Nos. 14-1522, 14-1529, 14-1593

IN THE UNITED STATES COURT OF APPEALS
FOR THE FOURTH CIRCUIT

MYLAN PHARMACEUTICALS, et al.,

Plaintiffs-Appellants,

v.

U.S. FOOD AND DRUG ADMINISTRATION, et al.,

Defendants-Appellees.

ON APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF WEST VIRGINIA

BRIEF FOR THE FEDERAL APPELLEE

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INTRODUCTION

Enacted as part of the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act, the statute at issue in this case rewards the first generic drug manufacturer to challenge assertions by brand-name manufacturers that a generic equivalent would infringe a valid patent, thus bearing the expense and the risk of patent infringement litigation. Under the statute, the generic drug manufacturer that first challenges a patent may be eligible for a 180-day period of exclusivity, during which it can

generally market the drug without competition from other generic manufacturers.

There is no dispute in this case that Teva Pharmaceuticals was the first generic manufacturer to challenge a patent invoked by the brand-name manufacturer. After Teva prevailed in patent infringement litigation, but before Teva's generic product was approved, the U.S. Patent and Trademark Office reissued the patent in response to the brand-name manufacturer's effort to correct the problem with the original patent. A district court subsequently held that the reissued patent presented the same problem as the original, and thus remained invalid.

The Food and Drug Administration (FDA), which is responsible for the administration of the Hatch-Waxman Amendments, reasonably concluded that Teva is eligible for an exclusivity period because it was the first generic manufacturer to challenge the original patent. FDA also properly reasoned that the exclusivity period would not begin until Teva marketed the drug or a court entered a decision, from which no appeal could be or was taken, invalidating the reissued patent or declaring that it would not be infringed by the generic equivalent.

JURISDICTIONAL STATEMENT

Plaintiffs' claims arise under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq.*, and the Administrative Procedure Act, 5 U.S.C. § 701 *et seq.* Plaintiffs invoked the district court's jurisdiction under 28 U.S.C. § 1331. The district court issued a final judgment on June 16, 2014. [JA 341]. Mylan Pharmaceuticals and Watson Laboratories filed timely notices of appeal that same day. [JA 342, 347]; *see* Fed. R. App. P. 4(a)(1)(B). This Court has jurisdiction under 28 U.S.C. § 1291.

Mylan and Lupin Pharmaceuticals had also filed notices of appeal of a preliminary injunction that had been issued by the district court. [JA 284, 287]. Although those appeals became moot upon entry of final judgment, the district court's final judgment is properly before this Court based on appeals that were subsequently filed, with which the prior appeals were consolidated.

STATEMENT OF THE ISSUE

Whether FDA reasonably interpreted the 180-day exclusivity provision of the Hatch-Waxman Amendments, 21 U.S.C. § 355(j)(5)(B)(iv) (2000), to provide a single period of exclusivity with respect to the original and reissued versions of a patent, which is not triggered by the invalidation

of the original patent if the patent is reissued before any generic drug application is approved.

STATEMENT OF THE CASE

A. Statutory Background

Under the Federal Food, Drug, and Cosmetic Act, the Food and Drug Administration regulates the manufacture, distribution, and labeling of drugs. *See generally* 21 U.S.C. § 301 *et seq.* To obtain FDA's approval to market a new drug, a manufacturer must submit a new drug application. *Id.* § 355(b). The application must include, among other things, scientific data and other information demonstrating that the drug is safe and effective for its intended uses. *Id.* § 355(b)(1).

In connection with new drug applications, brand-name manufacturers submit information about patents that claim the drug or methods of using the drug. *Id.* FDA publishes that information in *Approved Drug Products with Therapeutic Equivalence Evaluations*, commonly known as the "Orange Book." *See Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 132 S. Ct. 1670, 1676 (2012).

Under the Hatch-Waxman Amendments, Congress created a mechanism for manufacturers to obtain approval of generic versions of

approved brand-name drugs through the submission of abbreviated new drug applications (ANDAs). *See* 21 U.S.C. § 355(j). Generic manufacturers using this abbreviated pathway need not provide independent clinical evidence of safety or efficacy, but instead generally must demonstrate that the generic drug shares specified characteristics, including having the same active ingredient(s), dosage form, and strength, with a drug that has already been approved. *Id.* § 355(j)(2)(A)(ii), (iv).

Manufacturers who wish to market a generic equivalent of a given brand-name drug must explain how their drug can be marketed without infringing any patents listed in the Orange Book. *See id.* § 355(j)(2)(A)(vii)–(viii). That requirement is easily satisfied if the generic applicant does not request approval before the patent expires. *See id.* § 355(j)(2)(A)(vii)(II)–(III). If a generic manufacturer wishes to market the drug before a patent listed in the Orange Book expires, however, the manufacturer must include in its ANDA a certification that the patent is invalid or that the manufacture, use, or sale of the generic drug would not infringe the patent.

See id. § 355(j)(2)(A)(vii)(IV). This certification is known as a "paragraph IV certification."[1]

The generic manufacturer must give notice of its paragraph IV certification to the patent holder. *Id.* § 355(j)(2)(B). The filing of a paragraph IV certification is deemed an act of patent infringement, which allows the patent holder to file an infringement suit against the generic manufacturer without waiting for some other potentially infringing act. 35 U.S.C. § 271(e)(2)(A). The infringement suit provides a vehicle for the generic manufacturer to obtain a judicial determination of the validity or non-infringement of the challenged patent.

