 2003) (Posner, J.), appeal dismissed, 104 Fed. Appx. 178 (7th Cir. 2004). That reasoning is faulty. To be sure, any settlement that a defendant accepts presumably affords some benefit that the defendant would not receive if it litigated the suit *and lost*. The extraordinary and distinguishing feature of reverse-payment agreements, however, is that the defendant generic manufacturers receive something—a substantial cash payment from the brand-name manufacturer that holds a patent—that they could not hope to obtain even if they *prevailed* in the litigation. That feature in turn implies the other terms of the settlement agreement are disconnected from any justification they might otherwise have had in the Patent Act.

C. Reverse-Payment Agreements Frustrate The Purposes Of The Hatch-Waxman Amendments

"[A]ntitrust analysis must sensitively recognize and reflect the distinctive economic and legal setting of the regulated industry to which it applies." *Trinko*, 540 U.S. at 411 (brackets in original) (citation omitted). The Hatch-Waxman Amendments reflect a strong congressional policy that favors testing the scope and validity of pharmaceutical patents, with a view to realizing the benefits of generic competition at the earliest appropri-

ate time. See *Pharmaceutical Patent Settlement*, 81 N.Y.U. L. Rev. at 1614 (explaining how reverse-payment agreements undermine the Amendments' careful plan). Reverse-payment agreements frustrate that procompetitive policy by short-circuiting the Amendments' procedures in a way that tends to result in later generic entry than would otherwise occur. See *Pay-for-Delay Report* 2 (finding that Hatch-Waxman settlements with reverse payments were associated with generic entry an average of nearly 17 months later than settlements without). The lead sponsors of the eponymous Hatch-Waxman Amendments have both expressed sharp disapproval of the spread of reverse-payment agreements.[5]

In particular, Congress established the paragraph IV litigation framework to facilitate early and definitive resolution of patent disputes. The Hatch-Waxman Amendments offer substantial incentives both to generic applicants (the 180-day exclusivity period under 21 U.S.C. 355 (j)(5)(B)(iv)) and to brand-name manufacturers (the automatic 30-month stay of FDA approval under 21 U.S.C. 355(j)(5)(B)(iii)) to engage in such litigation. See pp. 5-6, *supra*. Although the Amendments do not compel parties to litigate paragraph IV cases to judgment, nothing in the Amendments contemplates that a patentee will pay an accused infringer in order to escape paragraph IV litigation.

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[5] Senator Orrin Hatch has said that he "f[ou]nd these type of reverse payment collusive arrangements appalling." 148 Cong. Rec. 15,354 (2002). Representative Henry Waxman has explained that "'[t]he law has been turned on its head.' * * * 'We are trying to encourage more generics and through different business arrangements, the reverse has happened.'" Cheryl Gay Stolberg & Jeff Gerth, *How Companies Stall Generics and Keep Themselves Healthy*, N.Y. Times, July 23, 2000, at A1.

The periods of brand-name monopoly pricing that accompany reverse-payment agreements upset the Amendments' "fundamental balance" between innovation and competition. 130 Cong. Rec. 24,425 (1984) (statement of Rep. Waxman); see *House Report* Pt. 2, at 30 (explaining that the Amendments achieve "what the Congress has traditionally done in the area of intellectual property law[:] balance the need to stimulate innovation against the goal of furthering the public interest"); see also *K-Dur*, 686 F.3d at 217 ("[I]n passing the Hatch-Waxman Act, Congress drew a careful line between patent protection and the need to provide incentives for competition in the pharmaceutical industry."). The Hatch-Waxman Amendments undoubtedly benefit generic applicants in some respects, and brand-name manufacturers may well be anxious when paragraph IV certifications force them into "rolling the dice and risking their monopoly profits in * * * patent litigation." Pet. App. 3a. But Congress balanced those features of the Amendments with substantial assurances of protection from generic competition for deserving brand-name manufacturers, both through extension of patent terms and through regulatory measures that delay generic manufacturers' opportunity to file or obtain approval of an ANDA.[6] Congress's balance would be upset by adding to these statutory assurances of protection from competition the opportunity for a brand-name manufac-

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[6] See, *e.g.*, 35 U.S.C. 156 (extension of patent term); 21 U.S.C. 355(j)(5)(D)(ii) (five-year exclusivity for new chemical entity drugs); 21 U.S.C. 355(j)(5)(D)(iii) (three-year exclusivity for new clinical studies); see generally FDA, *Frequently Asked Questions on Patents and Exclusivity* (Dec. 5, 2012), http://www.fda.gov/Drugs/DevelopmentApprovalProcess/ucm079031.htm.

turer to purchase still more protection by sharing its monopoly profits.

D. Reverse-Payment Agreements Are Appropriately Treated As Presumptively Unlawful Under A "Quick Look" Rule Of Reason Analysis

Although there are abundant reasons to be skeptical of reverse-payment agreements as a class, such agreements should not be treated as categorically unlawful, because per se condemnation would foreclose consideration of possible legitimate justifications for the payment or procompetitive potential that some such agreements may have. See *NCAA* v. *Board of Regents*, 468 U.S. 85, 103-104 (1984) (explaining that per se condemnation is appropriate only if "the likelihood of anticompetitive conduct [is] so great as to render unjustified further examination of the challenged conduct"). Rather, a "so-called 'quick look' or 'truncated rule of reason' analysis" is appropriate because 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, a reverse-payment agreement is presumed to be anticompetitive, and the antitrust defendants bear "the burden of procompetitive justification," *California Dental*, 526 U.S. at 771, by showing, for example, "some countervailing procompetitive virtue" to their agreement, *FTC* v. *Indiana Fed'n of Dentists*, 476 U.S. 447, 459 (1986).

