In the Supreme Court of the United States

FEDERAL TRADE COMMISSION, PETITIONER

v.

WATSON PHARMACEUTICALS, I

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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In the Supreme Court of the United States

No. 12-416

FEDERAL TRADE COMMISSION, PETITIONER

Code are reproduced in an appendix to this brief, App., *infra*, 1a-61a.

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.*,

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 gener-

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

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/genericdrug study3/062806gpha.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 infrinr(7of any lvit)-4iy

IHII_Medicines_in_U.S_Report_2011.pdf. Brand-name drugs accounted for 18% of total prescriptions for drugs and biologics (which include products such as vaccines), *id.* at 16, but 73% of total spending, *id.* at 27. That disparity reflects, *inter alia*, the monopoly reward the patent laws offer for brand-name innovation.

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).

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.*

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-

[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

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

mise date of generic entry, the generic manufacturer's incentive is to negotiate 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-

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.

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,

done the purchase of protection from uncertain competition any more than it condones the elimination of actual

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 compet-

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.

"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

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.").

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

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 juupp. Tc.2732 Tw732 -..0378 Tw1154 Tc-upp. Tc.-e suit atge w[(thin)

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 th

The periods of brand-name monopoly pricing that accompany reverse-payment agreements upset the Amendments' "fundamental balance" between innova-

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

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

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) (Ginsb-.0323 Tw

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

the subject matter of the side transaction; a history of demonstrated interest in or need for the property or

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

graph IV litigation in alternative ways that do not undo the manufacturers' competitive

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

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 liti-

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-

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.

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

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

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 T1.175 TD.0 28 U.S.C

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

* * * 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, *Sen-*

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 in-

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.

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

Respectfully submitted.

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

> Every contract, combination in the form of trust or otherwise, or conspiracy, in

(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:

* * * * *

Whenever the Commission has reason to believe—

(1) that any person, partnership, or corporation is violating, or is about to violate, any provision of

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:

* * * * *

(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)

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 approval of a petition filed under listed

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

(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

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 a9fi -p pprove]TJ13.325 0 TD.0218 Tw[fl)f a lrug wreereinge(p)ta

(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, an

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.

(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

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 EXCLUSI0180-

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

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 MAor

(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) W

(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

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 (in-

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 ac

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),

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 i

(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—

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

* * * * *

(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

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

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;

(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

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.

(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 Secreta

(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;

(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;

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

(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

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 ap-

(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

(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—

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

(C) damages or other monetary relief may be

(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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