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2004 Update—180-Day Exclusivity Under the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act

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This article updates the author's previously published article on the topic,[1] provides some insight into recent events in this area of the law, and specifies a few minor items that were noted incorrectly in the earlier work.

I. *DR. REDDY'S LABORATORIES*—EXCLUSIVITY IN THE EVENT OF PATENT EXPIRY

On October 14, 2003, a federal district court in New Jersey found that Dr. Reddy's Laboratories was not entitled to share Andrx's 180-day exclusivity for generic omeprazole (marketed as Prilosec® by Astra Zeneca).[2] The case as a whole does not add significantly to 180-day exclusivity jurisprudence, but it is notable in at least one respect. Although Andrx was the first to file a paragraph IV certification on ten of the eleven patents for the 40 mg version listed by Astra Zeneca, Dr. Reddy's was the first to file a paragraph IV on the tenth (Andrx had filed a paragraph III.) The patent expired after both abbreviated new drug applications (ANDAs) were tentatively approved, but before either was finally approved. The Food and Drug Administration (FDA) concluded that Dr. Reddy's "lost" its eligibility for exclusivity when that patent expired, on the theory that the company was required to amend its ANDA to convert the paragraph IV certification to a paragraph II under 21 C.F.R. § 314.94(a)(12)(viii)(C). The court noted that the agency had set forth this interpretation of the statute at least twice prior to its decision on Dr. Reddy's application.[3] Dr. Reddy's argued that FDA may not require generic applicants to amend their certifications prior to final ANDA approval, and that an ANDA is eligible for exclusivity if it contains the appropriate paragraph IV certification at the time of filing. The court found the statute ambiguous on both points, however, and upheld the agency's decision.[4]

II. MYLAN AND TEVA CITIZEN PETITIONS—AUTHORIZED GENERICS

The generic industry continues to argue that "authorized generics" should be subject to the exclusivity period awarded to the first generic applicant.[5] As described by FDA, the

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[1] *See* Erika King Lietzan, *A Brief History of 180-Day Exclusivity Under the Hatch-Waxman Amendments for the Federal Food, Drug, and Cosmetic Act*, 59 FOOD & DRUG L.J. 287 (2004).

[2] Dr. Reddy's Labs., Inc. v. Thompson, 302 F. Supp. 2d 340 (D.N.J. 2003).

[3] *Id.* at 351 (citing 59 Fed. Reg. 50,338, 50,348 (Oct. 3, 1994) ("a patent is deemed to be relevant until the end of the term of the patent or applicable 180-day period, whichever occurs first") and FDA Response to APP and Pharmachemie Citizen's Petitions, 99P-1271/PDN1 (Aug. 2, 1999) (on file with author)). The *Dr. Reddy's* court characterized the latter as stating that "because exclusivity cannot extend beyond the expiration of a patent, an ANDA applicant who is first to file a paragraph IV certification on a patent loses its eligibility based upon that patent when the patent expires before either of the triggering events occurs."

[4] *Id.* at 354-55.

[5] *See* Lietzan, *supra* note 1, at 314.

marketing of "authorized generics" is the "marketing of a product approved under a new drug application (NDA), by that NDA holder, under that NDA, but at a lower price and not under the 'brand' name, possibly through a different channel of distribution."[6] As the agency notes, these arrangements date back more than ten years.[7] Nevertheless, generic manufacturers argue now that distribution of authorized generics during the 180-day exclusivity period is "anticompetitive" because it diminishes the value of the exclusivity incentive. The original article noted a citizen petition filed by Mylan Pharmaceuticals in February 2004. Teva Pharmaceuticals USA, Inc., submitted a similar citizen petition in June, regarding an authorized generic of Pfizer's Accupril® (quinapril hydrochloride).[8] On July 2, FDA denied both petitions.[9] Among other things, the agency wrote that "FDA does not regulate drug prices and has no legal basis on which to prevent an innovator company from marketing its approved NDA product at a price that is competitive with that charged by a first generic applicant to the market."[10] Mylan promptly filed a court case against the agency in the Northern District of West Virginia.[11] Shortly after oral argument, it withdrew the suit.[12] Teva filed suit on August 20 in the District of Columbia against FDA, seeking review of FDA's denial of its citizen petition.[13] In its amended complaint filed October 8, Teva also named Pfizer and its subsidiary Greenstone Ltd. as defendants, seeking to enjoin the launch of a generic version of Pfizer's Neurontin® (gabapentin) by Greenstone. Greenstone launched the product on October 8,[14] and, in an oral ruling on October 13, the court denied Teva's motion for a temporary restraining order. The case is still pending, but both Senator Hatch and Representative Waxman have stated that Congress likely will look at the issue in the spring.[15]

