UNITED STATES DISTRICT COURT FOR
FOR THE DISTRICT OF COLUMBIA

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| APOTEX, INC., | ) | |
| Plaintiff, | ) | |
| v. | ) | Civil Action No. 10-00517 (RMC) |
| KATHLEEN SEBELIUS, et al., | ) | |
| Defendants. | ) | |

PLAINTIFF'S REPLY TO FEDERAL DEFENDANTS' AND TEVA'S
OPPOSITION TO MOTION FOR PRELIMINARY INJUNCTION

In interpreting the Hatch Waxman amendments to the Food, Drug, and Cosmetic Act ("FDCA"), the Food and Drug Administration ("FDA") is required to perform one task: ascertain what the intent of Congress is regarding the effect of the expiration of the '075 patent on 180-day exclusivity. The government does not disagree that this must be its initial inquiry nor does it dispute that under Chevron USA, Inc. v. Natural Res. Def. Council, 467 U.S. 837 (1984) its inquiry must end once it does so. Nor does the government retract its conclusion, having engaged in the Chevron inquiry, that it is the intent of Congress that exclusivity does not survive patent expiration. So long as FDA concludes this is the intent of Congress with respect to the expiration provisions, it is not free to depart from it, not even in favor of the reasoning the Court of Appeals applied to the delisting provisions.

The government's opposition at least confirms that its contrary conclusion is based on a misapprehension of the holding in Teva Pharm. USA, Inc. v. Sebelius, 595 F.3d 1303 (D.C. Cir. 2010) ("Teva"). The government apparently perceives that the Court of Appeals held broadly

that Hatch Waxman precludes the loss of exclusivity at any time an NDA holder can unilaterally deprive a generic applicant of exclusivity. Opp. at 6, (stating that "[t]he D.C. Circuit held that Congress did not intend to permit an NDA holder to unilaterally deprive a generic applicant of exclusivity, and that the forfeiture provisions added by the MMA did not alter that intent.").

There are three fundamental flaws with FDA's reasoning. First, the Teva decision was limited to delisting. What scant reference there is in the Teva decision to patent expiration reflects the court's view that patent expiration could result in loss of exclusivity. Second, unlike delisting, the effect of patent exclusivity is not controlled simply by the forfeiture provisions added in 2003, but rests on the 180-day provision itself, a provision that predates the 2003 amendments. Third, the agency fails to consider, let alone credit, the reasoning of court decisions that interpreted the 180-day forfeiture provisions as precluding exclusivity for an expired patent.

First, what the appellate court actually held, and what its reasoning implicates, is that FDA's pre-MMA "policy that allowed brand manufacturers to strategically delist challenged patents, thereby unilaterally stripping generic manufacturers of marketing exclusivity, was inconsistent with the structure of the statute," Teva 595 F.3d at 1305-06, and that the MMA, including the addition of Section (CC), did not evidence a Congressional intent to change that incentive structure, id. at 1318. In fact, the Teva opinion closely circumscribes its reasoning to delisting, and its language reflects this careful distinction:

> The agency . . . offers not a single cogent reason why Congress might have permitted brand manufacturers to trigger subsection (CC) [delisting] by withdrawing a challenged patent . . . .

Id. at 1317 (emphasis added).

> nothing in the 2003 amendments to the Food, Drug, and Cosmetic Act . . . changes the structure of the statute such that brand companies should be newly able to delist challenged patents,

> thereby triggering a forfeiture event that deprives generic companies of the period of marketing exclusivity they otherwise observe.

Id. at 1318 (emphasis added).

The D.C. Circuit had good reason to make this distinction. The expiration provisions have been the subject of other court rulings with entirely different reasoning. As discussed below, there are significant differences between the two, none of which FDA considered.

