UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

TEVA PHARMACEUTICALS USA, Inc. Plaintiff, v. KATHLEEN SEBELIUS, in her official capacity as Secretary of Health and Human Services; MARGARET HAMBURG, M.D., in her official capacity as Commissioner of Food and Drugs; UNITED STATES FOOD AND DRUG ADMINISTRATION, Defendants.	Case No. 1:09-cv-01111-GK

TEVA PHARMACEUTICALS USA, INC.'S MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT OF ITS MOTION FOR A PRELIMINARY INJUNCTION

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INTRODUCTION

Two basic principles allow our modern administrative state to function properly. The first is that federal agencies must follow clear statutory directives, as discerned from the text, structure, and purposes of the legislation that Congress passes and the President signs into law. The second is that parties aggrieved by an administrative agency's implementation of federal law must have an adequate opportunity to obtain meaningful judicial review of the agency's actions. In this case, FDA has attempted to circumvent both of these principles, and its actions irreparably will deprive Teva Pharmaceuticals of its statutory right to a 180-day period of exclusivity for sales of generic losartan potassium products—and literally hundreds of millions of dollars in revenues that can never be recovered from FDA or anyone else—unless this Court immediately grants Teva relief that effectively restores its statutory right to exclusivity.

The discrete legal issue presented in this case arises from recent amendments to the Hatch-Waxman Act, but the territory here is well-worn: Both this Court and the D.C. Circuit flatly rejected FDA's efforts to undermine the statutory incentives for generic market entry last time FDA adopted ***the very same*** substantive rule at issue here. *See Ranbaxy Labs. Ltd. v. FDA*, 469 F.3d 120 (D.C. Cir. 2006). That rule involves patent "delisting"—the removal of a patent from FDA's official list of patents for brand-name drugs. And as set forth below, FDA's recalcitrant approach to patent delisting threatens to undermine the entire Hatch-Waxman framework, to the detriment of the generic pharmaceutical industry, public and private insurers, and most important, the millions of consumers who depend on safe and affordable generic medicines.

In particular, both the Hatch-Waxman Act and FDA's regulations require each brand manufacturer to "list" in an official FDA compendium all patents that, according to the manufacturer, claim its approved drug products. Congress imposed that requirement for a

reason: so that generic manufacturers that wish to market competing versions of a brand-name drug know precisely which patents stand in their way. Armed with this knowledge, and encouraged by Congress, generic manufacturers devote significant resources to challenging the brand manufacturer's listed patents—either by designing generic formulations that have the same therapeutic benefits as their brand-name equivalents but do not infringe the brand manufacturer's patents, or by challenging the legal validity or enforceability of those patents. In an era of spiraling healthcare costs, this patent-challenge system gives millions of consumers an opportunity to buy generic drugs at far lower prices, long before the patents that nominally claim expensive brand-name drugs expire.

To encourage generic drug manufacturers to invest these resources and risk suit for infringing a brand manufacturer's patents, Congress rewards the first patent-challenging generic applicant with a 180-day period during which that applicant is the only generic company allowed to sell a generic version of the brand-name drug. This 180-day "exclusivity period" not only allows the first applicant to sell a particular product without generic competition for six months, but provides that applicant with an opportunity to establish mutually beneficial, long-term distribution arrangements with wholesalers and retailers. For this reason, the 180-day exclusivity incentive can be worth literally hundreds of millions of dollars to a generic manufacturer in cases involving drugs like losartan potassium, for which Merck's annual brand-name sales exceed $1.5 billion. *See* Declaration of David Marshall (the "Marshall Decl.") at ¶ 4 (attached as Exhibit A).

At the same time, fierce competition among generic applicants to secure such lucrative exclusivity periods has spawned hundreds of billions of dollars in healthcare savings for consumers since Hatch-Waxman first was enacted in 1984. Indeed, as a direct result of Hatch-Waxman's streamlined approval process for generic drugs and its 180-day exclusivity incentive,

generic medicines now account for more than 60 percent of all prescriptions dispensed in the United States (up from 18.6 percent when Hatch-Waxman first was passed in 1984), but less than 20 percent of every dollar spent on prescription drugs. Richard G. Frank, *The Ongoing Regulation of Generic Drugs*, 357 NEW ENG. J. MED. 1993-94 (2007); Laura J. Robinson, *Analysis of Recent Proposals To Reconfigure Hatch-Waxman*, 11 J. INTELL. PROP. L. 47, 48 (2003) ("In effect, the Hatch-Waxman amendments created the modern generic drug industry.").