III. PFIZER CITIZEN PETITION—TRANSFER AND WAIVER OF 180-DAY EXCLUSIVITY

On May 11, 2004, Pfizer submitted a citizen petition to FDA asking the agency to "acknowledge" that 180-day exclusivity cannot lawfully be waived or transferred.[16]

[6] FDA Response to Teva and Mylan Citizen Petitions, 2004P-0075/PDN1 and 2004P-0261/PDN1 (July 2, 2004) at 2, *available at* http://www.fda.gov/ohrms/dockets/dailys/04/july04/070704/04p-0261-pdn0001.pdf (last accessed Oct. 26, 2004).

[7] *Id.* at 5 n.9.

[8] Teva Pharmaceuticals USA, Inc., Citizen Petition, 2004P-0261/CP1 (June 9, 2004), *available at* http://www.fda.gov/ohrms/dockets/dailys/04/June04/061004/04p-0261-cp00001-01-vol1.pdf (last accessed Oct. 26, 2004).

[9] FDA Response to Teva and Mylan Citizen Petitions, 2004P-0075/PDN1 and 2004P-0261/PDN1 (July 2, 2004), *available at* http://www.fda.gov/ohrms/dockets/dailys/04/july04/070704/04p-0261-pdn0001.pdf (last accessed Oct. 26, 2004).

[10] *Id.* at 2.

[11] Mylan Pharms., Inc. v. Food and Drug Admin., Case No. 1:04cv174 (N.D. W.Va. filed Aug. 4, 2004).

[12] Notice of Voluntary Dismissal without Prejudice, Mylan Pharms., Inc. v. Food and Drug Admin., Case No. 1:04cv174 (N.D. W.Va. Aug. 30, 2004). Trade press reported that "[t]he judge seemed to indicate that Mylan might not be able to get FDA to act under the FDC Act because the law is silent on the issue." *Mylan Drops Authorized Generics Suit Against FDA*, INSIDE WASHINGTON'S FDA WEEK, Sept. 3, 2004, at 2.

[13] Teva Pharms. USA, Inc. v. Crawford, Case No. 1:04cv01416 (D.D.C. filed Aug. 20, 2004). Private litigation also is pending in California state court. In March 2004, Mylan sued both Procter & Gamble and fellow generic manufacturer Watson Pharmaceuticals, which is marketing an authorized generic of P&G's Macrobid® (nitrofurantoin). Mylan Pharms., Inc. v. Procter & Gamble Co., Case No. CGC-04-429860 (Cal. Super. Ct. filed Mar. 23, 2004).

[14] *"Authorized" Generics are "Legitimate Business Strategy," Pfizer Says*, F-D-C REP. ("The Pink Sheet"), Oct. 18, 2004, at 24.

[15] *Congress Needs to Review "Authorized" Generics, Hatch and Waxman Agree*, F-D-C REP. ("The Pink Sheet"), Oct. 11, 2004, at 40.

[16] Pfizer, Inc., Citizen Petition, 2004P-0227/CP1 (May 11, 2004), *available at* http://www.fda.gov/ohrms/dockets/dailys/04/may04/051304/04p-0227-cp00001-vol1.pdf (last accessed Oct. 26, 2004).

Pfizer argued, among other things, that the plain language of the statute does not permit waiver or transfer, and that permitting exclusivity to be fully alienable encourages ANDA applicants to file weak applications simply to vest a lucrative asset. On July 2, 2004, the agency denied that citizen petition.[17] FDA rejected the textual argument on the ground that section 505(j)(5)(B)(iv) is ambiguous and can reasonably be interpreted to permit waiver. Further, FDA added, the statute confers a private benefit to specific entities, and in such situations judicial precedent supports inferring that the agency may allow an alternative course of action more favorable to the beneficiary. Further, the agency noted, allowing generic applicants to waive their exclusivity promotes competition by enabling other generic applicants to market their products sooner.