If the generic manufacturer prevails in the patent litigation and obtains a declaration that the patent is invalid, other generic manufacturers that wish to market the drug generally may take advantage of that judgment. *See Blonder-Tongue Labs., Inc. v. Univ. of Ill. Found.*, 402 U.S. 313 (1971). To avoid a free-rider problem, the statute provides a reward to the generic manufacturer that filed the first paragraph IV certification

[1] For method-of-use patents, the generic manufacturer may also avoid infringement by choosing not to seek approval for uses claimed by the patent. 21 U.S.C. § 355(j)(2)(A)(viii). This process is not at issue here.

challenging the patent, and thus took on the expense and the risk of the patent litigation. In particular, Congress directed FDA not to approve any generic manufacturer's subsequent application until 180 days after (1) commercial marketing by the first generic applicant; or (2) a court decision, from which no appeal can be or has been taken, finding the patent invalid or not infringed. This provision, known as 180-day exclusivity, is at the heart of the present litigation.

In November 2003, when the first ANDA containing a paragraph IV certification in this case was filed, the exclusivity provision provided that

> If the application contains a [paragraph IV certification] and is for a drug for which a previous application has been submitted under this subsection [containing] 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 [infringement action] holding the patent which is the subject of the certification to be invalid or not infringed,
>
> whichever is earlier.

21 U.S.C. § 355(j)(5)(B)(iv) (2000). This provision was subsequently amended, and the issues presented in this litigation would not arise under

the current version of the provision. *See* Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("2003 Medicare Modernization Act"), Pub. L. No. 108-173, § 1102, 117 Stat. 2066, 2457. But the pre-amendment version applies here because the relevant ANDA was filed before the statute was amended. *See id.* § 1102(b), 117 Stat. 2460.

B. Facts and Prior Proceedings

This case concerns applications by generic drug manufacturers to market certain strengths of celecoxib capsules, a nonsteroidal anti-inflammatory drug marketed by Pfizer, Inc., under the brand name Celebrex. Plaintiffs Mylan Pharmaceuticals, Watson Laboratories, and Lupin Pharmaceuticals, and defendant-intervenor Teva Pharmaceuticals, have all filed ANDAs seeking approval to market celecoxib capsules in the strengths at issue here.

1. Teva was the first generic manufacturer to file an ANDA for the relevant strengths of celecoxib capsules, and its original ANDA contained a paragraph IV certification to three of Pfizer's patents. *See* PI Op. 9 [JA 259]. When Pfizer sued Teva for infringement, the Federal Circuit ultimately determined that two of the patents were infringed and not invalid, but agreed with Teva's challenges to the validity of the third patent (the '068

patent). *See Pfizer, Inc. v. Teva Pharm. USA, Inc.*, 518 F.3d 1353, 1358 (Fed. Cir. 2008). The first two patents did not expire until May 30, 2014, which prevented FDA from approving Teva's application prior to that date. After Teva demonstrated that it was otherwise ready for approval, FDA tentatively approved Teva's application, which was eligible for final approval no earlier than May 30, 2014.

Teva had prevailed in the patent litigation by arguing that the '068 patent resulted from "obviousness-type double patenting." *Pfizer*, 518 F.3d at 1358 (Fed. Cir. 2008). Double patenting is an effort to extend the term of a patent on an invention improperly by obtaining a later patent on the same invention or one that is an obvious variation. *See id.* at 1363. Here, the Federal Circuit determined that the relevant claims of the '068 patent, which involved a method of using the drug, were effectively for the same invention disclosed in an earlier patent on the composition of the drug itself (which is one of the two patents that expired on May 30, 2014), and were therefore invalid on obviousness-type double patenting grounds. *See id*.

In its decision, the Federal Circuit rejected Pfizer's effort to rely on a safe harbor provision in 35 U.S.C. § 121. That provision, the court

explained, applies only when an applicant files a so-called "divisional" patent application. *Pfizer*, 518 F.3d at 1359–60. The court concluded that Pfizer was ineligible for the safe harbor because the '068 patent did not result from a divisional application, but instead from a "continuation in part," a different kind of patent application that, unlike a divisional application, contains new matter as well as claims derived from an earlier application. *Id.* at 1361–62.

After the Federal Circuit decision, Pfizer attempted to cure the double patenting problem by persuading the Patent and Trademark Office to reissue the patent. A patent may be reissued when it is wholly or partly inoperative or invalid "[1] by reason of a defective specification or drawing, or [2] by reason of the patentee claiming more or less than he had a right to claim in the patent." 35 U.S.C. § 251(a). In those circumstances—and only in those circumstances—if the patentee files an application, surrenders the original patent, and satisfies certain other requirements, the Patent and Trademark Office will "reissue the patent for the invention disclosed in the original patent . . . for the unexpired part of the term of the original patent." *Id.* The application for a reissued patent may not introduce new matter. *Id.*

In March 2013, Pfizer obtained a reissued patent and submitted it to FDA for inclusion in the Orange Book. Teva, Mylan, and Watson all immediately amended their pending applications to include a paragraph IV certification to the reissued patent. *See* PI Op. 10 [JA 260]. Lupin subsequently amended its application to include a similar certification. *See* Lupin Compl. ¶ 42 [JA 107].