1. "The rule of reason is the accepted standard for testing whether a practice restrains trade in violation of [Sherman Act] § 1." *Leegin Creative Leather Prods., Inc.* v. *PSKS, Inc.*, 551 U.S. 877, 885 (2007). But an "elaborate study of the industry" is not always required. *National Soc'y of Prof'l Eng'rs* v. *United States*, 435 U.S. 679, 692 (1978). "What is required, rather, is an

enquiry meet for the case," *California Dental*, 526 U.S. at 781, arrived at by common-law decision-making, *State Oil Co.* v. *Khan*, 522 U.S. 3, 20-21 (1997). Accordingly, courts may "establish the litigation structure to ensure the rule [of reason] operates to eliminate anticompetitive restraints from the market and to provide more guidance to businesses." *Leegin,* 551 U.S. at 898. Such a structure may include rules "for offering proof, or even presumptions where justified, to make the rule of reason a fair and efficient way to prohibit anticompetitive restraints and to promote procompetitive ones." *Id.* at 898-899.

A presumption of illegality is appropriate under a "quick look" rule of reason analysis when "the great likelihood of anticompetitive effects can be easily ascertained," *California Dental*, 526 U.S. at 770, or "a confident conclusion about the principal tendency of a restriction" may be drawn, *id.* at 781. See, *e.g.*, *NCAA*, 468 U.S. at 110 ("[A] naked restraint on price and output requires some competitive justification even in the absence of a detailed market analysis."); *Indiana Fed'n of Dentists*, 476 U.S. at 459 (explaining that a restraint "imped[ing] the 'ordinary give and take of the market place'" cannot be sustained "[a]bsent some countervailing procompetitive virtue") (quoting *National Soc'y of Prof'l Eng'rs*, 435 U.S. at 692).

2. A "quick look" analysis is appropriate here. Reverse-payment agreements closely resemble other agreements not to compete that this Court has previously condemned. They also subordinate the public interest to the agreeing parties' collusive self-interest, in a manner that is generally devoid of any countervailing virtue.

"[A]bsent proof of other offsetting consideration, it is logical to conclude that the *quid pro quo* for [a reverse]

payment was an agreement by the generic to defer entry beyond the date that represents an otherwise reasonable litigation compromise." *K-Dur*, 686 F.3d at 218 (quoting *In re Schering-Plough Corp.*, 136 F.T.C. 956, 988 (2003), vacated, 402 F.3d 1056 (11th Cir. 2005), cert. denied, 548 U.S. 919 (2006)). As explained above, pp. 20-24, *supra*, such an agreement closely resembles those that this Court has consistently condemned as per se unlawful. Cf. *Polygram Holding, Inc.* v. *FTC,* 416 F.3d 29, 37 (D.C. Cir. 2005) (Ginsburg, C.J.) ("[A] rebuttable presumption of illegality arises * * * from the close family resemblance between the suspect practice and another practice that already stands convicted in the court of consumer welfare.").

Relatedly, a reverse payment reflects the "strong economic self-interest of the parties" to enter into settlements that delay entry. *California Dental*, 526 U.S. at 771 (quoting *United States* v. *Brown Univ.*, 5 F.3d 658, 677 (3d Cir. 1993)); see pp. 21-24, *supra* (discussing the financial motivations behind reverse-payment agreements in general and the agreements here in particular). To be sure, in negotiating any Hatch-Waxman settlement, the brand-name manufacturer will presumably attempt to obtain the longest period of market exclusivity that the perceived strength of its litigating position enables it to achieve. So long as reverse payments are treated as a disfavored settlement term, however, the generic manufacturer can be expected to function as an effective counterweight, seeking to negotiate the earliest possible entry date in order to maximize its own profits. If a settlement without a reverse payment is ultimately consummated, that dynamic provides good reason to presume that consumer interests have been adequately protected in the negotiating

process, and that the period of brand-name monopoly the settlement allows is roughly commensurate with the perceived strength and scope of the relevant patent.

By contrast, when a Hatch-Waxman settlement provides for a substantial reverse payment, the most natural inference is that the payment has purchased an additional increment of market exclusivity. Reverse payments also subordinate the public interests in judicial testing of patent scope and validity, see p. 48, *infra*, and in the integrity of the Hatch-Waxman Amendments' balance between competition and innovation, see pp. 30-33, *supra*. An antitrust court can appropriately treat such agreements as presumptively anticompetitive, particularly since their procompetitive potential is modest, speculative, or achievable by other means (such as a settlement without a reverse payment). See *K-Dur*, 686 F.3d at 218.[7] Such a presumption accords with the weight of legal and economic scholarship.[8]

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[7] Because the agreements challenged in this case involve direct payments of money, this case does not require this Court to address what other consideration would similarly justify a "quick look" analysis. If the economic realities of a settlement coupling an alternative form of consideration with delayed generic entry paralleled those of the direct payments here, such that a court could draw a similarly "confident conclusion about the principal tendency" of those alternative arrangements, *California Dental*, 526 U.S. at 781, then a similar "quick look" analysis would be justified. Cf. *Aggregate Approach to Antitrust,* 109 Colum. L. Rev. at 663-666 (offering possible examples of such arrangements).