Given the importance of the 180-day exclusivity incentive to both the generic industry and the public, Congress and the D.C. Circuit long have made clear that FDA may not permit brand manufacturers to undertake regulatory actions that improperly would divest the first generic applicant of its 180-day exclusivity period and thereby undermine Hatch-Waxman's incentive regime. In particular, as the D.C. Circuit held in *Ranbaxy*, FDA may not permit a brand manufacturer to remove a patent it previously submitted for listing in FDA's official list of drug-claiming patents—that is, to "delist" a previously submitted patent—after a generic applicant has challenged that patent through the Hatch-Waxman process and thereby qualified for 180-day exclusivity. As *Ranbaxy* explained, permitting patent delistings in these circumstances would effectively strip the first applicant of its right to 180-day exclusivity, and thus fundamentally would undermine the statutory scheme. Accordingly, *Ranbaxy* overturned—at *Chevron* step one—a prior FDA regulation that allowed brand manufacturers to delist challenged patents where doing so would divest the first applicant of its 180-day exclusivity period. And the D.C. Circuit in *Ranbaxy* repeatedly made clear that FDA may not lawfully undermine Hatch-Waxman's incentive structure by allowing brand manufacturers to manipulate the exclusivity reward through patent delistings. *Id*. at 125-26.

Despite the D.C. Circuit's stark repudiation of FDA's prior regulation authorizing exclusivity-divesting patent delistings, FDA once again has adopted a binding rule that effectively permits brand manufacturers to deprive the first generic applicant of its 180-day exclusivity by delisting a previously challenged patent ("the Delisting Rule"). According to FDA, however, its new Delisting Rule allegedly does not violate *Ranbaxy* because a new statutory provision not at issue in the *Ranbaxy* case now "expressly addresse[s]" the "effect of patent delisting on eligibility for 180-day exclusivity." Acarbose Letter Decision, FDA Docket No. 2007-N-0445 (May 7, 2008) at 8 ("Acarbose Dec.") (attached as Exhibit B) (citing 21 U.S.C. § 355(j)(5)(D)(i)(I)(bb)(CC)). In particular, that statutory provision—the so-called "delisting trigger"—provides that a first generic applicant can "forfeit" its right to 180-day exclusivity if it fails to begin marketing its products within 75 days after a delisting takes place. *See* 21 U.S.C. § 355(j)(5)(D)(i)(I)(bb)(CC).

The Agency's assertion that the delisting trigger renders *Ranbaxy* irrelevant because the trigger now "expressly addresses" the "effect of patent delisting" is a classic *non-sequitur*. While the delisting trigger unquestionably addresses "***the effect***" of patent delistings after they occur, it says nothing about ***when*** patent delistings are permissible—and thus can occur—in the first instance. Other amendments made by the MMA supply the answer to ***that*** question, by creating a new mechanism for delisting: a cause of action that for the first time allows patent-challenging generic applicants to seek a court order compelling the brand manufacturer to delist a challenged patent against its will. *See* 21 U.S.C. § 355(j)(5)(C)(ii)(I).

Read together, as statutory provisions must be, it thus is clear that these twin amendments—the delisting mechanism, on one hand, and the delisting trigger, on the other—were not remotely intended to open the proverbial floodgates to manipulative, exclusivity-

divesting patent delistings by brand manufacturers, and thus *sub silentio* to abrogate the longstanding prohibition against such delistings that *Ranbaxy* recognized. To the contrary, these interlinked provisions merely provide that when a first applicant secures a court-ordered patent delisting that clears the last remaining hurdle to generic competition, it cannot indefinitely delay generic competition by refusing to sell its product for more than 75 days after the court-ordered delisting. Beyond that, however, the delisting trigger does not remotely authorize manipulative patent delistings that take place apart from, and wholly outside the confines of, the statute's new delisting mechanism. FDA has no answer to this simple point, and it is dispositive.