Pfizer commenced new patent infringement litigation in the Eastern District of Virginia based on the paragraph IV certifications of these entities (among others). That court concluded that Pfizer "could not use the reissue process to correct its failure to file a divisional application." Order Invalidating Reissue Patent, at 10 [JA 63]. Because Pfizer was not entitled to use the reissue mechanism to convert its continuation in part into a divisional application, the court held that the Federal Circuit's analysis of the original patent applied to the reissued version, which remained invalid based on obviousness-type double patenting. *Id.* at 16 [JA 69] (citing *Pfizer*, 518 F.3d at 1363). Pfizer has appealed that decision, and the appeal is still pending.

2. The present dispute concerns the timing of approval for various applications to market generic versions of celecoxib capsules. FDA

interpreted the relevant provisions of the Hatch-Waxman amendments, in the context of this dispute, in a letter decision dated April 24, 2014. FDA's letter decision addressed two related questions. First, FDA concluded that the original and reissued versions of a patent give rise to a single 180-day exclusivity period, rather than to two separate periods. Second, FDA determined that when no generic manufacturer has been granted approval before the patent is reissued, the single exclusivity period begins to run upon commercial marketing or upon a court decision holding that the reissued patent is invalid or not infringed (and from which no appeal can be or has been taken), not upon invalidation of the original patent.

With respect to the first question, FDA explained that in each of its prior decisions involving reissued patents, it had "treated the original and reissued patent as a single 'bundle' of patent rights" for purposes of 180-day exclusivity. FDA Decision, at 8 [JA 48]. FDA observed that this treatment was "consistent with principles of patent law, including that: (1) a pending cause of action based on the original patent continues after reissuance to the extent that claims of the original and reissued patent are substantially identical (see 35 U.S.C. 252); (2) the limitation on reissuance to the unexpired part of the term of the original patent (see 35 U.S.C. 251(a));

and (3) the requirement that 'no new matter shall be introduced into the application for reissue' (35 U.S.C. 251(a))." *Id.* at 9 [JA 49]. FDA further explained that its decision was "consistent with the objectives of the Hatch-Waxman Amendments and provides a predictable approach that is consistent with [FDA's] ministerial role in patent listing decisions." *Id.*

With respect to the second question, FDA found that the text of the exclusivity provision was ambiguous as to whether a decision invalidating the original patent commences the running of the 180-day exclusivity period. But FDA concluded that interpreting the provision so that the exclusivity period does not begin to run until the invalidation of the reissued patent "best reconciles the complicated intersection between the Hatch-Waxman Amendments and patent law, while allowing FDA to administer the Act in a manner that is fair, predictable, and consistent with the goal of bringing generic products to the market." FDA Decision, at 10 [JA 50]. The agency further explained that its approach "is fair to [generic] applicants who first took on the risk of litigation by certifying to the original patent." *Id.* at 11 [JA 51].

In this case, the consequence of FDA's analysis is that Teva, as the first generic manufacturer to file a paragraph IV certification as to the

original patent, is eligible for a period of exclusivity. The 180-day period will begin to run when Teva first markets the drug, or when there is a final, nonappealable decision invalidating the reissued patent. (The decision of the Eastern District of Virginia is still on appeal and thus does not qualify. *See* 2003 Medicare Modernization Act, § 1102(b)(3), 117 Stat. at 2460.)

3. Mylan instituted this action in the Northern District of West Virginia, challenging FDA's decision under the Administrative Procedure Act. Mylan contended that, although it was not the first to file a paragraph IV certification to the original patent, it should nonetheless be entitled to approval on May 30, 2014, because it was one of the first generic manufacturers to file a paragraph IV certification as to the reissued patent. Mylan claimed that it should receive a shared period of exclusivity along with Teva and the other applicants that filed paragraph IV certifications to the reissued patent on the same date. Mylan thus took issue with FDA's conclusion that there is only a single period of exclusivity applicable to the original patent and its reissued form. Watson intervened as a plaintiff, agreeing with Mylan's position.

Lupin also intervened as a plaintiff, but took a slightly different position. Lupin agreed with FDA that reissuance of a patent does not give

rise to a separate period of exclusivity. But according to Lupin, the single period of exclusivity was triggered by the Federal Circuit's decision regarding the original patent, and has thus expired. Lupin therefore argued that no exclusivity period currently applies, and that all generic manufacturers who have filed applications should be approved on May 30, 2014.

Teva intervened as defendant to support FDA's decision, asserting that Teva, and only Teva, was eligible for approval on May 30, 2014.

The district court denied Mylan's motion for a preliminary injunction. Reviewing FDA's construction of the exclusivity provision under the principles of *Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984), the court first addressed whether the provision speaks specifically to the issues addressed by FDA, then whether FDA's interpretation of the provision with respect to those issues is permissible.

The court noted that the federal district court for the District of Columbia and the D.C. Circuit had concluded that the statute "was silent as to how many exclusivity periods may arise in connection with a single drug product." PI Op. 19 [JA 269] (citing *Apotex Inc. v. FDA*, 414 F. Supp. 2d 61, 69 (D.D.C. 2006), *aff'd*, 226 F. App'x 4 (D.C. Cir. 2007) (unpublished)

(per curiam)). The district court concluded that the statute was similarly ambiguous as to the treatment of reissued patents, and that when Congress drafted the provision at issue here, it did not mean to express a view on the proper treatment of reissued patents. *Id.* at 21–22 [JA 271–72]. The Hatch-Waxman Amendments' silence on the treatment of reissued patents "illustrat[es] that Congress left it for the FDA to decide how reissued patents affect generic exclusivity rights." *Id.* at 23 [JA 273].