[8] See, *e.g.*, Jeremy Bulow, *The Gaming of Pharmaceutical Patents*, in 4 *Innovation Policy and the Economy* 145, 166 (Adam B. Jaffe et al. eds., 2004); Michael A. Carrier, *Unsettling Drug Patent Settlements: A Framework for Presumptive Illegality*, 108 Mich. L. Rev. 37, 67-79 (2009); Einer Elhauge & Alex Krueger, *Solving the Patent Settlement Puzzle*, 91 Texas L. Rev. 283, 292 (2012); *Aggregate Approach to Antitrust*, 109 Colum. L. Rev. at 645-670; Herbert

3. If the plaintiff establishes the existence of a reverse-payment agreement, then the burden shifts to the defendants in a rule-of-reason analysis that "focuses directly on the challenged restraint's impact on competitive conditions." *National Soc'y of Prof'l Eng'rs*, 435 U.S. at 688. The parties to the agreement bear the "heavy burden of establishing an affirmative defense which competitively justifies [their agreement's] apparent deviation from the operations of a free market." *NCAA*, 468 U.S. at 113; see *Polygram Holding*, 416 F.3d at 36 (Ginsburg, C.J.) ("[T]o avoid liability, the defendant must either identify some reason the restraint is unlikely to harm competition or identify some competitive benefit that plausibly offsets the apparent anticompetitive harm.").

There are two primary ways in which the parties to a reverse-payment settlement, if later sued for alleged antitrust violations, could rebut the presumption that the agreement is anticompetitive. First, the parties could show that "any money that changed hands was for something other than a delay," *K-Dur*, 686 F.3d at 218, such as the generic manufacturer's provision of property or services unrelated to the brand-name manufacturer's monopoly. Although there is no fixed formula for making that showing, and a court would need to consider the totality of the circumstances surrounding the agreement, relevant considerations would include whether the payment reflected bona fide fair consideration for the property or services; whether other terms of the side transaction comported with industry standards; the existence of previous dealings between the parties on

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Hovenkamp et al., *Anticompetitive Settlement of Intellectual Property Disputes*, 87 Minn. L. Rev. 1719, 1759 (2003); Carl Shapiro, *Antitrust Limits to Patent Settlement*, 34 RAND J. Econ. 391, 408 (2003).

the subject matter of the side transaction; a history of demonstrated interest in or need for the property or services on the part of the brand-name manufacturer; and the course and content of the manufacturers' negotiations over the agreements. Sufficient evidence on such subjects could dispel the presumptive inference that the payment secured a delayed entry date.

Second, the defendants in the antitrust suit could rebut the presumption by showing that the payment was commensurate with the litigation costs that the brand-name manufacturer avoided by settling. Because such a payment is most naturally understood to reflect the parties' agreed division of their savings from avoiding litigation, it does not suggest that the compromise date of generic entry specified in the settlement reflects anything but the parties' true assessment of the merits of the litigation. See *Schering-Plough*, 136 F.T.C. at 1000 n.69; Michael A. Carrier, *Unsettling Drug Patent Settlements: A Framework for Presumptive Illegality*, 108 Mich. L. Rev. 37, 76-77 (2009) ("A reverse payment that does not exceed [litigation] costs does not present significant concern since the parties would have been required to spend this money in any event.").

In other circumstances (which are likely rare), certain unusual business or litigation justifications may also supply a rebuttal. For example, the Third Circuit noted that "a modest cash payment that enables a cash-starved generic manufacturer to avoid bankruptcy and begin marketing a generic drug might have an overall effect of increasing the amount of competition in the market." *K-Dur*, 686 F.3d at 218. Lower courts have had little opportunity to explore the other possible "countervailing procompetitive virtue[s]," *Indiana Fed'n of Dentists*, 476 U.S. at 459, to particular settle-

ments, but in general defendants should be fully heard on each of their "proffered justifications," *NCAA*, 468 U.S. at 113. The evidence supporting any of those rebuttals is likely to be uniquely in the possession of the parties to the reverse-payment agreement. The defendants' superior access to evidence of any procompetitive tendencies of their agreement is a further reason to favor the burden-shifting approach of a "quick look" analysis. See, *e.g.*, 2 Kenneth S. Broun et al., *McCormick on Evidence* § 343, at 500 (6th ed. 2006).

4. The "fundamental goal of antitrust law" is to enhance consumer welfare by increasing output and decreasing the price of goods and services. *NCAA*, 468 U.S. at 107; cf. Robert H. Bork, *The Antitrust Paradox: A Policy at War with Itself* 67 (1978) ("The per se rule against naked price fixing and similar agreements not to compete * * * can be explained only by a preference for consumer welfare as the exclusive goal of antitrust."). Antitrust law seeks to achieve that goal, however, not by inducing business entities to behave altruistically, but by channeling companies' pursuit of their own self-interest into conduct that is likely to benefit consumers. See *Premier Elec.*, 841 F.2d at 369-370 (Easterbrook, J.). If the governing legal regime treated payments not to compete as a legitimate means of earning income, firms could not be faulted for accepting (or making) such payments when doing so appeared likely to maximize company profits. By proscribing such arrangements, antitrust law seeks to benefit consumers by making actual competition in the marketplace the profit-maximizing course of conduct.