The government observes that the Teva court held that the use of the term "delisting" in subsection (CC) was not sufficient evidence that Congress intended that a delisting deprive a first applicant of exclusivity. See, e.g., Opp. at 2 ("the Court of Appeals in Teva held that its interpretation of the incentive structure took precedence over the plain language of the statute . . . .") (emphasis added). That statement may be true, but it is not relevant to this case. Logically, it does not necessarily follow that the appellate court would hold that the use of the term expiration in section 355(j)(5)(D)(i)(VI), the expiration forfeiture trigger, should be treated in the same way. More importantly, however, the effect of patent expiration does not rest solely on the 2003 amendments, so that the reasoning of Teva with respect to the language in subsection (CC) cannot control the interpretation of the 180-day exclusivity provision, 21 U.S.C. § 355(j)(5)(B)(iv).

The courts, including the D.C. Circuit, have reasoned that 21 U.S.C. § 355(j)(5)(B)(iv), the 180-day exclusivity provision does not allow exclusivity after patent expiration. E.g., Ranbaxy Labs Ltd. v. FDA, 307 F. Supp. 2d 15, 21 (D.D.C.), aff'd 2004 WL 886333 (D.C. Cir. 2004); Dr. Reddy's Labs, Inc. v. Thompson, 302 F. Supp. 2d 340, 354-5 (D.N.J. 2003). Nothing in the post-MMA structure undermines that conclusion. If anything, the enactment of 21 U.S.C. § 355(j)(5)(D)(i)(VI) in 2003, which specifically recognizes expiration as a forfeiture event, together with the history of court and FDA decisions holding that forfeiture does not survive

patent expiration, reinforces that the previous decisions reflect the proper balance of incentives Congress recognized when a patent expires.

Time and again FDA has argued to the courts that the forfeiture provision best effectuates the statutory goals by excluding expired patents from the ambit of patents giving rise to exclusivity.

> The 180-day exclusivity provisions were drafted to give ANDA applicants an incentive to be first to challenge a listed patent and remove that patent as a barrier to approval. Once a listed patent expires and is no longer a barrier to ANDA approval, there is no longer a need to provide an incentive to challenge it in court. Thus, an expired patent does not serve as the basis for a 180-day exclusivity aware and 180-day exclusivity does not extend beyond the life of the patent.

Letter from Gary J. Buehler, Director, Office of Generic Drugs at 11 Docket No. FDA-2007-N-0090 (April 18, 2007). In so concluding, FDA relied on the text, the structure and the policy goals underlying the statute; in short it employed the "'traditional tools of statutory construction' to determine whether Congress has spoken directly to the issue." Prime Time Int'l Co. v. Vilsak, 2010 WL 1133810 (D.C. Cir. 2010). The courts have agreed with FDA's reasoning and recognized the bright line drawn by the statute at patent expiration.

Just how deficient FDA's decision is best illustrated by Teva's opposition, which attempts in 38 pages to supply answers to questions that FDA should have addressed. But its efforts are for naught, "a reviewing court, in dealing with a determination . . . which an administrative agency alone is authorized to make, must judge the propriety of such action solely by the grounds invoked by the agency." SEC v. Chenery Corp., 332 U.S. 194, 196 (1947). The APA requires that an agency consider all relevant factors and a failure to do so provides a sound basis to set aside FDA's administrative decision. Motor Vehicle Mfrs. Ass'n. of U.S., Inc. v. State Farm Motor Auto Ins. Co., 463 U.S. 29 (1983).

Balance of Harms

One matter remains before addressing Teva's arguments. While the government argues that the harm to Apotex does not constitute irreparable harm, Opp. at 7-9,[1] it does not dispute that the public interest favors injunctive relief. Consumers suffering from hypertension spend 1.5 billion dollars a year to buy Cozaar and Hyzaar. The cost of their treatment will go down more than 50% almost immediately if Apotex and others can enter the market as they are entitled to do. Apotex Mem. at 29. But consumers will be deprived of the hundreds of millions of dollars in savings that Congress intended them to enjoy if Teva gets the six month exclusivity it seeks. Ironically, the brand name manufacturer also will benefit because the price it can charge for its own branded drugs will not decrease as much. The public interest strongly and clearly favors injunctive relief and it is neither accident nor oversight that the government does not contest that a preliminary injunction is in the public interest.