Having concluded that the statute was ambiguous, the district court next held that FDA had reasonably determined that original and reissued patents give rise to a single period of exclusivity, and that the single period would be triggered upon marketing of the generic drug or a final court decision relating to the reissued patent. The court concluded that "FDA's treatment of reissued patents for exclusivity purposes is consistent with the statutory treatment of reissued patents generally." *Id.* at 25 [JA 275]. The court accepted FDA's "well-reasoned explanation for its decision," which stated that FDA's approach was fair to the applicant "'who first took on the risk of litigation by certifying to the original patent.'" *Id.* at 26–27 [JA 276–77] (quoting FDA Decision, at 11 [JA 51]). The court further observed that

FDA's analysis was consistent with its prior treatment of reissued patents. *Id.* at 27–28 [JA 277–78].[2]

4. After the district court denied the preliminary injunction, FDA approved Teva's application, effective May 30, 2014. *See* FDA News Release, *FDA approves first generic versions of celecoxib* (May 30, 2014).[3] Consistent with the interpretation of the exclusivity provision sustained by the district court, FDA has not yet approved plaintiffs' applications, because Teva's 180-day period has not yet expired (or even started to run).

On Mylan's unopposed motion, the district court converted its preliminary-injunction ruling to a final judgment. Order Granting Motion for Final Judgment [JA 320]. Mylan, Watson, and Lupin appeal.

SUMMARY OF ARGUMENT

The Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act reward the first generic drug manufacturers to take on the expense and the risk of patent litigation involving brand-name drugs. In

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[2] The district court also concluded that Mylan had failed to establish the other factors necessary to obtain a preliminary injunction. PI Op. 28–33 [JA 278–83].

[3] http://www.fda.gov/newsevents/newsroom/pressannouncements/ucm399428.htm

particular, if a patent is invalidated, the statute allows the first generic manufacturer that challenged the patent to market the drug for 180 days without competition from other generic manufacturers.

Plaintiffs do not dispute that the exclusivity provision is ambiguous as to whether the 180-day exclusivity period may be awarded only to a single manufacturer for each drug product, or whether separate exclusivity periods are available for each patent held by the brand-name manufacturer. The Food and Drug Administration has resolved the ambiguity by awarding separate exclusivity periods for each individual patent. That approach has been upheld by the courts as a reasonable interpretation of the statute, and is not challenged here.

In this case, the district court properly concluded that FDA was not compelled to go beyond that policy by awarding a separate and independent exclusivity period when a patent is reissued. Reissued patents are not unrelated new patents, but instead corrected versions of previously granted patents, issued to address specified errors or defects that have been identified in the original version.

Once the original and reissued patents are treated together for purposes of the 180-day exclusivity provision, it follows that a generic

manufacturer is not entitled to exclusivity merely by being the first to challenge the reissued version of the patent, but rather must have been the first to challenge the patent when it was issued in its original form. FDA properly went on to conclude that in the circumstances presented here, the exclusivity period does not begin to run until the generic drug is marketed or until there is a court decision, from which no appeal can be or has been taken, holding that the reissued patent is invalid or not infringed.

Treating the original and reissued versions of a patent together promotes the objectives of the exclusivity scheme. Under FDA's approach, the generic manufacturer that first challenged the original version of the patent is eligible to receive a reward of 180-day exclusivity, whether or not the brand-name manufacturer has attempted to correct the patent's defect through reissuance.

STANDARD OF REVIEW

This court reviews *de novo* the district court's legal conclusions. Like the district court, this Court defers to the agency's reasonable construction of the statute it is charged with administering. *Chevron U.S.A. Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837 (1984).

ARGUMENT

THE DISTRICT COURT PROPERLY SUSTAINED FDA'S CONSTRUCTION OF THE HATCH-WAXMAN 180-DAY EXCLUSIVITY PROVISION

A. FDA reasonably treated the original patent and the reissued patent together for purposes of determining the exclusivity period.

1. The controversy in this case concerns the date on which the Food and Drug Administration will first permit plaintiffs to market generic versions of the anti-inflammatory drug celecoxib. In response to an assertion by the brand-name manufacturer that marketing a generic version of its drug would infringe a patent, each of the plaintiffs included in its abbreviated new drug application a paragraph IV certification, asserting that the patent in question was invalid. *See* 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

Paragraph IV certifications can affect the permissible effective date of generic drug applications. In particular, the Hatch-Waxman Amendments contain a provision that is designed to reward the first generic manufacturer to challenge a patent, by delaying the marketing of the drug by other generic manufacturers who made later paragraph IV certifications. During the period relevant here, that provision stated that "[i]f [an]

application contains a [paragraph IV certification] and is for a drug for which a previous application has been submitted under this subsection [containing] such a certification, the application shall be made effective not earlier than one hundred and eighty days after" the earlier of (1) the date on which the previous generic applicant first markets the drug; or (2) "the date of a decision of a court in an [infringement action] holding the patent which is the subject of the certification to be invalid or not infringed." 21 U.S.C. § 355(j)(5)(B)(iv) (2000).