Similarly here, a rule treating reverse payments as presumptively unlawful will preserve incentives for brand-name and generic manufacturers to resolve para-

graph IV litigation in alternative ways that do not undo the manufacturers' competitive relationship. Most obviously, the parties may settle with an earlier entry date and no reverse payment, which would benefit consumers by lengthening the period during which price competition could occur. That is by far the most common type of settlement of paragraph IV litigation. See FTC, *Agreements Filed with the Federal Trade Commission Under the Medicare Prescription Drug, Improvement, and Modernization Act* 2 (FY 2012), http://www.ftc.gov/os/2013/01/130117mmareport.pdf (*2012 MMA Report*).

To be sure, in some paragraph IV litigation that might otherwise have been settled through reverse-payment agreements, a rule discountenancing reverse payments may cause the parties to litigate to judgment. But in the aggregate, those judgments on the merits will reflect results more in keeping with the policies of the antitrust laws, the Patent Act, and the Hatch-Waxman Amendments than if all the cases had been settled with reverse payments. The judgments in such cases will reflect determinations by judges or juries, based on adversary presentations by the brand-name and generic manufacturers, as to the *actual* exclusionary force of the relevant patents. By contrast, the presumptive purpose of a reverse payment is to compensate the generic manufacturer for accepting an entry date later than the parties' assessments of the merits (and thus of their own bargaining power) would otherwise have produced.

II. THE "QUICK LOOK" APPROACH, UNDER WHICH REVERSE-PAYMENT AGREEMENTS ARE TREATED AS PRESUMPTIVELY UNLAWFUL, IS SUPERIOR TO THE TWO PRINCIPAL ALTERNATVE MODES OF ANALYSIS

The case law has identified two principal alternatives to the "quick look" approach described above and adopt-

ed by the Third Circuit in *K-Dur*. First, the court below 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." Pet. App. 28a. The Second and Federal Circuits have also adopted that legal standard, which is commonly known as the scope-of-the-patent approach. See *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 212-213 (2d Cir. 2006), cert. denied, 551 U.S. 1144 (2007); *In re Ciprofloxacin Hydrochloride Litig.*, 544 F.3d 1323, 1336 (Fed. Cir. 2008), cert. denied, 557 U.S. 920 (2009) (*Cipro*). Second, it has been suggested that antitrust analysis of a reverse-payment agreement should focus on "the strength of the patent as it appeared at the time at which the parties settled." *Tamoxifen*, 466 F.3d at 228 (Pooler, J., dissenting). The "quick look" approach is superior to both of those alternatives.[9]

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[9] The view that reverse-payment agreements are presumptively unlawful 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 U.S. Amicus Br., *K-Dur*, *supra* (No. 10-2077) (filed May 18, 2011); U.S. Amicus 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. Amicus Br., *Arkansas Carpenters*, *supra* (No. 05-2851) (filed June 4, 2010, on petition for rehearing). 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 (2006) (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 approach is an "insufficiently

A. The Scope-Of-The-Patent Approach Inappropriately Insulates Reverse-Payment Agreements From Meaningful Antitrust Scrutiny

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.*, Pet. App. 23a-24a; *Tamoxifen*, 466 F.3d at 201-202, 213-214; *Valley Drug Co.* v. *Geneva Pharms., Inc.*, 344 F.3d 1294, 1304-1306 (11th Cir. 2003), cert. denied, 543 U.S. 999 (2004). 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 patentee had prevailed. Use of that forgiving baseline is contrary to basic competition-law

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stringent standard" for determining the propriety of those settlements. U.S. Br. at 8, *Joblove* v. *Barr Labs., Inc.*, 551 U.S. 1144 (2007) (No. 06-830); 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 anticompetitive, 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, *FTC* v. *Schering-Plough Corp.*, 548 U.S. 919 (2006) (No. 05-273). This Court denied certiorari in all three cases. See *Andrx Pharms., Inc.* v. *Kroger Co.*, 543 U.S. 939 (2004); *Schering-Plough*, *supra*; *Joblove*, *supra*.

principles; it derives no support from the Patent Act; and it disserves consumer welfare.[10]

1. As explained above (see pp. 20-21, *supra*), 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. Parties to such an agreement cannot avoid antitrust liability simply by demonstrating that 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 therefore does not mean that the same result can lawfully be achieved through an agreement between competitors.

2. Nothing in the Patent Act suggests that, in determining the appropriate baseline against which the anticompetitive potential of a reverse-payment agreement will be measured, the antitrust court should assume that the relevant patent is valid and infringed. Reverse-payment agreements in Hatch-Waxman cases serve by definition to settle litigation whose outcome is uncertain. The parties to any such agreement, moreover, include both the generic manufacturer, who has submitted a

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[10] The reverse-payment agreements at issue here allow generic entry on August 31, 2015, five years before the relevant patent will expire. See Pet. App. 10a, 12a. The agreement thus contemplated a greater degree of generic competition than might have occurred if the case had been litigated to judgment and the patentee (Solvay) had prevailed. Under the scope-of-the-patent approach, however, that fact is irrelevant to the antitrust inquiry. Rather, because that approach effectively condemns only agreements that limit generic competition *more severely* than would a court judgment in the patentee's favor, it would treat the agreement here as no less lawful if the generic manufacturers had agreed to defer competition until the date of patent expiration.

paragraph IV certification stating that the patent is invalid or that its own product will not be infringing, and the brand-name manufacturer, who has responded to the paragraph IV certification by initiating an infringement action.