Teva's Arguments

In the very first sentence of its memorandum Teva mistakes what the D.C. Circuit said. The D.C. Circuit did not say that there is "not a single cogent reason why Congress might have permitted . . . a scenario in which a brand manufacturer can unilaterally deprive a generic of exclusivity." Teva Opp. at 1. It said that there is no cogent reason why Congress might have permitted brand manufacturers to trigger forfeiture "by withdrawing a challenged patent." 595 F.3d at 1317 (emphasis added). This is a significant difference in a case in which the issue is whether the D.C. Circuit's delisting decision applies to patent expiration.

1. The harm alleged by Apotex is more than mere economic loss, but rather the kind of long term irreparable injury that courts do recognize as the basis for injunctive relief. Apotex Mem. at 26.

In fact, the D.C. Circuit has not always concluded that brand interference with generic exclusivity is not permitted by Congress. In Teva v. Crawford, 410 F.3d 51, 54 (D.C. Cir. 2005), the D.C. Circuit concluded that preserving the 180-day incentive to challenge brand drug patents is not "without limitation," rejecting Teva's argument there that permitting brand manufacturers to market their own generic drugs would interfere with an ANDA applicant's incentives to file paragraph IV certifications. FDA evidently considered Teva v. Sibelius, but neglected to note Teva v. Crawford.

Teva works itself into a constitutional frenzy arguing that Apotex is trying to undermine Marbury v. Madison, 5 US 137 (1803). Teva Opp. at 21. This is absurd. All Apotex observed was that the agency had to determine whether the Teva decision was binding, that FDA had already determined it was not, and that once having done so, the agency must be guided by Chevron, which undoubtedly is binding precedent. Far from being upset, Mr. Madison and Justice Marshall would applaud this analysis as faithful to the bedrock principles of Marbury v. Madison.

A more pertinent question is which court decisions contain reasoning that bears most closely on patent expiration, those pertaining to delisting or those pertaining to expiration. Dr. Reddy's Labs., Inc. v. Thompson, 302 F. Supp. 2d 340 (D.N.J. 2003) and Ranbaxy Labs., Ltd. v. Leavitt, 307 F. Supp. 2d 15 (D.D.C. 2004), aff'd 96 Fed. Appx. 1 (D.C. Cir. 2004), both hold that patent expiration precludes exclusivity even if the paragraph IV applicant had been sued by the brand. In each situation the paragraph IV applicant took the risk and bore the cost of "showing the invalidity or inefficacy of a patent that a brand-name drug manufacturer has said blocks competition," Teva at 1304, yet neither received 180-day exclusivity because of the expiration of a patent.

A. The Same Considerations Do Not Apply to Patent Delisting and Patent Expiration

Teva attempts to equate patent delisting with patent expiration, arguing that Merck's decision to stop paying maintenance fees was part and parcel of its delisting decision. Teva Opp. at 2. In fact, as discussed below, there is no reason to think that this is so, or that the reasoning of Teva applies to patent expiration. The D.C. Circuit's concern in Ranbaxy, on which the Teva decision relied, was that an FDA policy that allowed brand manufacturers to "strategically" delist challenged patents was inconsistent with the structure of the statute. Teva at 1305, citing Ranbaxy, 469 F.3d at 125. The D.C. Circuit evidently believed that brand manufacturers might delist patents for the purpose of interfering with a generic's exclusivity, which would discourage ANDA applicants from filing paragraph IV certifications and undermine the incentive structure adopted by Congress. It is the potential for strategic interference that the D.C. Circuit finds objectionable.[2]

As Apotex pointed out in its opening brief, the potential for such strategic interference is far less real in the patent expiration context because unlike the delisting situation, brand manufacturers have different incentives if they have to give up control of a patented invention in order to interfere with an ANDA applicant's exclusivity. Without ever actually disagreeing that brand companies are not likely to give up patent protection to interfere with exclusivity, Teva takes great exception to Apotex' statements. Its objections are without merit.