Perhaps because it recognizes that its post-*Ranbaxy* Delisting Rule is untenable, however, FDA has adopted a corollary procedural rule that effectively thwarts meaningful judicial review of the Delisting Rule. In particular, FDA—after its loss in the *Ranbaxy* case—adopted a policy under which it refuses to issue a formal determination that a given generic applicant has forfeited its exclusivity under the Delisting Rule until the Agency is prepared simultaneously to approve competing generic applications. FDA applies this policy even when the first applicant's alleged forfeiture under the Delisting Rule occurred months or years before FDA formally announces its application of the Delisting Rule, and even though the facts necessary to render such a determination have been known for years.

The effect of FDA's new procedural approach is predictable and—for generic applicants who would be eligible for exclusivity but-for the Delisting Rule—financially devastating. Because 180-day exclusivity can never be regained after FDA approves subsequent applicants (as this Court has long recognized), FDA's procedural approach effectively prevents first applicants that have had their exclusivity stripped by the Delisting Rule from obtaining meaningful or effective judicial relief. Indeed, in both prior cases in which FDA formally

announced its application of the Delisting Rule, the aggrieved first-applicants effectively abandoned their efforts to secure meaningful injunctive relief because any judicial remedy would have come too late to salvage their statutory right to 180-day exclusivity.

FDA should not be permitted to evade judicial review of its Delisting Rule again. As set forth below, Teva already has been stripped of its right to 180-day exclusivity for generic losartan potassium products under the Delisting Rule. Teva thus has suffered an actionable harm that, if allowed to stand, will cost the company literally ***hundreds of millions of dollars*** in lost sales that never can be recovered. Teva's investors know that. Teva's suppliers know that. Teva's customers know that. And FDA knows that. None of the relevant facts are in dispute, and there are no impediments to this Court's review of the narrow legal question presented by this case—namely, whether FDA properly held that the MMA's delisting trigger abrogated *Ranbaxy*'s bar against exclusivity-divesting patent delistings.

Moreover, any delay in adjudicating this discrete issue invariably and irreparably will harm Teva. If, as Teva argues, the Delisting Rule is unlawful, the company needs to commit human and capital resources to producing launch-ready quantities of this product ***now***. Vindication of Teva's rights at some later date would be Pyrrhic, since the market for losartan potassium is so vast that Teva could not, at that point, possibly produce enough product to fully supply the market during its exclusivity period. As a result, delaying the resolution of this case could force millions of consumers who rely on losartan potassium products to continue purchasing expensive, brand-name versions even after the brand manufacturer's monopoly ends—in direct contravention of Hatch-Waxman's purposes. Because FDA's Delisting Rule is arbitrary, capricious and contrary to law, and because any delay will deprive both Teva of its

right to meaningful judicial relief and the public of its right to access generic losartan potassium products, the Delisting Rule immediately must be invalidated.

BACKGROUND

A. The Hatch-Waxman Framework

As modified by the Drug Price Competition and Patent Restoration Act of 1984 (the "Hatch-Waxman Act") and the Medicare Modernization Act of 2003 ("MMA"), the Food, Drug, and Cosmetic Act (the "FDCA" or "statute") establishes the procedure for obtaining approval to market pharmaceutical products in the United States. *See* 21 U.S.C. § 355.[1] The FDCA requires the manufacturer of a pioneer or brand-name (*i.e.*, non-generic) drug to file a complete New Drug Application ("NDA") that contains, among other things, extensive scientific and clinical data demonstrating the safety and effectiveness of the proposed new drug. *See id.* § 355(b)(1). The NDA must also include information about each patent the applicant asserts as claiming that drug. *See id.* § 355(b)(2); *see also* 21 C.F.R. § 314.50(h); *id.* § 314.53(b).

Prior to Hatch-Waxman's passage, generic manufacturers generally were required to complete a full NDA in order to obtain approval for a proposed generic drug—even though generic drugs contain the same active ingredients, and provide the same therapeutic value, as their brand-name counterparts. As a result, generic market entry often was cost-prohibitive, and patients lacked widespread access to generic medicines that typically are sold at lower, more competitive prices to consumers, private insurers, and public insurers. In 1984, Congress enacted Hatch-Waxman to remove those barriers to entry, increase the availability of generic drugs, and thereby reduce the average cost of pharmaceuticals. *See, e.g.*, *Serono Labs., Inc. v.*

[1] The FDCA has subsequently been amended by the Food and Drug Administration Amendments Act of 2007 ("FDAAA"), but those amendments have no bearing on this case. All citations to statutes and regulations are to the current versions, unless otherwise noted.