When a brand-name drug is the subject of multiple patents listed in FDA's Orange Book, FDA has interpreted the exclusivity provision as operating on a patent-by-patent basis, so that approval of a generic drug application containing a paragraph IV certification for a particular patent will be delayed by 180 days only if the previous application contained a paragraph IV certification to the same patent. Courts have upheld that patent-by-patent approach as a reasonable construction of an ambiguous statute, and it is not challenged here. *See Apotex Inc. v. FDA*, 414 F. Supp. 2d 61, 69–70 (D.D.C. 2006), *aff'd*, 226 F. App'x 4 (D.C. Cir. 2007) (unpublished) (per curiam).

In the decision at issue here, FDA concluded that although multiple periods of exclusivity may arise when there is more than one distinct patent, reissuance of a patent does not give rise to a separate exclusivity period. Given that the statute is concededly ambiguous as to whether unrelated patents give rise to independent periods of exclusivity (*see Apotex*, 414 F. Supp. 2d at 69–70), plaintiffs cannot plausibly suggest that the statute unambiguously compels FDA to award a separate period of exclusivity for a reissued patent, independent of the exclusivity period for the original patent from which it arose. Because Congress has not spoken to the issue presented here, FDA's reasonable construction of the statute it is charged with administering is entitled to deference. *See Chevron U.S.A. Inc. v. Natural Res. Def. Council*, 467 U.S. 837, 842–43 (1984).

FDA's approach is entirely consistent with the statutory language, which, as the district court recognized, does not speak to the issue presented here. Nothing in the statutory language—which, as noted, is ambiguous as to whether FDA must provide separate periods of exclusivity for entirely unrelated patents—requires FDA to award separate exclusivity periods for the original patent and the reissued version.

As FDA explained, awarding a single exclusivity period is "consistent with the objectives of the Hatch-Waxman Amendments." FDA Decision 9 [JA 49]. The purpose of providing a 180-day period of exclusivity is to provide an incentive for generic manufacturers to challenge patents by filing paragraph IV certifications. *See Teva Pharm., USA, Inc. v. Leavitt*, 548 F.3d 103, 104 (D.C. Cir. 2008) ("Marketing exclusivity is . . . designed to compensate manufacturers for research and development costs as well as the risk of litigation from patent holders."). That purpose is well served by treating a reissued patent together with the original patent, rather than treating reissued patents as triggering an entirely separate and independent exclusivity period. Under FDA's approach, the generic manufacturer that first challenged the original patent and filed a paragraph IV certification may receive the benefit of 180-day exclusivity, and the period begins to run when the first applicant begins to market the drug or when the brand-name manufacturer's efforts to correct the defect through reissuance have been defeated.

This case illustrates the logic of treating the original and reissued versions of a patent together for purposes of applying the exclusivity provision. Teva was the first manufacturer to challenge the original patent,

and it prevailed in the resulting patent infringement action. *See Pfizer, Inc. v. Teva Pharmaceuticals USA, Inc.*, 518 F.3d 1353, 1358 (Fed. Cir. 2008). But before Teva's application to market the drug was approved, the patent was reissued. The reissued patent was subsequently held to be invalid based on the same defects that the Federal Circuit found in the original patent. *See* Order Invalidating Reissue Patent, at 16 [JA 69] (concluding that the reissued patent "is as vulnerable as the [original] patent" to an obviousness-type double patenting challenge and is thus invalid based on the Federal Circuit's decision regarding the original patent).

Providing a period of exclusivity to Teva—the first generic manufacturer to challenge the patent by filing a paragraph IV certification—promotes the objectives of the Hatch-Waxman Amendments. *See* FDA Decision, at 11 [JA 51] (noting that FDA's interpretation "is fair to the . . . applicants who first took on the risk of litigation by certifying to the original patent"). The statute was designed to provide an incentive for generic manufacturers to litigate patent infringement cases and to obtain judgments invalidating patents that improperly prevent generic manufacturers from competing with the brand-name manufacturer. Providing Teva with a period of exclusivity, triggered by commercial

marketing or a final court decision on the reissued patent, rewards the precise conduct that Congress sought to encourage.

2. In addition to advancing the purposes of the Hatch-Waxman Amendments, FDA's approach properly took account of the relationship between original and reissued patents. As FDA and the district court both recognized, when a patent is reissued, the reissued patent and the original patent are closely connected to each other. When the requirements for reissuance are met, the Patent and Trademark Office "reissue[s] the patent for the invention disclosed in the original patent . . . for the unexpired part of the term of the original patent." 35 U.S.C. § 251(a). The reissued patent must correct an "error" in the original patent, and the reissue application cannot contain "new matter" that was not introduced in the original patent application. *Id.* And "every reissued patent shall have the same effect and operation in law, on the trial of actions for causes thereafter arising, as if the same had been originally granted in such amended form." *Id.* § 252. Further, where the claims of the original and reissued patents are "substantially identical," the surrender of the original patent does not affect any pending causes of action. *Id.*

Thus, in several important respects, the reissued patent is not a wholly new patent. Rather, it is a corrected version of the original patent. The language of the statute authorizing reissuance highlights this relationship. The statute does not direct the Patent and Trademark Office to issue a "new" patent, but rather to "reissue *the* patent for the invention disclosed in the original patent." 35 U.S.C. § 251(a) (emphasis added). In light of the close relationship and the degree of continuity between the reissued patent and the original, FDA reasonably determined that it would consider the original and reissued versions of a patent together when applying the exclusivity provisions of the Hatch-Waxman Amendments.