Teva first argues, in response to Apotex's argument that a brand manufacturer sacrifices far more when it lets a patent expire than it does when it delists a patent, that brand manufacturers cannot bring patent infringement suits against a generic applicant after delisting

2. It seems clear that the D.C. Circuit would not object to the fact that expiration interferes with exclusivity in that it has previously concluded that patent expiration extinguishes exclusivity. Ranbaxy Labs., Ltd. v. FDA, 96 Fed. Appx. 1 (D.C. Cir. 2004) (unpublished).

the patent. This is not so. There are many reasons that brand manufacturers seek to withdraw patents from the Orange Book (delist the patent). Some applicable patents cannot be listed pursuant to FDA's regulations, 21 C.F.R. § 314.53. Such patents may be enforced despite being withdrawn from the Orange Book. This is not true of an expired patent, which cannot be enforced. That brand manufacturers continue to believe that unexpired, delisted patents have value is graphically illustrated by the fact that, of the 27 delisting requests currently reflected in the Orange Book, only four involve patents have been allowed to expire.[3]

Teva next challenges Apotex's assertion that a brand manufacturer is most unlikely to give up patent protection by letting a patent expire to interfere with a generic's exclusivity. It first takes exception to Apotex's use of the term "valid patent' in its opening brief, saying that the point of a paragraph IV certification is that the patent is invalid. It is true that some paragraph IV certifications challenge patents as invalid. It is also true that many other paragraph IV certifications do not assert that the patent is invalid, but rather that the patent is not infringed because the ANDA applicant has "designed around" the patent; that is, has formulated its product so as not to infringe the patent. Teva cannot assume that a paragraph IV certification means the patent is invalid. All patents are presumptively valid. Trasonic Sys., Inc. v. Non-Invasive Medical Technologies Corp., 75 Fed. Appx. 765, 781 (Fed. Cir. 2003) ("a patent issued

3. Approved Drug Products with Therapeutic Equivalence Evaluations, 30th ed., U.S. Department of Health and Human Services, 2010, Patent and Exclusivity Information Addendum; and Approved Drug Products with Therapeutic Equivalence Evaluations, Cumulative Supplement, U.S. Department of Health and Human Services, February 2010, Patent and Exclusivity Drug Product List. Exhibit 1 is a compilation of the Orange Book pages containing the patents for which delisting requests have been submitted. United States Patent and trademark Office's PAIR database, http://portal.uspto.gov/external/portal/pair (last visited March 31, 2010). Exhibit 2 is a compilation of data from the USPTO containing information corresponding to the patents for which delisting requests have been submitted. Teva also takes exception to Apotex's citation to Mylan v. Thompson, 332 F. Supp. 2d 106 (D.D.C. 2004). Apotex cited to this case to support the proposition that brand manufacturers do not always rely on patent listing to support patent infringement lawsuits, a point that the case aptly illustrates.

by the PTO is presumed to be valid, 35 U.S.C. § 282."). Until and unless a court has said that a patent is invalid, the brand manufacturer has the opportunity to enforce it, and an innovator has an incentive not to surrender its patent.

Teva goes on to say that Apotex's assertion that brand manufacturers are unlikely to engage in "'strategic gamesmanship' conflicts with the evidence in the record." The "evidence" offered is that brand manufacturers do cease paying maintenance fees. But Teva offers no evidence that the fact that brand manufacturers sometimes stop paying maintenance fees has anything to do with "strategic gamesmanship." That is because there is none. Finally, Teva asserts that patents that lapse for non-payment of maintenance fees may be revived and "shall be considered as not having expired," quoting 35 U.S.C. § 41(c)(1). If a brand manufacturer let a patent lapse and revived it, Teva's exclusivity would not be forfeited because the patent would be considered as not having expired.

Teva's entire argument depends on its premise that brand manufacturers will allow patents to expire in order to cheat generics of their exclusivity. But it offers not a shred of evidence to establish that this is so. Teva Opp. at 26-30 ("rob the generic maker of earned exclusivity" "simple artifice of ceasing to pay maintenance fees on a challenged patent," "concern with brand manipulation in both the delisting and patent-expiry contexts," "allowing brand manufactures to 'strip' the first applicant's exclusivity," "punitive manipulation,"). There simply is no evidence that brand manufacturers will do so.