Given the uncertainty as to the outcome of the infringement suit, and the contracting parties' divergent positions on the merits of that litigation, it would be unsound to assume for antitrust purposes that one party to the reverse-payment agreement was right and the other was wrong. Moreover, because the scope-of-the-patent approach assumes (at least once the non-sham threshold has been surmounted) that all patents are equally valid and infringed, it "produces the absurd result that an ironclad patent and a trivial patent have the same exclusionary force." *Aggregate Approach to Antitrust*, 109 Colum. L. Rev. at 638. Thus, the scope-of-the-patent approach allows the patentee to purchase the same period of exclusivity that a successful infringement suit would produce, even if all would concede that the patentee had little likelihood of prevailing in the infringement litigation. See *Tamoxifen*, 466 F.3d at 211 (expressing concern about the "troubling dynamic" that "the patents most likely to be the subject of exclusion payments would be precisely those patents that have the most questionable validity") (citation omitted).

3. The scope-of-the-patent approach, which effectively assumes for antitrust purposes that the relevant patent is valid and infringed, likewise finds no support in the available empirical evidence concerning actual outcomes in litigated patent cases. Both in the Hatch-Waxman context and more generally, accused infringers have prevailed in a substantial percentage of such lawsuits. See pp. 6-7, *supra*. Consumers have reaped

enormous benefits from the intense competition—in both the marketplace and the courtroom—between brand-name and generic manufacturers. When the brand-name manufacturer holds a strong patent, it is likely to prevail in litigation and to prevent or significantly delay generic entry—as it should, in order to preserve the incentives to innovate that benefit consumers in the long run. Yet generic manufacturers have fulfilled the promise of the Hatch-Waxman Amendments by repeatedly succeeding in inventing around narrow drug patents and invalidating others, bringing competition to the marketplace years before the patents would have expired and saving consumers billions of dollars. See, *e.g.*, *Generic Pharmaceuticals: Marketplace Access and Consumer Issues: Hearing Before the Senate Comm. on Commerce, Science & Transportation*, 107th Cong., 2d Sess. 61 (2002) (Statement of Kathleen D. Jaeger, President & CEO, Generic Pharm. Ass'n) (estimating successful challenges to patents related to the widely used drugs Prozac, Zantac, Taxol, and Platinol alone as saving consumers more than $9 billion).

If this Court were to adopt the scope-of-the-patent approach as the applicable nationwide rule, brand-name manufacturers would have little reason *not* to offer their potential generic competitors payments not to compete, and the generic manufacturers would have little reason to refuse. Consumers would then bear the costs of the increased frequency and severity of reverse-payment agreements. Such agreements are demonstrably associated with delayed entry of generic competition, costing consumers billions of dollars each year. See *Pay-for-Delay Report* 2. A large fraction of the drug market would be susceptible to the influence of such agreements: 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. See *id.* at 9. This Court's adoption of the scope-of-the-patent approach would likely embolden manufacturers to enter into more such agreements, on more harmful terms.

B. The Scope-Of-The-Patent Approach Relies On An Uncritical Acceptance Of The Benefits Of Settlement In General, And Of The Necessity Of Reverse Payments In Particular

Some courts have found the scope-of-the-patent approach to be justified by 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. Although settlements of litigation often further the public interest and benefit consumers, the scope-of-the-patent approach mistakenly assumes both that Hatch-Waxman settlements are always in the public interest and that reverse payments are a necessary component of such settlements.

1. The "quick look" approach that we advocate neither precludes nor treats as presumptively unlawful all voluntary settlements of patent-infringement suits between brand-name and generic drug manufacturers. To the contrary, if the "quick look" approach is adopted, the parties to Hatch-Waxman suits will retain broad latitude to avoid the burdens and uncertainty of litigation by agreeing on a compromise date of generic entry. Only those settlements that involve a reverse payment (or its functional equivalent) from the plaintiff to the defendant would be presumed anticompetitive. See pp. 34-36 & note 7, *supra*; *K-Dur*, 686 F.3d at 218. Such payments are scarcely an essential or traditional feature of settlement practice, and they raise distinct threats to con-

sumer interests, since the natural effect of a reverse payment is to dilute the generic manufacturer's usual incentive to negotiate for the earliest achievable entry date. See *Aggregate Approach to Antitrust*, 109 Colum. L. Rev. at 666, 668-669; p. 28, *supra*.

Even in the Hatch-Waxman setting, reverse payments are not necessary to achieve settlements. In the early 2000s, before any court had adopted the scope-of–the-patent approach, it appears that manufacturers regularly settled paragraph IV litigation without reverse payments. In 2012, more than 70% of Hatch-Waxman settlements did *not* involve the brand-name manufacturer compensating the generic manufacturer and the generic manufacturer agreeing to delay entry. *2012 MMA Report* 2. Adopting the "quick look" approach therefore "w[ould] leave the vast majority of pharmaceutical patent settlements unaffected." *K-Dur*, 686 F.3d at 218.

