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Patent Expiration and 180-Day Generic Exclusivity Under the Hatch-Waxman Act: *Teva v. Sebelius*

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The D.C. Circuit recently rejected arguments designed to limit the 180-day exclusivity period statutorily granted to the first to file an abbreviated new drug application (ANDA). First, the court held that a branded drug producer cannot trigger a forfeiture of the exclusive right to market a generic equivalent of a branded drug for 180 days by delisting patents covering the branded drug.[1] Second, in implementing the D.C. Circuit's decision, the D.C. District Court rejected the Food and Drug Administration's argument that the 180-day exclusivity period was forfeited when the patent for the branded drug expired due to failure to pay maintenance fees.[2] In both decisions, the D.C. courts reinforced the public policy purpose of the 180-day exclusivity period to promote competition by creating an incentive for prospective entrants to bring generic equivalents to market and, in the process, challenge suspect patents.[3]

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[1] *See Teva Pharmaceuticals USA Inc. v. Sebelius*, No. 09-5281 (D.C. Cir. March 2, 2010) (Teva I) (8 PLIR 267, 3/5/10).

[2] *See Teva Pharmaceuticals USA Inc. v. Sebelius*, No. 09-1111 (D.D.C. March 16, 2010) (Teva II).

[3] *See* Teva I at 4.

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I. Delisting a Patent Does Not Affect Exclusivity

Under the Federal Food, Drug, and Cosmetic Act (FDCA), as amended by the Drug Price Competition and Patent Term Restoration Act of 1984 (the Hatch-Waxman Act)[4] and the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (the 2003 amendments),[5] the first to file an ANDA to market a generic equivalent of a branded drug is entitled to a 180-day exclusivity period to sell the generic drug, beginning from the FDA's final approval of its application, unless one of six ''forfeiture events'' occurs.[6]

In *Teva Pharmaceuticals USA Inc. v. Sebelius*, Teva was the first to file an ANDA for losartan potassium tablets and losartan potassium-hydroclorothiazide tablets, which are used to treat hypertension. Merck holds the new drug application (NDA) for those drugs, and markets them as Cozaar and Hyzaar, respectively. The NDA initially identified U.S. Patent No. 5,608,075 (the '075 patent) as covering the losartan potassium drugs. The FDA tentatively approved Teva's ANDA. While Teva awaited final approval, Merck asked the agency to delist the '075 patent from FDA's *Orange Book*, claiming that the patent did not, in fact, cover its losartan potassium drugs. Under the FDA's interpretation of the FDCA, this vitiated Teva's right to 180-day exclusivity as the first applicant by triggering a forfeiture event. Under § 505(j)(5)(D)(i)(I) of the FDCA, a first applicant forfeits 180-day exclusivity if it fails to market a drug for which it has submitted an ANDA within 75 days after the date on which the holder of the related NDA withdraws the patent information submitted in conjunction with the NDA.[7] The FDA interpreted this provision so that a forfeiture event occurs when a patentee delists the patent or patents covering the branded drug.

Faced with the loss of exclusivity, Teva filed suit in federal court in the District of Columbia, seeking a declaration that the FDA's interpretation was unlawful and an injunction compelling the agency to adopt an interpretation that would preserve Teva's 180-day exclusivity. The district court held in favor of the FDA's interpretation,[8] and Teva appealed.

The D.C. Circuit rejected the FDA's interpretation as failing step one of *Chevron U.S.A. Inc. v. Natural Resources Defense Council Inc.*, 467 U.S. 837 (1984).[9] Although the court of appeals considered the FDA's interpretation plausible linguistically,[10] it held that the structure of the Hatch-Waxman Act forecloses an interpretation that would give the branded drug manufacturer the power to vitiate the first applicant's 180-day exclusivity because that would alter the incentive structure of the act.[11] The court affirmed its prior decision in *Ranbaxy Labs. Ltd. v. Leavitt*,[12] which dealt with nearly identical facts, but was decided prior to the 2003 amendments that added the forfeiture event provisions.