Teva goes even farther. Teva accuses Merck of engaging in such conduct in this case. Teva Opp. at 30 ("sanctioning the kind of conduct Merck engaged in here would allow brand manufacturers" would allow patents to be removed from the Orange Book). There is not a single fact suggesting that Merck has the slightest interest in Teva's exclusivity in this case. After all,

Teva's first paragraph IV certification was filed in 2003. The patent did not expire in 2009. Teva also asserts that brand manufacturers will let patents expire when they lose a patent infringement lawsuit, but neglects to mention that allowing a patent to expire is a long-term proposition and that such a stratagem would rarely be possible.

B. There is a Single Standard for Patent Expiration

Teva argues that the definition of patent expiration should be determined independent of the patent law. Teva Opp. at 22-26. This argument is crucial to Teva's construct, but Teva's purported distinction, however, is nothing but artifice; it finds no support in patent law, the Hatch Waxman statute or FDA's implementing regulations or in FDA precedent. Indeed, even Teva's own distinction betrays its imprecision; a patent "naturally" expires for any number of reason under patent law. Each reason is a "natural" consequence of the underlying event.

At the time the Hatch Waxman amendments were adopted in 1984, Section 41(b) of the Patent Act provided that a patent "will expire" if the maintenance fees are not paid. 35 U.S.C. § 41(b). Unlike the practice of delisting, which emerged from the agency's administration of the Orange Book and evolving administrative rulings of what kinds of patents could be listed,[4] patent expiration has been defined by patent law to include patent expiration as a consequence of a failure to pay maintenance fees. Congress was aware when it drafted the 180-day exclusivity provision how patent law defined expiration, and nevertheless elected to exclude paragraph II certifications from triggering exclusivity. As the D.C. Circuit has held, "[h]ow a manufacturer triggers the 180-day marketing exclusivity is clear under the text of the statute: no ANDA applicant can obtain exclusivity without a proper paragraph IV certification." Teva

4. Applications for FDA Approval To Market a New Drug, 68 Fed. Reg. 36676 (June 18, 2003) (codified at 21 C.F.R. § 314.53).

Pharmaecuticals, USA, Inc. v. Leavitt, 548 F.3d 103, 106 (D.C. Cir. 2008); see also 21 U.S.C. § 355(j)(2)(AA)(vii).

Whether a patent has expired or not is defined by patent law. The length of a patent might be affected by a number of factors, payment of maintenance fees or patent term restoration, for example, but whatever the length of the term, once a patent expires, it no longer protects the invention and cannot claim the drug or block approval. Unitronics (1989) (R " G) LTD v. Gharb, 532 F. Supp. 2d 25, 28 (D.D.C. 2008) (stating that patentee "relinquished his rights to assert any claim under the . . . [p]atent, which has expired because he failed to pay the required maintenance fees to the Patent Office."); Pequignot v. Solo Cup Co., 540 F. Supp. 2d 649 (E.D. Va. 2008) (stating that "[a]n article that was once protected by a now-expired patent is no different than an article that has never received protection from a patent. Both are in the public domain.").

The failure to pay maintenance fees is one way in which a patent can expire. The holder of a patent is required to pay maintenance fees at three points during the life of the patent. 35 U.S.C. § 41(b); 37 C.F.R. § 1.362. Unless the maintenance fee and any applicable surcharge is paid within the applicable time period, the patent "will expire…." 35 U.S.C. § 41(b); 37 C.F.R. § 1.363(g).

The relevant question for purposes of Section 505(j)(5)(D)(i)VI) is whether the patent has expired. If the patent has expired, then any 180-day exclusivity has been forfeited. The statute makes no distinction based on the cause of a patent's expiration. Section 41(b) if the Patent Act specifically states that a failure to pay maintenance fees gives rise to patent expiration.