Shalala, 158 F.3d 1313, 1326 (D.C. Cir. 1998) (citing *inter alia* H.R. Rep. No. 98-857, pt. 1, at 14 (1984), reprinted in 1984 U.S.C.C.A.N. 2647, 2647)).

To accomplish those goals, Hatch-Waxman permits generic companies to obtain approval so long as they can show that a proposed generic drug is bioequivalent to a "listed" (or previously approved) drug that FDA already has deemed safe and effective. Generic applicants do so by submitting an Abbreviated New Drug Application ("ANDA") that includes, among other things, studies showing the proposed generic drug's bioequivalence to the previously approved drug. 21 U.S.C. § 355(j). If FDA accepts the applicant's bioequivalence studies, the generic applicant need not repeat the safety and efficacy studies that were conducted on the brand-name drug. *Id.* § 355(j)(2)(A); *see also Mova Pharm. Corp. v. Shalala*, 140 F.3d 1060, 1063 (D.C. Cir. 1998).

To balance the public's interest in prompt generic market entry against the intellectual-property rights of brand-name manufacturers, Congress required each ANDA to include a "certification" for every patent the brand manufacturer has identified as claiming a previously approved drug. *Id.* § 355(j)(2)(A)(vii). To make this system work, the statute requires brand manufacturers to submit to FDA "the patent number and the expiration date of any patent which claims the[ir] drug … or … a method of using such drug," *id.* § 355(b)(1), and obligates FDA to "publish," "make available to the public," and regularly "revise" a list of the patent information submitted by brand manufacturers, *id.* § 355(j)(7)(a)(i)-(iii). FDA does so in a compilation known colloquially as "the Orange Book." *Purepac Pharm. Co. v. Thompson*, 354 F.3d 877, 880 (D.C. Cir. 2004); *Am. Bioscience, Inc. v. Thompson*, 243 F.3d 579, 580 (D.C. Cir. 2001).

Because the Agency lacks patent-law expertise, it plays only a "ministerial role" in maintaining the Orange Book's patent listings. *See, e.g.*, *Apotex, Inc. v. Thompson*, 347 F.3d

1335, 1349-50 (Fed. Cir. 2003); *see also* 21 C.F.R. § 314.53(f). As a result, generic applicants must submit "an appropriate certification for each listed patent," even if they disagree about "the correctness of the patent information … published by FDA in the list." 21 C.F.R. § 314.53(f); *see also Apotex*, 347 F.3d at 1350; *Sandoz, Inc. v. FDA*, 439 F. Supp. 2d 26, 31 (D.D.C. 2006). Four such certifications are available:

> (I) that patent information has not been filed with respect to the previously approved drug [a "Paragraph I certification"],
>
> (II) that the patent identified as claiming the previously approved drug has expired [a "Paragraph II certification"],
>
> (III) that the generic drug will not be marketed until the date on which the patent identified as claiming the previously approved drug will expire [a "Paragraph III certification"], or
>
> (IV) that the patent identified as claiming the previously approved drug is invalid or will not be infringed by the manufacture, use, or sale of the generic drug for which the ANDA is submitted [a "Paragraph IV certification"].

21 U.S.C. § 355(j)(2)(A)(vii).

Paragraph IV certifications play a critical role in the statutory scheme. Such certifications signal a generic applicant's intent to market its product prior to the expiration of a competition-blocking patent, and thus that the applicant intends to provide consumers with expedited price relief through early market competition. *See, e.g., Teva Pharms. USA, Inc. v. Leavitt*, 548 F.3d 103, 106 (D.C. Cir. 2008) ("The legislative purpose underlying paragraph IV is to enhance competition by encouraging generic drug manufacturers to challenge the patent information provided by NDA holders in order to bring generic drugs to market earlier.").

But filing a Paragraph IV certification carries significant risks. Paragraph IV applicants must invest significant resources to identify weaknesses in a competition-blocking patent and develop a non-infringing alternative or legal defense based on patent invalidity or

unenforceability. If those efforts succeed and the applicant attempts to break the patent logjam by filing a Paragraph IV certification, the very act of submitting that certification is an "artificial" act of patent infringement that could require the applicant to spend years defending its actions in costly patent litigation. 35 U.S.C. § 271(e); *see also Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 678 (1990). Indeed, if the brand manufacturer sues the applicant within 45 days of receiving notice of the applicant's Paragraph IV certification, FDA may not approve the applicant's ANDA for 30 months (while the patent case unfolds). 21 U.S.C. § 355(j)(5)(B)(iii). This period of delay is known as the "30-month stay." *Eli Lilly & Co. v. Teva Pharms. USA, Inc.*, 557 F.3d 1346, 1348-49 (Fed. Cir. 2009).