FDA does not dispute that reissued patents are, in some respects, new and distinct from the original patents from which they arise. FDA merely concluded that the relationship between an original and a reissued patent is sufficiently close to justify treating them together when applying the ambiguous effective-date provision of the Hatch-Waxman Amendments, and in particular when applying FDA's patent-by-patent approach.

As discussed below, treating the original and reissued patents together leads naturally to the conclusions FDA reached in this case. First,

the only entity eligible for exclusivity is the first generic manufacturer to challenge the original patent. Second, in the absence of commercial marketing, only a court decision invalidating the reissued patent extinguishes the brand-name manufacturer's patent rights and thus causes the single exclusivity period to begin to run. (Mylan and Watson challenge both of these conclusions, and Lupin challenges only the second.)

B. Teva filed a relevant "previous application."

FDA's conclusion that only the first applicant to file a paragraph IV certification to the original patent is eligible for exclusivity flows naturally from the agency's conclusion that the original and the reissued version of the patent should be considered together. The first paragraph IV certification relevant to the single period of exclusivity is the certification to the original patent, and it is the filer of that certification that is eligible for exclusivity.

FDA's approach is also entirely consonant with the statutory language. Plaintiffs all submitted abbreviated new drug applications after Teva had already submitted an application containing a paragraph IV certification challenging the original patent. FDA thus reasonably concluded that plaintiffs' "application[s] contain[ed] a [paragraph IV

certification] and [were] for a drug for which a previous application ha[d] been submitted . . . [containing] such a certification." 21 U.S.C. § 355(j)(5)(B)(iv) (2000).

Mylan and Watson do not and cannot dispute that at the time they submitted an application containing a paragraph IV certification, Teva had already filed a previous application containing a paragraph IV certification. Instead, plaintiffs argue that Teva's previous paragraph IV certification does not count because it challenged the original, and not the reissued, version of the patent.

As noted above, plaintiffs cannot seriously contend that FDA's decision is inconsistent with the statutory language, which did not require FDA to distinguish between even entirely unrelated patents. *See Apotex*, 414 F. Supp. 2d at 69–70 (noting statutory ambiguity on this point). Instead, plaintiffs' argument boils down to their contention that FDA impermissibly "treated two functionally indistinguishable categories of [generic drug] applicants—those who submit Paragraph IV certifications to a reissue patent and those who submit Paragraph IV certifications to an original patent—differently, without a justifiable explanation for doing so." Mylan Br. 41.

But FDA provided ample justification for its distinction. FDA highlighted the relationships between the original and reissued versions of a patent. *See* FDA Decision, at 9 [JA 49]. Reissued patents may only contain claims to the same invention that was disclosed in the original application, may be obtained only upon surrender of the original patent, runs for the unexpired part of the term of the original patent, and cannot present new matter that was not presented in the original application. *See* 35 U.S.C. § 251(a). Generic applicants who challenge reissued patents, when the original patent had already been challenged by another applicant, are not similarly situated to generic applicants who were the first to provoke patent litigation by challenging an entirely new patent. There is nothing arbitrary about providing a single period of exclusivity for original and reissued versions of a patent, while providing separate periods of exclusivity when two distinct and unrelated patents are at issue.

C. FDA reasonably concluded that a court decision on the original version of the patent could not control the date on which plaintiffs' applications could be approved.

Having determined that the original and reissued patents should give rise to a single 180-day exclusivity period, FDA reasonably concluded that in the circumstances presented here, the court decision addressing the

patent in its original form did not affect the date on which that single period began to run.

1. Mylan and Watson state, without explanation, that "the issue with respect to the court decision trigger in this case is *not* [FDA's] treatment of any exclusivity period tied to the . . . reissue patent, but its treatment of the exclusivity period tied to the original . . . patent, which was only much later the subject of a reissue." Mylan Br. 28. This statement of the issue presumes what plaintiffs are trying to prove: that the court-decision trigger should be applied separately to the original patent and the reissued version. FDA reasonably concluded that its patent-by-patent approach should be applied in a manner that treats the original and reissued patents together, for the reasons discussed above. Under this approach, if the original version of a patent was surrendered and a reissued version was obtained, a court decision pertaining only to the original version did not invalidate the patent.

Plaintiffs once again presume that the reissued patent should be treated separately from the original version when they argue that "a literal reading of the statutory language dictates that 'the patent' refers only to the [original] patent." Mylan Br. 22. This argument ignores both the facts of

this case and FDA's approach of considering the original and the reissued version of a patent together for exclusivity purposes. Teva made a paragraph IV certification to a patent and prevailed in patent litigation, but the patent was reissued before Teva was eligible for FDA approval. The statute does not address what version of the patent is relevant to the court-decision trigger in these unique circumstances, and FDA has reasonably determined that the court decision on the original version of the patent, which has since been surrendered and replaced by the reissued patent, is no longer the relevant court decision for purposes of the trigger. The contrary view would consider the court decision on the original patent to be sufficient to have triggered (and exhausted) 180-day exclusivity, despite the fact that the patent at issue in that case was in effect in reissued form.