The original article noted that in 1999, FDA proposed regulations pursuant to which, after a triggering event, a first generic would be permitted to transfer its rights to another company.[18] Prior to occurrence of the triggering event, however, the first generic would not be permitted to do so. It could waive, or relinquish, the exclusivity entirely, but not selectively waive, or transfer, the exclusivity to another applicant. The original article stated that with the 2002 withdrawal of the proposed regulations, the use of a triggering event as a threshold requirement would not be implemented. FDA's response to Pfizer's 2004 citizen petition makes it clear, however, that FDA continues to require a triggering event in order to distinguish between relinquishment and selective waiver. Indeed, the requirement of a triggering event forms the basis of FDA's response to Pfizer's point about encouraging weak applications. "As to potential 'gaming,' if the first applicant could selectively waive [transfer] its exclusivity at any time, the agency could reasonably expect the development of a 'market' for 180-day exclusivity, with a resulting increase in ANDA's submitted solely to claim exclusivity." The agency concluded, however, "that by permitting selective waiver [transfer] only once the exclusivity is triggered, it can prevent 'gaming' of exclusivity, avoid unnecessary exclusivity disputes, and still maintain exclusivity as an adequate incentive and reward."[19]

IV. *TORPHARM*—SHARED EXCLUSIVITY

As noted in the earlier article,[20] on January 2 the U.S. District Court for the District of Columbia entered judgment for TorPharm, declaring that FDA's decision to award shared exclusivity to multiple ANDA applicants for the generic Paxil® (paroxetine hydrochloride) was contrary to the plain language of the Federal Food, Drug, and Cosmetic Act (FDCA).[21] The Department of Justice appealed, and the case is still pending.[22] Oral argument was scheduled for December 2004.[23]

V. *PUREPAC II*—CONTROLLING DATE FOR EXCLUSIVITY PURPOSES, SHARED EXCLUSIVITY

As noted in the original article,[24] on January 20, 2004, the D.C. Circuit affirmed a district court decision that: a) the operative date for the filing of an amended certification is the

[17] FDA Response to Pfizer Citizen Petition, 2004P-0227/PDN1 (July 2, 2004), *available at* http://www.fda.gov/ohrms/dockets/dailys/04/july04/070704/04p-0227-pdn0001.pdf (last accessed Oct. 26, 2004).

[18] *See* Lietzan, *supra* note 1, at 302.

[19] FDA Response to Pfizer Citizen Petition, *supra* note 17, n.5.

[20] Lietzan, *supra* note 1, at 308.

[21] *See* 2004 WL 64064 (D.D.C. Jan. 8, 2004).

[22] Apotex, Inc. v. Food and Drug Admin., Case No. 04-5046 (D.C. Cir. notice of appeal filed Feb. 13, 2004).

[23] *Court Split on FDA's Patent-by-Patent Approach to 180-Day Exclusivity*, INSIDE WASHINGTON'S FDA WEEK, June 11, 2004.

[24] Lietzan, *supra* note 1, at 306-07.

day that the certification is received by the agency, rather than the date that the certification was mailed by the applicant, and b) because where a section viii statement is proper, a paragraph IV certification is not, TorPharm's paragraph IV certification was improper and the company was not eligible for exclusivity. Two additional points are worth making about this case. First, with respect to the first ruling, the case involved only an amended certification, and both the ruling and FDA's policy[25] may be limited to that context. Second, after the *TorPharm* decision discussed *infra*, this case spawned new litigation over shared exclusivity and prompted a split of opinions within the same district court.