2. In any event, the public policy favoring settlement of litigation does not invariably "displace countervailing public policy objectives." *K-Dur*, 686 F.3d at 217. "While public policy wisely encourages settlements," some settlements can impose "too high a price." *McDermott, Inc.* v. *AmClyde*, 511 U.S. 202, 215 (1994); cf. *United States* v. *Reliable Transfer Co.*, 421 U.S. 397, 408 (1975) ("Congestion in the courts cannot justify a legal rule that produces unjust results in litigation simply to encourage speedy out-of-court accommodations.").

Competition law itself embodies some of those countervailing objectives. Two parties to an ordinary commercial dispute might be willing to put their differences aside if they could enjoy the rewards of a price-fixing conspiracy. But the mere fact that such an agreement was memorialized in a litigation settlement would not

exonerate it. See, *e.g.*, 12 *Antitrust Law* ¶ 2046c1, at 342-343 ("[W]e would not permit parties to settle an ordinary breach of contract dispute by an agreement fixing their prices or dividing their markets.").

Another countervailing objective is the public benefit from judicial testing of patent scope and elimination of invalid patents. "A patent by its very nature is affected with a public interest. * * * The far-reaching social consequences of a patent, therefore, give the public a paramount interest in seeing that patent monopolies * * * are kept within their legitimate scope." *Precision Instrument Mfg. Co.* v. *Automotive Maint. Mach. Co.*, 324 U.S. 806, 816 (1945). "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." *Pope Mfg. Co.* v. *Gormully*, 144 U.S. 224, 234 (1892); see *Cardinal Chem. Co.* v. *Morton Int'l, Inc.*, 508 U.S. 83, 100-101 (1989); see also pp. 30-33, *supra* (discussing strong congressional policy in Hatch-Waxman Amendments favoring testing the scope and validity of pharmaceutical patents).

Still another countervailing consideration is the steep price consumers would pay (in comparison to the parties' relatively modest savings from settlement) under the scope-of-the-patent approach. See C. Scott Hemphill & Mark A. Lemley, *Earning Exclusivity: Generic Drug Incentives and the Hatch-Waxman Act*, 77 Antitrust L.J. 947, 980 (2011) ("[L]itigation costs are dwarfed by the magnitude of the stakes at issue in these cases."); *Aggregate Approach to Antitrust,* 109 Colum. L. Rev. at 649-650 & n.85 (estimating a one-year delay in generic entry resulted in an average harm to consumers of at least $661 million per drug product); Am. Intellec-

tual Prop. Law Ass'n, *Report of the Economic Survey 2011*, at 35-36 (finding that patent litigation costs rarely exceed $10 million).

C. The Economic Incentives Created By The Hatch-Waxman Amendments Do Not Justify The Scope-Of-The-Patent Approach

Reverse-payment agreements bypass the Hatch-Waxman Amendments' framework for resolving patent disputes in a way that upsets the Amendments' balance between innovation and competition. See pp. 30-33, *supra*. Courts that have adopted the scope-of-the-patent approach have nonetheless invoked the Amendments as a purported source of support, characterizing reverse-payment agreements as a natural response to the incentives that the Amendments create. That reasoning is faulty.

1. The particular risks to brand-name manufacturers from Hatch-Waxman litigation do not excuse anti-competitive conduct by those manufacturers

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 Corp.* v. *FTC*, 402 F.3d 1056, 1074 (11th Cir. 2005), cert. denied, 548 U.S. 919 (2006). Those courts have reasoned that, because paragraph IV litigation typically occurs before the generic manufacturer has made commercial sales, the generic manufacturer has minimal exposure to a damages award, eliminating one subject of compromise that is often available in patent-infringement suits. See *Tamoxifen*, 466 F.3d at 206-207; *Schering-Plough*, 402

F.3d at 1074-1075. That aspect of the Hatch-Waxman Amendments provides no justification for the scope-of-the-patent approach.

First, the absence of a damages claim in paragraph IV litigation does not put brand-name manufacturers in a position substantially different from what other patentees might face. The Declaratory Judgment Act (DJA), 28 U.S.C. 2201, is available to a potential infringer who establishes a "real and substantial" and "definite and concrete" dispute with a patentee. *Aetna Life Ins. Co.* v. *Haworth*, 300 U.S. 227, 240-241 (1937). In some cases, that standard may be satisfied even though the DJA plaintiff has not yet engaged in conduct that could subject it to damages liability. See *Medimmune, Inc.* v. *Genentech, Inc.*, 549 U.S. 118, 126-134 (2007). Outside the Hatch-Waxman context, however, reverse payments have not been used (at least with any meaningful frequency) to settle declaratory judgment actions challenging the validity of patents.