The MMA has no express definition of "expiration". But the expiration of a patent has been well defined in the patent statute, regulations and case law. Statutory provisions *in pari*

*materia* must be construed together. Nat'l Ass'n of Life Underwriters v. Clarke, 736 F. Supp. 1162, 1171 (D.D.C. 1990), rev'd by Independent Insurance Agents of America, Inc. v. Clarke, 955 F.2d 731 (D.C. Cir. 1992), judgment rev'd by U.S. Nat'l Bank of Oregon v. Independent Insurance Agents of America, Inc., 508 U.S. 439 (1993) ("The canon of *in pari materia* is a rather narrow exception to the general rule that different statutes should be read differently."). All that is required for statutory provisions to be construed under the *in pari materia* doctrine is that they relate to the same subject or object. Common Cause v. Federal Election Comm'n, 842 F.2d 436, 441-42 (D.C. Cir. 1988); U.S. v. Freeman, 44 U.S. 556, 564 (1845) ("The correct rule of interpretation is, that if diverse statutes relate to the same thing, they ought all to be taken into consideration in construing any one of them, and it is an established rule of law, that all acts *in pari materia* are to be taken together, as if they were one law."); Linquist v. Bowen, 813 F.2d 884, 888-89 (8th Cir. 1987) ("A primary rule of statutory construction is that when a court interprets multiple statutes dealing with a related subject or object, the statutes are *in pari materia* and must be considered together."); e.g., U.S. v. Stewart, 311 U.S. 60, 64 (1940) (two provisions in the Revenue Act of 1916 and the Farm Loan Act were *in pari materia* because they dealt with the same subject matter, "viz., the scope of the tax exemption afforded farm loan bonds."); Nitterright v. Claytor, 454 F. Supp. 130, 135 (D.D.C. 1978) (Title VII and the Equal Pay Act were read *in pari materia* because they both seek to eliminate employment discrimination).

Hatch Waxman and patent law both deal with the same subject of patent rights and should be considered *in pari materia*. In fact, the formal name of Hatch Waxman, the Drug Price Competition and Patent Term Restoration Act, reflects that it was meant to deal with patent rights and Hatch Waxman amended both the FDCA and patent laws. See also Eli Lilly & Co. v.

Medtronic, Inc., 496 U.S. 661, 669 (1990) ("the 1984 [Hatch Waxman] Act was designed to respond to two unintended distortions of the 17-year patent term produced by the requirement that certain products must receive premarket regulatory approval."); id. at 665 (stating that Hatch Waxman amended both laws); Warner-Lambert Co. v. Apotex Corp., 316 F.3d 1348, 1358 (Fed. Cir. 2003) (Hatch Waxman was a compromise between the interests of innovative drug manufacturers who had seen their effective patent terms shortened and those of generic drug manufacturers). Certainly the relationship between Hatch Waxman and patent law is at least as similar to that between patent law and antitrust law, which the Supreme Court has found to be *in pari materia*. Simpson v. Union Oil Co. of Cal., 377 U.S. 13, 24 (1964) ("The patent laws which give a 17-year monopoly on 'making, using, or selling the invention' are *in pari materia* with the antitrust laws and modify them pro tanto. That was the ratio decidendi of the General Electric case."). In General Electric the Supreme Court considered the monopoly given under the patent law in considering whether General Electric's actions were in violation of the restrictions against monopolies in the Anti-Trust Act. United States v. General Electric Co., 272 U.S. 476, 485 (1926). Similarly here, both provisions of the patent law and Hatch Waxman deal with scope of patent rights and patent expiration, as both statutes dealt with monopolies in General Electric.

If statutes are *in pari materia* then they are "construed together to discern their meaning." Motion Picture Ass'n of America, Inc. v. FCC, 309 F.3d 796, 801-02 (D.C. Cir. 2002); United States v. Stewart, 311 U.S. 60, 64 ("It is clear that 'all acts *in pari materia* are to be taken together, as if they were one law.'") (quoting United States v. Freeman, 44 U.S. 556, 564 (1845)); Hornbeck Offshore Transportation, LLC v. U.S. Coast Guard, 424 F. Supp. 2d 37, 52 (D.D.C. 2006) ("This Circuit follows the canon of statutory construction that holds that '[s]tatutory provisions *in pari materia* normally are construed together to discern their