To encourage generic manufacturers to undertake those investments and accept those risks, Hatch-Waxman offers a significant "reward" to the first Paragraph IV challenger: a 180-day period during which it is entitled to market its generic product without competition from subsequent generic applicants. *See, e.g., Teva Pharms. USA, Inc.*, 548 F.3d at 104 ("Marketing exclusivity is valuable, designed to compensate manufacturers for research and development costs as well as the risk of litigation from patent holders."); *see also Ranbaxy*, 354 F.3d at 879. Under the original statute, that 180-day period began to run on the earlier of (a) the date on which the first applicant first begins to sell its product (the "commercial marketing trigger"), or (b) the date of a court decision holding that the patent grounding the first applicant's exclusivity was invalid, not infringed, or otherwise unenforceable ("the court decision trigger"). 21 U.S.C. § 355(j)(5)(B)(iv) (2002); *see also Apotex, Inc. v. FDA*, No. 06-0627-JDB, 2006 WL 1030151 (D.D.C. Apr. 19, 2006), *summarily aff'd*, 449 F.3d 1249 (D.C. Cir. 2006). Among other things, the MMA eliminated the court decision trigger, and exclusivity now begins to run only upon the applicant's first commercial sale. 21 U.S.C. § 355(j)(5)(B)(iv).

B. Three Problems Under Hatch-Waxman—And Three Solutions

Three problems commonly arose under Hatch-Waxman. *First*, brand manufacturers often sought to discourage Paragraph IV challenges, and thereby manipulate the incentives for generic market entry, by improperly ***delisting*** exclusivity-grounding patents. Because 180-day exclusivity is based on the maintenance of a Paragraph IV certification, and because applicants can only maintain patent certifications to listed patents, delisting a challenged patent effectively allowed a brand manufacturer to divest the first-filer of its 180-day exclusivity period. FDA's own Hatch-Waxman regulations facilitated that practice, by freely allowing brand manufacturers to delist exclusivity-grounding patents so long as the brand manufacturer had not initiated litigation prior to seeking a delisting. *See* 21 C.F.R. § 314.94(a)(12)(viii)(B) ("If a patent is removed from the list, any applicant with a pending application … who has made a [Paragraph IV] certification with respect to such patent shall [withdraw] its certification [unless that] patent … is the subject of a lawsuit.").

Teva and Ranbaxy challenged that regulation and practice in court, and both this Court and the D.C. Circuit invalidated FDA's prior delisting rule at *Chevron* step one. *Ranbaxy*, 469 F.3d at 125-26; *see also Ivax Pharms., Inc. v. Leavitt*, 459 F. Supp. 2d 1 (D.D.C 2006) (Roberts, J.). There, as here, Merck unilaterally sought to delist patents from the Orange Book. As the D.C. Circuit explained, FDA's delisting rule undercut two central features of the Act. First, FDA's approach to patent delistings effectively wrote the commercial-marketing trigger out of the statute, and thus was "inconsistent with the structure of the statute because, if the patent is delisted before a pending ANDA is approved, then the generic manufacturer may not initiate a period of marketing exclusivity." *Ranbaxy*, 469 F.3d at 125. Second, and perhaps more important, FDA's policy eviscerated the exclusivity incentive altogether, since it allowed brand manufacturers to "reduce[e] the certainty of receiving a period of marketing exclusivity [and

thereby] diminishe[d] the incentive for a manufacturer of generic drugs to challenge a patent listed in the Orange Book." *Id*. at 126. As a result, the court held, FDA's delisting rule was "inconsistent with the text and structure of the Act and, because it diminishes the incentive the Congress gave manufacturers of generic drugs, inconsistent with the purpose of the Act." *Id*.