Plaintiffs mistakenly suggest that the FDA decision would impermissibly cause the agency to create a "retroactive exemption" from the court-decision trigger or to "resurrect a terminated exclusivity period." Mylan Br. 21–22; *see also* Lupin Br. 9. Decisions on 180-day exclusivity are made only when FDA has received a generic drug application that appears to be eligible for exclusivity and FDA has also received another, potentially competing, application that would be eligible for approval but for that

potential exclusivity. At that time, FDA must decide whether to approve or tentatively approve the subsequent application (in other words, decide whether the first applicant is eligible for 180-day exclusivity that has not yet been triggered and run, thus temporarily blocking the subsequent applicant).

Here, because of the unexpired patents that the Federal Circuit held to be infringed and not invalid, FDA was not required to, and did not, make any exclusivity determination until earlier this year, after the reissuance of the patent at issue here. The decision letter in this case thus addressed only the circumstance where "the Patent and Trademark Office reissues the patent before any other applicant has an [application] that is in a position 'to be made effective not earlier than one hundred and eighty days' after a triggering event." FDA Decision, at 10 [JA 50] (quoting 21 U.S.C. § 355(j)(5)(B)(iv) (2000)). Where, as here, FDA has not had occasion to make an exclusivity determination before the patent was reissued, it is reasonable for FDA to take account of all relevant information in determining whether exclusivity has been triggered and run.

Plaintiffs do not advance their argument by pointing out that the reissued patent might change settled expectations of generic manufacturers

applying for drug approval. *See* Mylan Br. 26–27. It is undisputed that a brand-name manufacturer may have a new patent infringement cause of action based on the reissued patent, which could impede a generic manufacturer from marketing. In this context, it is unsurprising that reissuance may also have ramifications for the exclusivity period in the event that the patent is invalidated.

2. Lupin agrees with FDA that reissuance of a patent does not give rise to a separate exclusivity period, but argues that the single exclusivity period expired based on the Federal Circuit's decision regarding the original patent. *See* Lupin Br. 4–5. But because the patent was reissued, no court decision relating to the original patent alone could extinguish the brand-name manufacturer's rights with respect to the patented invention. The court-decision trigger would be invoked only if there were a final, nonappealable court decision invalidating the reissued patent. Treating the invalidation of the original patent as dispositive would be tantamount to treating the reissued patent separately, an approach that Lupin disclaims.

By arguing both that there is only a single exclusivity period and that the reissued patent does not affect it, Lupin's preferred approach would ignore the reissued patent entirely. Lupin is quite candid about that

ramification of its argument, contending that "under FDA's single bundle of patent rights approach, the reissued patent is of no relevance." Lupin Br. 8. FDA reasonably declined to ignore the reissued patent.

Finally, Lupin argues that its interpretation would serve to expedite the marketing of generic drugs because generic celecoxib would go to market sooner under its approach. Lupin Br. 10. But the promise of marketing exclusivity provided Teva with an incentive to challenge the patents and ultimately pave the way for approval of other generics after Teva enjoyed its exclusivity reward. *See Ark. Carpenters Health & Welfare Fund v. Bayer AG*, 604 F.3d 98, 108 (2d Cir. 2010) ("The purpose of the Hatch–Waxman Act was to make available more low cost generic drugs . . . by providing an incentive . . . for generic manufacturers to challenge presumptively valid patents, which, if successful, would result in exclusivity for the first successful challenger and the entry of generic drugs into the market." (citations and internal quotation marks omitted)). By Lupin's logic, exclusivity should never be granted to any generic applicant that took a risk and challenged a patent, because exclusivity serves only to preclude other generic applicants from marketing. Lupin simply

disregards the role of the exclusivity period in providing the incentive needed to challenge patents in the first place.

D. Plaintiffs' remaining contentions are without merit.

As FDA explained, the approach taken in this case is consistent with the agency's approach to reissued patents in earlier decisions. *See* FDA Decision, at 7–8 [JA 47–48]. Plaintiffs do not dispute that the decisions cited by FDA are consistent with the agency's current reasoning, but merely observe that the prior administrative decisions did not present the precise issues presented here, and were not challenged in court. Mylan Br. 36. This observation in no way undermines FDA's reasoning, which explicitly acknowledged that the issue here involved "a question of first impression." FDA Decision, at 9 [JA 49]. Plaintiffs point to an administrative decision in a prior case that happened to involve a reissued patent, but the questions posed here were not presented or discussed in that decision, and the prior decision therefore does nothing to undermine

FDA's reasoning. *See* Mylan Br. 37 (citing FDA Approval Letter, Fluoxetine Delayed-release Capsules, ANDA 078572 (Mar. 22, 2010)[4]).

Plaintiffs do not advance their argument by noting that FDA has disclaimed the expertise or authority to resolve questions of patent law. Mylan Br. 32–33. FDA's decision in this case does not require FDA to determine the scope or validity of any patent or to resolve any other questions that have been reserved to courts adjudicating patent infringement actions. Instead, FDA concluded that the Hatch-Waxman provisions, which FDA is charged with administering, were best interpreted to provide a single period of exclusivity to the first generic manufacturer to challenge a patent, even if that patent was subsequently reissued. In light of its lack of patent expertise, FDA declined to adopt a case-by-case approach to analyzing the relationship between the reissued and original versions of each individual patent, instead concluding as a categorical matter that the reissuance of a patent does not create a separate period of exclusivity under the Hatch-Waxman Amendments.