The court noted that the Hatch-Waxman Act's ''promise of initial marketing exclusivity is . . . intended to increase competition by expediting the availability of generic equivalents,''[13] and that the ''grant of a 180-day delay in multiple generic competition for the first successful paragraph IV filer is a pro-consumer device. And it happens to be precisely the device Congress has chosen to induce challenges to patents claimed to support brand drugs.''[14] The court explained that the Hatch-Waxman Act:

> deliberately sacrifices the benefits of full generic competition at the first chance allowed by the brand manufacturer's patents, in favor of the benefits of earlier generic competition, brought about by the promise of a reward for generics that stick out their necks (at the potential cost of a patent infringement suit) by claiming that patent law does not extend the brand maker's monopoly as long as the brand maker has asserted.[15]

Because it determined that allowing the patentee to vitiate the first applicant's 180-day exclusivity would subvert the Hatch-Waxman Act's incentive structure, and that the 2003 amendments had not altered that incentive structure,[16] the D.C. Circuit held that the FDA's interpretation subverted congressional intent and was thus unlawful.[17]

II. Not All Patent Expirations Affect 180-Day Exclusivity

After the D.C. Circuit issued its decision in *Teva Pharmaceuticals*, the FDA learned that the '075 patent had expired in March 2009 because Merck, the patentee, had failed to pay the applicable maintenance fee. Unlike the delisting of relevant patent, the FDCA specifically provides that one forfeiture event is the ''[e]xpiration of all patents,'' so that ''[a]ll of the patents as to which the applicant submitted a certification qualifying it for the 180-day exclusivity period have expired.''[18]

The D.C. Circuit held that the FDA's interpretation of the law subverted congressional intent.

Thus, the question arose: did the expiration of the '075 patent change the outcome of the D.C. Circuit's decision in *Teva Pharmaceuticals*? In its order awarding Teva its 180-day exclusivity period and enjoining the

[4] Pub. L. No. 98-417, 1984 Stat. 1545 (1984).
[5] Pub. L. No. 108-173, 117 Stat. 2066 (2003).
[6] 21 U.S.C. § 355(j)(5)(D)(i).
[7] 21 U.S.C. § 355(j)(5)(D)(i)(I)(bb)(CC).
[8] *See Teva Pharm. USA Inc. v. Sebelius*, 638 F. Supp. 2d 42 (D.D.C. 2009) (7 PLIR 964, 8/21/09).
[9] Teva I at 29.
[10] *Id.* at 24.
[11] *Id.* at 24-29.
[12] 469 F.3d 120 (D.C. Cir. 2006) (4 PLIR 1189, 11/17/06). *Ranbaxy Labs.* states, ''By . . . reducing the certainty of receiving a period of marketing exclusivity, the FDA's delisting policy diminishes the incentive for a manufacturer of generic drugs to challenge a patent listed in the Orange Book in the hope of bringing to market a generic competitor for an approved drug without waiting for the patent to expire. The FDA may not, however, change the incentive structure adopted by the Congress, for the agency is bound not only by the ultimate purposes Congress has selected, but by the means it has deemed appropriate, and prescribed, for the pursuit of those purposes.'' *Id.* at 126.
[13] Teva I at 4.
[14] *Id.* at 28-29.
[15] *Id.* at 24-25 (citing *Ranbaxy Labs.*, 469 F.3d at 126).
[16] *Id.* at 25.
[17] *Id.* at 29.
[18] 21 U.S.C. § 355(j)(5)(D)(i)(VI).

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FDA from approving any other ANDA application until after the expiration of that 180-day exclusivity period, the D.C. district court tacitly found that the outcome was the same whether the branded pharmaceutical company delists its patent or whether it fails to pay maintenance fees on its patent—the generic company that filed the first ANDA on a drug retains its rights to a 180-day exclusive sales period.[19]

While the district court did not fully describe its reasoning, the decision is firmly grounded in both the patent laws and in the reasoning of the D.C. Circuit in *Teva Pharmaceuticals*. Under the Patent Act, a patent expires 20 years from the filing date of the application for that patent.[20] This provision is unconditional, clear, and operates independent of any action by the patent holder. By contrast, a patent also might expire if the patentee fails to pay the appropriate maintenance fees, which are fees due periodically throughout the life of the patent.[21] This provision for early termination of a patent creates considerable uncertainty, because it is subject to exceptions that depend heavily on the patent holder's behavior. For example, the Patent Act gives the patentee a six-month grace period after a maintenance fee is due during which it may pay the fee with no further requirements.[22] Next, for 24 months after the grace period runs, the patentee may have the patent reinstated by paying the maintenance fee and showing that the delay in payment was ''unintentional.''[23] Further, ''at any time after the six-month grace period,'' the patentee may have the patent reinstated by paying the maintenance fee and showing that the delay was ''unavoidable.''[24] Importantly, if the patentee pays the overdue fee, ''[t]he patent shall be considered as *not having expired* at the end of the grace period.''[25]