Second, brand manufacturers attempted to manipulate generic market entry by improperly ***listing*** new patents in the Orange Book—in some cases by submitting new patents that plainly did not qualify for listing under the statute and FDA regulations. Such anticompetitive patent listings were particularly troubling to first applicants that were prepared to start selling their products, since brand manufacturers were able to exploit the statute's 30-month stay to delay FDA approval. *See aaiPharma Inc. v. Thompson*, 296 F.3d 227, 236 (4th Cir. 2002) (noting that a "serious[] problem arises when an NDA holder wrongly lists a patent in the Orange Book that does not actually claim its approved drug under the standard set forth in [21 U.S.C.] § 355(c)(2). Once the patent is listed, the NDA holder can delay an ANDA applicant's entry into the marketplace for up to thirty months (and extend its monopoly power) simply by filing a patent infringement suit," and observing that "[t]he harm to generic drug manufacturers, and ultimately to the consuming public, is obvious"); *see also Mylan Pharms., Inc. v. Thompson*, 268 F.3d 1323, 1332 (Fed. Cir. 2001) (holding that the original FDCA did not create a private cause of action for delisting).

Around the same time the courts first began to tackle brand-initiated patent delistings, Congress addressed the problem of improper patent listings in the MMA. To dissuade brand manufacturers from manipulating generic entry by listing new patents after a patent-challenging applicant has been filed, the MMA now provides that the 30-month stay applies only in litigation based on a patent that the brand manufacturer "submitted to [FDA] ***before*** the date on which the

[ANDA] was submitted." 21 U.S.C. § 355(j)(5)(B)(iii) (emphasis added). Moreover, and of central import to this case, Congress empowered patent-challenging generic applicants who are sued for patent infringement to force brand manufacturers to delist improperly submitted patents. In particular, the MMA established a new counterclaim right of action "seeking an order requiring the [NDA] holder to correct or delete the patent information submitted" for listing in the Orange Book. *Id*. § 355(j)(5)(C)(ii)(I). The addition of this latter provision was a direct response to the problems identified in *aaiPharma*, and the *Mylan* court's holding that generic applicants could not assert a private right of action for delisting under the original version of the Hatch-Waxman Act. *Mylan*, 268 F.3d at 1332; *see also id*. at 1333 (specifically noting that at the time of decision Congress actively was considering legislation that would address the problem of improper patent listings by creating a private right of action).

Third, applicants who managed to preserve their exclusivity despite these opportunities for brand-initiated manipulation sometimes failed promptly to initiate commercial marketing following FDA approval. Because the applicant's continued eligibility for 180-day exclusivity prevented the Agency from approving subsequent applicants, first applicants who failed to launch their own products effectively delayed the onset of any generic competition, sometimes for years at a time. *See Mova*, 140 F.3d at 1072.

The MMA thus added a series of "forfeiture triggers" in order "to 'ensure that the 180-day exclusivity period enjoyed by the first generic to challenge a patent cannot be used as a bottleneck to prevent additional generic competition.'" *Hi-Tech Pharmacal Co. v. FDA*, 587 F. Supp. 2d 1, 4 (D.D.C. 2008) ("*Hi-Tech I*") (quoting 149 Cong. Rec. S15746 (Nov. 24, 2003) (statement of Sen. Schumer)). As pertinent here, the statute now deems the exclusivity period to be forfeited if the first

> applicant fails to market the drug by ***the later of***:
>
> > ***(aa)*** the earlier of the date that is—
> >
> > > (AA) 75 days after the date on which the approval of the application of the first applicant is made effective under subparagraph (B)(iii); or
> > >
> > > (BB) 30 months after the date of submission of the application of the first applicant;
> > >
> > > ***or***
> >
> > ***(bb)*** with respect to the first applicant or any other applicant (which other applicant has received tentative approval), the date that is 75 days after the date as of which, as to each of the patents with respect to which the first applicant submitted [a paragraph IV certification], at least 1 of the following has occurred:
> >
> > > (AA) … a court enters a final decision … that the patent is invalid or not infringed.
> > >
> > > (BB) … a court signs a settlement order or consent decree that enters a final judgment that includes a finding that the patent is invalid or not infringed.
> > >
> > > (CC) The patent information submitted under subsection (b) or (c) of this section is withdrawn by the [NDA] holder.