[4] http://www.accessdata.fda.gov/drugsatfda_docs/appletter/2010/078572s000ltr.pdf

Plaintiffs note that reissued patents must be submitted separately to FDA from the original version, and are the subject of separate paragraph IV certifications. *See* Mylan Br. 24–25. It is perfectly reasonable to keep FDA's listings up to date by requiring new listings and new certifications for reissued patents, which may have a somewhat different scope and which have new patent numbers that replace the original numbers that had been submitted to FDA. *See* 35 U.S.C. § 251(a) (requiring surrender of the original version to obtain a reissued patent). This administrative processing has no bearing on the substantive issue presented.

Finally, at various points in their analysis, plaintiffs assert that FDA erred in interpreting these or other provisions of the Hatch-Waxman Amendments with regard to other disputes not before this Court. *See* Mylan Br. 24, 29–30; Lupin Br. 5 n.1. These cases presenting separate issues shed no light on the issue presented, as to which the leading case, unchallenged here, held that the statute is ambiguous. *See Apotex*, 414 F. Supp. 2d at 69–70.

CONCLUSION

For the foregoing reasons, the district court's judgment should be affirmed.

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AUGUST 2014

CERTIFICATE OF COMPLIANCE WITH
FEDERAL RULE OF APPELLATE PROCEDURE 32(A)(7)

I certify that this brief complies with the type-volume limitation of Fed. R. App. P. 32(a)(7)(B). This brief contains 7,210 words.

s/ Daniel Tenny
Daniel Tenny

CERTIFICATE OF SERVICE

I hereby certify that on August 1, 2014, I electronically filed the foregoing brief with the Clerk of the Court for the United States Court of Appeals for the Fourth Circuit by using the appellate CM/ECF system. Participants in the case are registered CM/ECF users and service will be accomplished by the appellate CM/ECF system.

s/ Daniel Tenny
Daniel Tenny

ADDENDUM

TABLE OF CONTENTS

21 U.S.C. § 355(j) (2000) states, in pertinent part:

Abbreviated new drug applications

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

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

* * * * *

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

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

(II) that such patent has expired,

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

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

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

* * * * *

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

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

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

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

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

* * * * *

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

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

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

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

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

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

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

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

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

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

(iv) If the application contains a certification described in subclause (IV) of paragraph (2)(A)(vii) and is for a drug for which a previous application has been submitted under this subsection continuing such a certification, the application shall be made effective not earlier than one hundred and eighty days after--

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

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

whichever is earlier.

35 U.S.C. § 251 provides:

Reissue of defective patents

(a) IN GENERAL.--Whenever any patent is, through error, deemed wholly or partly inoperative or invalid, by reason of a defective specification or drawing, or by reason of the patentee claiming more or less than he had a right to claim in the patent, the Director shall, on the surrender of such patent and the payment of the fee required by law, reissue the patent for the invention disclosed in the original patent, and in accordance with a new and amended application, for the unexpired part of the term of the original patent. No new matter shall be introduced into the application for reissue.

(b) MULTIPLE REISSUED PATENTS.--The Director may issue several reissued patents for distinct and separate parts of the thing patented, upon demand of the applicant, and upon payment of the required fee for a reissue for each of such reissued patents.

(c) APPLICABILITY OF THIS TITLE.--The provisions of this title relating to applications for patent shall be applicable to applications for reissue of a patent, except that application for reissue may be made and sworn to by the assignee of the entire interest if the application does not seek to enlarge the scope of the claims of the original patent or the application for the original patent was filed by the assignee of the entire interest.

(d) REISSUE PATENT ENLARGING SCOPE OF CLAIMS.--No reissued patent shall be granted enlarging the scope of the claims of the original patent unless applied for within two years from the grant of the original patent.

35 U.S.C. § 252 provides:

Effect of reissue

The surrender of the original patent shall take effect upon the issue of the reissued patent, and every reissued patent shall have the same effect and operation in law, on the trial of actions for causes thereafter arising, as if the same had been originally granted in such amended form, but in so far as the claims of the original and reissued patents are substantially identical, such surrender shall not affect any action then pending nor abate any cause of action then existing, and the reissued patent, to the extent that its claims are substantially identical with the original patent, shall constitute a continuation thereof and have effect continuously from the date of the original patent.

A reissued patent shall not abridge or affect the right of any person or that person's successors in business who, prior to the grant of a reissue, made, purchased, offered to sell, or used within the United States, or imported into the United States, anything patented by the reissued patent, to continue the use of, to offer to sell, or to sell to others to be used, offered for sale, or sold, the specific thing so made, purchased, offered for sale, used, or imported unless the making, using, offering for sale, or selling of such thing infringes a valid claim of the reissued patent which was in the original patent. The court before which such matter is in question may provide for the continued manufacture, use, offer for sale, or sale of the thing made, purchased, offered for sale, used, or imported as specified, or for the manufacture, use, offer for sale, or sale in the United States of which substantial preparation was made before the grant of the reissue, and the court may also provide for the continued practice of any process patented by the reissue that is practiced, or for the practice of which substantial preparation was made, before the grant of the reissue, to the extent and under such terms as the court deems equitable for the protection of investments made or business commenced before the grant of the reissue.