Therefore, unlike the natural expiration of a patent after 20 years, a patent that temporarily lapses for failure to pay maintenance fees does so as a result of a unilateral act of the patent holder. And, such an act may be reversed—again unilaterally—by the patent holder. In *Teva Pharmaceuticals*, the D.C. Circuit specifically condemned an interpretation of the FDCA that would permit a unilateral decision by the patent holder to deprive generic manufacturers of the 180-day exclusivity period mandated by Congress, noting that the FDA ''offer[ed] *not a single cogent reason* why Congress might have permitted brand manufacturers to trigger [forfeiture] by withdrawing a challenged patent, outside the counterclaim scenario [existing elsewhere in the Act] identified by Teva.''[26]

Similarly, a brand manufacturer should not be permitted to unilaterally stop paying maintenance fees on a patent in order to deprive a generic competitor of its right of exclusivity. Following the court's rationale in *Teva Pharmaceuticals*, if a patent is in effect when a generic files an ANDA application certifying under paragraph IV that the patent is either invalid or not infringed, no unilateral act by the brand manufacturer should be able to vitiate the 180-day exclusivity right bestowed on that applicant by statute. Interpreting the Hatch-Waxman Act to prevent patent holders—who have an enormous financial incentive to block generic competition—from single-handedly eradicating the 180-day exclusivity period comports with Congress's intent to encourage prospective manufacturers to challenge suspect patents and bring generic equivalents to market for the benefit of consumers.

A contrary interpretation would lead to results that directly conflict with the objectives of the Hatch-Waxman Act. Recall that the Patent Act provides that a patent that has been reinstated ''shall not abridge or affect the right'' of any person who undertook acts that would otherwise infringe that patent during the period between the end of the grace period and reinstatement.[27] Thus, if a person practiced the patent for the first time during the period the patent was ''expired'' before reinstatement, that person is given intervening rights or vested rights and still may practice that patent once it is reinstated.[28]

Consider the following scenario if the patent holder's decision to suspend payment of maintenance fees were sufficient to extinguish the 180-day exclusivity period Congress enacted. A first applicant files an ANDA, risking patent infringement litigation. The patentee then elects to stop paying the maintenance fee, causing that patent to become unenforceable and inviting other firms to bring generic equivalents to market. Next, the patentee reverses course, pays the maintenance fee and reinstates, the patent. The result is that the first ANDA applicant would have borne the risk of entering the market without reaping the reward of exclusivity.

The difference between a patent expiring naturally and a patent temporarily lapsing for failure to pay maintenance fees is significant.

Under this scenario, only the first applicant would be subject to a suit for patent infringement, because it filed its ANDA during the time the patent was in effect.[29] The Patent Act would protect the other generic's otherwise infringing activities undertaken during the period between the patentee's refusal to pay the maintenance fee and reinstatement.[30] Therefore, the party that bore the risk of litigation not only is deprived of its incentive for doing so (the 180-day exclusivity would be forfeited due to the failure to pay a maintenance fee), but also would suffer a powerful disincentive for taking such a risk (costly litigation). Such an outcome would frustrate Congress's intent of promoting early entrance by generic manufacturers.

[19] *See Teva Pharmaceuticals USA Inc. v. Sebelius*, Civil Action No. 09-01111 (D.D.C. March 16, 2010) (Teva II).

[20] 35 U.S.C. 154(a)(2). If the patent application was filed before June 8, 1995, the term for a patent issuing from that application is 17 years from the date the patent issues.

[21] *See* 35 U.S.C. § 41(b).

[22] *See* 35 U.S.C. § 41(c)(1).

[23] *Id.*

[24] *Id.*

[25] *Id.* (emphasis added); *see also Cardiac Pacemakers Inc. v. St. Jude Med.,Inc.*, 381 F.3d 1371 (Fed. Cir. 2004) (affirming district court's decision that patent had not expired due to failure to pay correct maintenance fee because Patent Office accepted late payment of fee).