21 U.S.C. § 355(j)(5)(D)(i)(I). These provisions are known as the statute's "failure-to-market" clause.

In certain cases, none of the events described in the (bb) subsection of the "failure-to-market" clause will have occurred by the time the first applicant's ANDA otherwise is eligible for approval. In such cases, FDA quite correctly has held that there can be no forfeiture of 180-day exclusivity based on the applicant's failure to market. *See generally* Granisetron Letter Decision, FDA Docket No. 2007-N-0389 (Jan. 17, 2008) (attached as Exhibit C). That is so, FDA has explained, because forfeiture occurs only on ***the later of*** (1) the date determined in the (aa) subsection ***or*** (2) the date determined in the (bb) subsection. If none of the events described in the (bb) subsection has occurred, it necessarily will be the "later" of the two possible dates,

and the first applicant will not have failed to meet any of condition set forth in that subsection (*i.e.*, that it begin marketing within 75 days of an event listed in that subsection). *Id*. at 5.

C. The New Delisting Rule

Questions soon arose regarding the scope of the MMA's new forfeiture provisions—and in particular with respect to the delisting trigger. One of the earliest such cases involved 180-day exclusivity for acarbose tablets (sold by Bayer as Precose®). In that case, Cobalt Pharmaceuticals ("Cobalt") filed the first Paragraph IV certification to a patent that Bayer had listed as claiming its brand-name version of acarbose tablets. Cobalt thereby became eligible for 180-day exclusivity under the statute. After receiving Cobalt's exclusivity-grounding Paragraph IV certification, however, Bayer chose not to sue Cobalt for patent infringement. Instead, on April 16, 2007 (more than two years after Cobalt filed its ANDA), Bayer unilaterally asked FDA to delist the patent from the Orange Book.

On September 26, 2007, FDA *sua sponte* issued a public notice soliciting comments regarding Cobalt's continued eligibility for 180-day exclusivity in light of Bayer's delisting request. *See* 9/26/07 Ltr. from G. Buehler to ANDA Applicants (the "Acarbose Notice") (attached as Complaint Exhibit 2). In particular, FDA's Acarbose Notice stated that the Agency intended to interpret, and thus wished to obtain the public's "views regarding[,] the applicability of [FDCA] section 505(j)(5)(D)(i)(I)(bb)(CC)—relating to the delisting of a patent." *Id*. Because FDA at that time had never interpreted the delisting trigger, and because its decision in the acarbose case would definitively establish FDA's interpretation of the delisting trigger for future cases, FDA faxed its solicitation for public comment to every company that had filed an ANDA for generic acarbose tablets and posted the Notice on its public website. *Id*. At least five companies submitted responses, including Teva. *See* Docket, FDA 2007-N-0445 (attached as Complaint Exhibit 3).

FDA's interpretation of the delisting trigger was essential to determining Cobalt's continued eligibility for 180-day exclusivity. If Bayer's unilateral delisting of the challenged patent was lawful (despite the D.C. Circuit's decision in *Ranbaxy*), it would have triggered the delisting trigger in the (bb) subsection of the failure-to-market forfeiture section. Cobalt thus would have forfeited its exclusivity because there would have been applicable dates in both subsections of the failure-to-market forfeiture clause—(1) September 22, 2007 for the (aa) subsection (*i.e.*, 30 months from the time Cobalt submitted its ANDA to FDA), and (2) June 30, 2007 for the (bb) subsection (*i.e.*, 75 days after Bayer requested the delisting). Because both of those dates had passed, Cobalt would have forfeited its exclusivity on September 22, 2007 (*i.e.*, "the later of" the two dates). If, by contrast, Bayer's unilateral delisting of the challenged patent were impermissible, and thus did not activate the delisting trigger, there would be no applicable date in the (bb) subsection, and Cobalt would have retained its eligibility for 180-day exclusivity. *See* Granisetron Dec. at 5.

After it received FDA's Notice in the acarbose matter, Teva prepared and filed a lengthy response to the questions FDA had raised in the Notice. Of particular import here, Teva argued that Cobalt had not forfeited its exclusivity under the delisting trigger because the statute did not permit Bayer to delist the '769 patent after Cobalt's Paragraph IV challenge, and because Bayer's delisting request thus could not lawfully activate the delisting trigger under 21 U.S.C. § 355(j)(5)(D)(i)(I). *See* 10/16/07 Ltr. from M. Goshko to G. Buehler ("Teva Acarbose Response") (attached as Complaint Exhibit 4).