VI. *APOTEX*—SHARED EXCLUSIVITY

Purepac had been the first to challenge an earlier Warner-Lambert patent on Neurontin®. Arguably, in light of the decision in the *TorPharm* (Paxil®) case—that there can be only one exclusivity period for an innovator product, rather than patent-by-patent exclusivity—Purepac's exclusivity already had run.[26] On precisely this theory, Apotex brought suit against FDA in April 2004, challenging FDA's failure to grant final approval of Apotex's ANDA for generic gabapentin capsules.[27] In a June 3 ruling from the bench, the court denied Apotex's motion for a preliminary injunction, and granted the government's motion to dismiss.[28] Although the written order is spare, apparently the judge in open court disagreed with the ruling in the *TorPharm* case, found the statute ambiguous, and concluded that the agency's patent-by-patent approach was reasonable.[29] Two federal judges from the same federal district court have, therefore, ruled differently on shared exclusivity.[30] Apotex appealed this decision,[31] and the case is still pending. The court of appeals likely will consolidate the two shared exclusivity cases. The final decision will be relevant only to old ANDAs (those filed before December 8, 2003, and those filed afterwards, if a paragraph IV certification for the listed drug was filed before December 8, 2003), because exclusivity under the statute as amended in 2003 is product-by-product rather than patent-by-patent.

VII. RESPONSE TO TWO CITIZEN PETITIONS—DISCLOSURE OF DATE OF SUBMISSION

On March 2, FDA responded to citizen petitions that had been filed in 1999 and 2000, by announcing that it would now disclose on its website the date on which the first substantially complete generic drug application containing a challenge to a patent listed for the innovator drug was submitted to the agency.[32] The list of paragraph IV patent

[25] And, therefore, *id.* at 290 (fourth bullet) and 291 (third bullet).

[26] See *Appeals Court Backs FDA: Purepac Gets Gabapentin 180-Day Award*, INSIDE WASHINGTON'S FDA WEEK, Jan. 23, 2004, at 3.

[27] Apotex, Inc. v. Food and Drug Admin., 1:04-cv-00605-ESH (D.D.C. filed Apr. 14, 2004).

[28] Order, Apotex, Inc. v. Food and Drug Admin., 1:04-cv-00605-ESH (D.D.C. June 3, 2004); *see Court Split on FDA's Patent-by-Patent Approach to 180-Day Exclusivity*, *supra* note 23.

[29] *See Court Split on FDA's Patent-by-Patent Approach*, *supra* note 23.

[30] Another federal court—the New Jersey court in the *Dr. Reddy's* case—has addressed FDA's patent-by-patent approach to 180-day exclusivity, but it did not rule on FDA's policy of shared exclusivity. *See Dr. Reddy's Labs.*, 302 F. Supp. 2d at 340.

[31] Apotex, Inc. v. Food and Drug Admin., Case No. 04-5211 (D.C. Cir. notice of appeal filed June 9, 2004).

[32] Biovail Corp. Int'l, Citizen Petition, 99P-2778/CP1 (July 27, 1999) (on file with author); Hyman, Phelps, & McNamara, Citizen Petition, 00P-1556/CP1 (Oct. 4, 2000), *available at* http://www.fda.gov/ohrms/dockets/dailys/00/ Oct00/100400/cp00001.pdf (last accessed Oct. 29, 2004); FDA Response to Biovail and Hyman Phelps Citizen Petitions, 00P-1556/PAV1 (Feb. 27, 2004), *available at* http://www.fda.gov/ohrms/dockets/dailys/04/mar04/030504/00p-1556-pav00001-vol1.pdf (last accessed Oct. 29, 2004); News Release (P04-25), FDA, FDA Announces Measures to Improve Generic Drug Access (Mar. 2, 2004). Hyman Phelps also had asked that the agency disclose the patents to which ANDA applicants have made paragraph IV certifications, and the date of the first certification for each. FDA declined to do so, because the 2003 statutory amendments mooted the request. *See* FDA Response at 5-6 ("Eligibility for 180-day exclusivity for applications governed by the amended statute no longer turns on individual patents, but is product-based.").

certifications maintained on FDA's website now includes a column for "date of submission."[33]

VIII. TYPOGRAPHICAL CORRECTION

In the earlier article, the reference in footnote 29 to section 1101(b)(3) of Pub. L. No. 108-173 should be replaced with a reference to section 1102(b)(3). The D.C. Circuit decision in *Inwood*, cited in footnote 44, occurred in 1989, not 1998. And the citation at the top of page 299 to 21 C.F.R. § 214.107(c)(4) should be a citation to 21 C.F.R. § 314.107(c)(4).

[33] *See* http://www.fda.gov/cder/ogd/ppiv.htm (last accessed Oct. 29, 2004).