meaning.'"). As the Supreme Court stated in Erlenbaugh "[t]he rule of *in pari materia* – like any cannon of statutory construction – is a reflection of practical experience in the interpretation of statutes: a legislative body generally uses a particular word with a consistent meaning in a given context." Erlenbaugh v. U.S., 409 U.S. 239, 243 (1972). Accordingly, there is no reason to craft an additional definition solely for purpose of Hatch Waxman. Moreover, in order to distinguish based on the cause of expiration would require a wholesale rewriting of the provision, a task contrary to basic principles of statutory construction. Ali v. Fed. Bureau of Prisons, 552 U.S. 214, 228 (2008) ("We are not at liberty to rewrite the statute to reflect a meaning we deem more desirable."); Doe v. Dept. of Veterans Affairs, 519 F.3d 456, 461 (8th Cir. 2008) (a statute is to be interpreted as written, "the power to redraft laws…is reserved to the legislative branch"); Palisades Collections LLC v. Shorts, 552 F.3d 327, 336 (4th Cir. 2008) (a statute is to be interpreted as it was written).

C. Interpreting the Statute As Written Will Not Allow Brand Manufacturers to Negligently Strip the First Challenger of Exclusivity

Teva argues that interpreting the statute to preclude exclusivity for a patent that has expired for failure to pay maintenance fees would allow brand manufacturers to negligently strip the first challenger of exclusivity. Teva Opp. at 25. FDA has already explained why this would not happen.

> A patent holder that has overlooked a payment would not confirm that the patent has expired; the patent would remain in the Orange Book, all ANDA applicants would have to maintain their exclusivity and the exclusivity provision would work to preserve 180-day exclusivity: As an initial matter, FDA will not change the applicable patent expiration date unless the NDA holder tells the Agency to do so. If the NDA holder (who is also likely to be the patent owner or licensee) notifies FDA that the patent has expired due to failure to pay fees, it can be presumed to have resolved at least to a reasonable certainty the finality of the patent expiration. Further, the concerns about uncertainty of expiration would presumably extend to all situations in which a patent has expired

> due to failure to pay fees, including those in which, although 180-day exclusivity is not an issue, reliance on a later expiration date could delay generic drug approvals. For example, if an NDA holder notified FDA that a patent on a drug as to which no ANDA had yet been submitted had expired due to failure to pay fees, but FDA refused to accept the NDA holder's representation because of uncertainty that the patent would remain "expired," future ANDA applicants would be required to submit patent certifications for a patent that may have its natural patent expiration years in the future. If the NDA holder is sufficiently certain its patent has expired that it notifies FDA of that fact, FDA believes that generic drug applicants are entitled to rely on that patent expiration date in seeking approval for their drug products.

FDA Administrative Decision at 5.

Teva's related argument that a company that loses a patent infringement litigation will then turn around and let the patent expire fails to account for patent law. Even if a brand name company wanted to do so, it cannot do so. Maintenance fees are due only three times during the life of a patent. 35 U.S.C. § 41(b) Pub. L. No. 96-517, § 2(c) (1980). A patent can expire only at three times during the life of a patent. Id. Merck, for example, may have wanted the patent to expire in 2005, but it could not. The '075 patent did not expire for another four years.

D. Teva Correctly Understands the Policy Rationale for Exclusivity In Connection With an Expired Patent

Interestingly, Teva sets forth a quite cogent rationale for why exclusivity should not be awarded in connection with an expired patent. Teva Opp. at 30-31. Teva explains that paragraph IV certifications are intended to enable the early entry of generic drugs and that, where the patent expires before the first generic enters the market, the certification has accomplished "virtually nothing." Id. at 31, quoting Dr. Reddy's Labs., Inc. v. Thompson, 302 F. Supp. 2d 340 (D.N.J. 2003); and citing Andrx Pharms., Inc. v. Biovail Corp. Int'l, 256 F.3d 799, 809 (D.C. Cir. 2001); In re Barr Labs., Inc., 930 F.2d 72, 76 (D.C. Cir. 1991). Apotex agrees that this is in fact an important reason why expired patents do not support exclusivity. But, says Teva, where a