[26] Teva I at 27.

[27] *Id.* at § 41(c)(2).

[28] *Id.*

[29] 35 U.S.C. § 271(e)(2)(A).

[30] *See* 35 U.S.C. § 41(c)(2).

The difference between a patent expiring naturally and a patent temporarily lapsing for failure to pay maintenance fees is significant. Only in the instance of a patent's natural expiration can one be certain that the patent is dedicated to the public. A provisional and conditional pause in the enforceability of a patent based on a decision to stop paying administrative fees provides uncertainty as to the continuing viability of a patent, at best. At worst, it encourages patent holders to convert statutory relief for missed payments into a strategic weapon that undermines the will of Congress.

In the Hatch-Waxman Act, Congress balanced the need to protect patent rights of innovator companies with the need to promote competition by generics. An essential part of this balance is the 180-day exclusivity period a first ANDA applicant receives under the act. Interpreting the Hatch-Waxman Act so that a patentee's temporary failure to pay the maintenance fee on its patent vitiates this exclusivity creates unnecessary uncertainty when applied to the Patent Act and undermines the congressional intent of the Hatch-Waxman Act.

III. Postscript to the Teva Litigation

As a postscript to the litigation between Teva Pharmaceuticals USA and the FDA, two competing ANDA applicants filed a motion for a preliminary injunction to stop the FDA from granting Teva its 180-day exclusivity.[31] Again, applying the reasoning of the D.C. Circuit, the D.C. District Court denied the motion for a preliminary injunction thus allowing Teva to enjoy its 180-day exclusivity period.[32]

In *Apotex Inc. v. Sebelius*, Apotex Inc. and Roxane Laboratories Inc., two manufacturers of generic drugs, asserted that the FDA's actions were arbitrary and capricious in applying the analysis of Teva I and allowing Teva to have its 180-day exclusivity. The district court acknowledged that the Hatch-Waxman statute provides that a patent expiration is a separate basis on which to forfeit the exclusivity provision and such a basis was not addressed by the Teva I court.[33] Nevertheless, the court held that the FDA was not arbitrary and capricious when it expressed disagreement with the D.C. Circuit decision in Teva I but nonetheless applied the reasoning of the circuit ''to a different but, on these facts, closely related question.''[34] Thus, the court determined that plaintiffs could not establish that they would succeed on the merits and denied the motion for a preliminary injunction.

In a further postscript to the litigation, on April 5, 2010, the FDA filed a Petition for Panel Rehearing and Rehearing *En Banc* with the D.C. Circuit.[35] In its petition, the FDA asserts that the court did not adequately consider whether Teva's original action was ripe because the FDA had not approved its ANDA application and therefore the court's decision was merely advisory. In the meantime, however, on April 7, 2010, the FDA approved Teva's ANDA application and triggered its 180-day exclusivity period. The FDA also challenges the D.C. Circuit's original interpretation of the Hatch-Waxman statute arguing that the FDA's original interpretation denying Teva its exclusivity was the correct interpretation of the statutory provisions. The FDA's petition still is pending at the D.C. Circuit, making it clear that there may be more to come on the interpretation of the generic exclusivity provisions of the Hatch-Waxman Act.

IV. Conclusion

It appears that the issue of whether a generic drug manufacturer can be denied its 180-day period of exclusivity based on the unilateral actions of the branded manufacturer and patent holder has been put to rest. The D.C. courts have repeatedly reinforced the public policy purpose of the 180-day exclusivity period, which is to promote competition by creating an incentive for prospective entrants to bring generic equivalents to market and, in the process, challenge suspect patents. This public policy has been challenged from many angles in Teva I, Teva II, and the Apotex decisions. All of those decisions have upheld the exclusivity right of a generic manufacturer when that exclusivity is challenged by actions outside of the control of the generic manufacturer.

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[31] *See Apotex Inc. v. Sebelius*, No. 10-517 (D.D.C. April 5, 2010).

[32] *See id.* at 5.

[33] *See id.* at 5.

[34] *Id.*

[35] *Teva Pharmaceuticals Inc. v. Sebelius*, No. 09-5281, Petition for Panel Rehearing and Rehearing *En Banc* (D.C. Cir. April 5, 2010) (8 PLIR 451, 4/9/10).

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