Second, if a brand-name manufacturer faces unusually strong pressure to settle a particular Hatch-Waxman suit (either because its likelihood of prevailing is unusually low or because the costs of defeat would be unusually high), the generic challenger can exploit that pressure in either of two ways. The generic manufacturer can seek to negotiate the earliest possible date of generic entry, thereby maximizing its own ability to compete in the relevant market. Alternatively, the generic manufacturer can demand a substantial monetary payment in exchange for agreeing to a later entry date. So long as the agreed-upon entry date is no later than the date of patent expiration, the scope-of-the-patent approach treats those two responses as equally legitimate means of exploiting the generic manufacturer's bargaining

power. Collusion between competitors, however, has traditionally been viewed as "the supreme evil of antitrust." *Trinko*, 540 U.S. at 408. As between the two negotiating tactics described above, requiring the generic manufacturer to pursue the course that maximizes competition and consumer welfare accords with basic antitrust norms. See pp. 39-40, *supra*.

Third, the existence of financial motives for reverse-payment agreements is ultimately beside the point. The competition laws exist precisely to counteract commercial "environment[s] that encourage[]," *Tamoxifen*, 466 F.3d at 206, 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," *Socony-Vacuum*, 310 U.S. at 221; see *Masonite*, 316 U.S. at 276 ("Since there was price-fixing, the fact that there were business reasons which made the arrangements desirable to the [antitrust defendants] * * * would be no more a legal justification for price-fixing than were the 'competitive evils' in the *Socony-Vacuum* case."). Firms agree to restrain trade precisely because it is in their economic self-interest, and the antitrust laws condemn such restraints because they are socially harmful.

2. The possibility that other generic manufacturers will challenge the brand-name manufacturer's monopoly does not support the scope-of-the-patent approach

The court below expressed the views that "there usually are many potential challengers to a patent, at least to drug patents," and that "[i]f the patent actually is vulnerable, then presumably other generic companies

* * * will attempt to enter the market and make their own challenges to the patent." Pet. App. 35a-36a. That reasoning is unsound.

In general, the threat of subsequent generic competition is unlikely to mitigate concerns about a reverse-payment agreement with the first generic applicant. As the Third Circuit explained, "the initial challenger is necessarily the most motivated because, unlike all subsequent challengers, it stands to benefit from the 180-day exclusivity period of 21 U.S.C. § 355(j)(5)(B)(iv)." *K-Dur*, 686 F.3d at 215; see Herbert Hovenkamp, *Sensible Antitrust Rules for Pharmaceutical Competition*, 39 U.S.F. L. Rev. 11, 25-26 (2004). A subsequent generic applicant's entry can be delayed for a much lower price because a later applicant has much less to gain if it submits a paragraph IV certification and ultimately prevails in court. That is so not only because a successful second or later filer is not awarded a period of exclusivity, but also because it is likely to face competition from generic manufacturers who previously settled litigation. See Complaint ¶¶ 65, 76, J.A. 46, 49 (alleging that the settlements here, like typical Hatch-Waxman settlements, permit the settling generic manufacturer to enter the market immediately if a third-party prevails in patent litigation against the brand-name manufacturer).

Experience bears out this analysis: When multiple generic manufacturers have found it worthwhile to make paragraph IV certifications, brand-name manufacturers have often responded by simply making reverse payments to each generic competitor. See *2012 MMA Report* 1 (reporting 26 drug products associated with more than one reverse-payment agreement, and 14 drug products associated with at least three reverse-payment agreements).

D. The "Quick Look" Approach Is Preferable To An Alternative That Requires The Antitrust Court To Assess The Likely Outcome Of The Underlying Infringement Suit

A second alternative to the "quick look" approach is to compare the level of competition that a particular reverse-payment settlement allows to the likelihood that the patent holder would have prevailed in the underlying infringement suit. Under that mode of analysis, the antitrust court would assess the relative strength of the brand-name and generic manufacturers' competing arguments, as of the time of settlement, with respect to contested issues of patent validity and infringement. That approach would afford greater protection to consumer interests than does the scope-of-the-patent rule. This alternative is inferior to the "quick look" approach, however, because it is doctrinally anomalous and likely unworkable in practice.

Under usual antitrust principles, a collusive effort by firms to avoid competing is forbidden even if the prospect of competition was already uncertain. "[Competition] law does not condone the purchase of protection from uncertain competition any more than it condones the elimination of actual competition." 12 *Antitrust Law* ¶ 2030b, at 220; see pp. 20-21, *supra*. An agreement to divide markets or to fix prices can ordinarily be condemned as per se unlawful, without regard to the likelihood that actual competition would have occurred, or that the prices charged would have been different, in the absence of the agreement. Cf. 3 Phillip E. Areeda & Herbert Hovenkamp, *Antitrust Law* ¶ 657a2, at 162 (3d ed. 2008) ("[T]he government suitor need not show that competition is in fact less than it would be in some alternative universe in which the challenged conduct had not occurred. It is enough to show that anticompetitive

consequences are a naturally-to-be-expected outcome of the challenged conduct."). If a reverse-payment settlement is functionally comparable to the sorts of agreements that have previously received per se condemnation, it would be anomalous to hold the agreement lawful based on an after-the-fact determination that the patent holder's position in the infringement suit was particularly strong. By the same token, a Hatch-Waxman settlement that does not include any reverse payment (or its functional equivalent), but simply provides for a compromise date of generic entry, should ordinarily raise no antitrust concern, regardless of the perceived likelihood that the patent holder would have prevailed if the suit had been litigated to judgment.