paragraph IV certification caused the patentee to cease paying maintenance fees, the paragraph IV certification has accomplished something. Teva Opp. at 31. Once again, there is absolutely no reason to believe that paragraph IV certifications have caused brand manufacturers to let patents expire. Teva offers not a single example of where such a thing has happened and no reason why a paragraph IV certification should cause a brand manufacturer to let a patent expire. As explained above, the odds that a brand manufacturer would sacrifice a patent to interfere with a generic's exclusivity are remote at best. Brand manufacturers generally gain from 180-day exclusivity because there are fewer competitors on the market during the exclusivity period. See, e.g., Remarks of J. Thomas Rosch, Commissioner, Federal Trade Commission, "Pay-for-Delay Settlements, Authorized Generics, and Follow-on Biologics: Thoughts on How Competition Law Can Best Protect Consumer Welfare in the Pharmaceutical Context," November 19, 2009 (during the 180-day exclusivity period, the brand "still has a 'monopoly' so-to-speak over those purchasers interested in buying a generic). Teva itself has argued that brand manufacturers have an incentive to preserve exclusivity. In Teva Pharmaceuticals USA, Inc. v. Pfizer, Inc., 395 F.3d 1324 (Fed. Cir. 2005), Teva was attempting to trigger a competitor's exclusivity so as to avoid a delay in its own approval. Teva there argued that the brand manufacturer, Pfizer, was manipulating the process by refusing to engage in patent litigation because "if Pfizer can avoid triggering [the competitor's] exclusivity period, . . . it can expect to enjoy six months of selling [the brand drug] with only one royalty-paying generic competitor." Id. at 1337.

E. Teva's Other Arguments

Teva also argues that we should "[m]ake no mistake: Teva has earned its statutory reward here," by making "enormous investment" to design around the '075 patent. Teva Opp. at 32. In fact, Teva is no different from Apotex, Roxane, and several other companies who also designed around the '075 patent. Those companies made the investment even though they would

not get exclusivity. Apotex recognizes that the statute provides for 180-day exclusivity in the right circumstances, but Teva should not be allowed to cast itself as a martyred victim when it did no more than many other companies have done.

Teva's two final points are no stronger. Teva finds it curious that Apotex should argue that Apotex's own ANDA contains a paragraph II certification and is therefore not blocked even if Teva has exclusivity. Teva Opp. at 32. Teva's curiosity has been piqued only because it does not understand what FDA did. Teva evidently thinks that FDA found that the '075 patent has not expired for purposes of the Hatch Waxman Act, and that Apotex must therefore convert its paragraph II certification to a paragraph IV certification. Teva Opp. at 33. But FDA did not find that the '075 patent had not expired, and Apotex has no obligation to convert its paragraph II certification to a paragraph IV certification. Teva has put its finger on one of the anomalies in FDA's logic – FDA has reached a conclusion that its totally at odds with its own statute and regulations, which require that it approve an ANDA with a paragraph II certification, without offering any explanation of how it will reconcile its actual decision with the statute and regulations that it administers.[5]

Teva closes by arguing that Apotex cannot argue that FDA's "ministerial role" extinguishes Teva's exclusivity. Teva here sets up a straw man. Apotex does not argue that FDA's ministerial role extinguishes Teva's exclusivity. Apotex argues that FDA's construction of the statute that it administers forecloses Teva's exclusivity. FDA's ministerial role is just one

5. Teva argues that Apotex's argument is foreclosed by Sandoz, Inc. v. FDA, 439 F. Supp 2d 26, 30-31 (D.D.C. 2006). There is one crucial difference between this case and Sandoz. There, FDA had requested that Sandoz change its certification to effectuate Teva's exclusivity because the agency had concluded that a delisted patent did not affect Teva's exclusivity. But FDA has not concluded here that an expired patent does not extinguish exclusivity, and has not requested that Apotex change its certification. FDA has concluded only that it will follow the D.C. Circuit's Teva decision, regardless of the conflict with the statute and regulations.

piece of the agency's longstanding interpretation of the statute, and, as FDA's decision states, is a part of its regulations. FDA Decision at 6. This is another illustration of how FDA's Decision is entirely inconsistent with its statute and regulations.

Conclusion

For the reasons stated above and in Apotex's initial memorandum, FDA's administrative decision is arbitrary, capricious and contrary to law and should be set aside.

Dated: April 1, 2010

Respectfully submitted,

/s/

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