Administrative concerns also strongly disfavor an approach that would tie the lawfulness of the manufacturers' agreement to a comparison with the projected outcome of the paragraph IV litigation. Many courts (including the one below) have recognized the disadvantages of effectively retrying the patent case inside the subsequent antitrust action. See Pet. App. 36a (describing the prospect of "deciding a patent case within an antitrust case about the settlement of the patent case" as an "[un]palatable" "turducken task"). Among those disadvantages are the powerful disincentive to settlement it creates (because the manufacturers know they may be forced by an antitrust plaintiff to effectively litigate the patent-infringement suit anyway) and the troublesome realignment of the generic manufacturer's interests it produces (because the generic manufacturer will argue in the subsequent antitrust suit that it had no hope of prevailing in patent litigation it had previously triggered through its own paragraph IV certification). The "quick look" approach avoids an inappropriate and

cumbersome retrial of the patent case by asking whether, in avoiding the risks that accompany patent infringement litigation, the parties have by contract obtained more exclusion than warranted in light of those risks.[11]

III. THE FTC'S COMPLAINT STATES A CLAIM UPON WHICH RELIEF CAN BE GRANTED

The FTC's complaint in this case states a claim under a "quick look" approach that treats reverse-payment agreements as presumptively unlawful. It alleges that Solvay is the seller of AndroGel® and was issued a patent that (Solvay contended) claimed the drug's formulation. Complaint ¶¶ 16, 31, 39-42, J.A. 32, 36, 38-39. The complaint further alleges that Watson and Par/Paddock are generic drug manufacturers that filed ANDAs with FDA seeking approval to market generic versions of AndroGel®, and that they made paragraph IV certifications to Solvay's patent, asserting that their products did not infringe Solvay's patent and that the patent was invalid. *Id.* ¶¶ 13-15, 44, 46, J.A. 31, 39-40. The complaint explains that entry by Watson and Par/Paddock would have substantially reduced Solvay's sales of AndroGel® and would have saved consumers hundreds

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[11] Quantification of damages in a private antitrust action might require an assessment of what sequence of events would likely have ensued in the absence of a reverse payment. Cf. *Atlantic Richfield Co.* v. *USA Petroleum Co.*, 495 U.S. 328, 341-342 (1990) ("The *per se* rule is a method of determining whether [Section] 1 of the Sherman Act has been violated, but it does not indicate whether a private plaintiff has suffered antitrust injury and thus whether he may recover damages."). That issue is not presented here because the FTC seeks only declaratory and prospective injunctive relief. See Pet. 31.

of millions of dollars a year. *Id.* ¶¶ 49-50, 58, 98, J.A. 41, 43, 57-58.

The complaint alleges that Solvay filed patent infringement actions against the generic challengers, which the parties later agreed to settle. Complaint ¶¶ 47, 65, 76, J.A. 40, 46, 49. In particular, Watson, Par, and Paddock agreed to refrain from marketing generic AndroGel® for nine years, until August 31, 2015. *Id.* ¶¶ 65, 76, J.A. 46, 49. Solvay agreed to make payments to Watson (starting at approximately $19 million during the first year of their agreement in 2006 and rising to more than $30 million annually by 2015), to Par (of $10 million annually), and to Paddock (of $2 million annually). *Id.* ¶ 66, 73-74, J.A. 46, 48. The agreements also stated that the generic manufacturers would provide certain services in support of Solvay's manufacturing and marketing of AndroGel®. See *id.* ¶¶ 66, 77, J.A. 46, 49. "By deferring competition, the parties would preserve monopoly profits that could be shared amongst them—at the expense of the consumer savings that would result from price competition." *Id.* ¶ 58, J.A. 43.

CONCLUSION

The judgment of the court of appeals should be reversed and the case remanded for further proceedings.

Respectfully submitted.

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APPENDIX

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:

Unfair methods of competition unlawful; prevention by Commission

(a) Declaration of unlawfulness; power to prohibit unfair 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(b) provides:

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, thereon 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 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 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 commercial 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 applicant 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 infringe-

ment 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 qualifying 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 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)(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 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.

(C) For a drug that is not intended to be absorbed into the bloodstream, the Secretary may es-

tablish 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) provided:

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), infor-

mation 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)(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 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 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 in-

fringed, 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 Sep-

tember 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 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 therapeutic 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 (2006 & Supp. V 2011) 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,

(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, or

(C)(i) with respect to a patent that is identified in the list of patents described in section 351(1)(3) of the Public Health Service Act (including as provided under section 351(1)(7) of such Act), an application seeking approval of a biological product, or

(ii) if the applicant for the application fails to provide the application and information required under section 351(1)(2)(A) of such Act, an application seeking approval of a biological product for a

patent that could be identified pursuant to section 351(1)(3)(A)(i) of such Act,

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, veterinary biological product or 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, veterinary biological product, or biological product,

(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, veterinary biological product, or biological product.

(D) the court shall order a permanent injunction prohibiting any infringement of the patent by the biological product involved in the infringement until a date which is not earlier than the date of the expiration of the patent that has been infringed under paragraph (2)(C), provided the patent is the subject of a final court decision, as defined in section 351(k)(6) of the Public Health Service Act, in an action for infringement of the patent under section 351(1)(6) of such Act, and the biological product has not yet been approved because of section 351(k)(7) of such Act.

The remedies prescribed by subparagraphs (A), (B), (C), and (D) 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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