More specifically, Teva reminded the Agency that *Ranbaxy* had held—at *Chevron* step one—that the plain text and structure of the statute did not permit brand manufacturers unilaterally to delist a patent where doing so effectively would deprive the first Paragraph IV

applicant of its 180-day exclusivity. *Id*. at 2, 5. Nothing in the MMA changes that. As Teva argued, there was no indication that Congress intended the delisting trigger *sub silentio* to abrogate what *Ranbaxy* had identified as the statute's fundamental bar against manipulative patent delistings, by implicitly allowing brand manufacturers to engage in the very kind of manipulation that the statute always had prohibited. Instead, Teva explained, the delisting trigger was inextricably tied to the MMA's new delisting mechanism, which for the first time permitted patent-challenging generic applicants to seek a court order requiring the brand manufacturer involuntarily to delist the challenged patent from the Orange Book. *Id*. at 6 (discussing 21 U.S.C. § 355(j)(5)(c)(ii)(I)).

In those circumstances, and only in those circumstances, the delisting trigger made sense: Just as the MMA now provided that a first applicant could not delay generic competition by failing to sell its products promptly after obtaining a court decision holding, or entering into a settlement or consent decree that included a finding, that a challenged patent was invalid, unenforceable or not infringed, *see* 21 U.S.C. §§ 355(j)(5)(D)(i)(I)(bb)(AA)-(BB), so Congress had provided through the delisting trigger that a first applicant could not hold up generic competition by "parking" its 180-day exclusivity after obtaining a court order requiring the brand manufacturer to delist an improperly submitted patent from the Orange Book. *See id*. § 355(j)(5)(D)(i)(I)(bb)(CC); *see also* Teva Acarbose Response at 5-6.

Outside that context, however, Teva argued that the delisting trigger's "tail" could not reasonably be interpreted to "wag the dog." While the delisting trigger makes clear that a first applicant can lose its exclusivity by refusing to begin marketing promptly after securing an involuntary, court-ordered delisting, it does not remotely suggest that brand manufacturers now are free to divest the first applicant of its exclusivity by voluntarily and unilaterally delisting a

challenged patent before the first applicant is able to launch—and thereby to manipulate the statutory incentive for generic manufacturers to challenge brand-name patents in the first place. Teva Acarbose Response at 5-6; *cf. Ranbaxy*, 469 F.3d at 126.

On May 7, 2008, FDA announced its Delisting Rule. In the process, FDA explicitly "considered and rejected" Teva's arguments. Acarbose Dec. at 8-9. FDA first held that it was free to ignore the D.C. Circuit's *Ranbaxy* decision simply because that case interpreted and applied the pre-MMA version of the statute. *Id*. at 8. According to FDA, *Ranbaxy* offers no pertinent guidance on the delisting question because "[t]he effect of patent delisting on eligibility for 180-day exclusivity is expressly addressed by the plain language" of the MMA. *Id*.. While FDA thus agreed with Teva that the delisting trigger applies whenever a first applicant obtains a court order requiring the brand manufacturer to delist a challenged patent, it rejected Teva's argument that the trigger is activated only in that context. According to the Agency, "the scope of the patent delisting forfeiture provision is much broader" and must be applied "whenever a patent is withdrawn (or requested to be 'delisted') by the NDA holder." *Id*. (emphasis added).

Applying its Delisting Rule, FDA thus announced that Cobalt had forfeited its exclusivity on September 22, 2007—eight months before FDA issued its decision applying the Delisting Rule. *Id*. at 7-8. On the same day it issued the decision, FDA granted final approval to ANDAs filed by both Cobalt and Roxane Laboratories (a subsequent generic applicant). *See id*. at 1 n.1. Although Cobalt initiated litigation in this Court challenging FDA's decision, Cobalt soon dismissed its action because FDA had already approved Roxane's acarbose products and thus irremediably had deprived Cobalt of its 180-day exclusivity. *See Cobalt Labs., Inc. v. FDA*, No. 08-cv-00798-RBW; *see also Sandoz*, 439 F. Supp. 2d at 32 ("'Once the statutory entitlement has

been lost, it cannot be recaptured.'") (quoting *Apotex, Inc. v. FDA*, 2006 WL 1030151, *17 (D.D.C. Apr. 19, 2006)).

Shortly after FDA promulgated the Delisting Rule, the same issue arose in a case regarding 180-day exclusivity for dorzolamide/timolol maleate opthalmic solution (branded by Merck as COSOPT®). In that case, Merck originally had listed three patents as claiming COSOPT®, one of which (the '413 patent) would expire in October 2008, and two of which (the '735 and '443 patents) were scheduled to expire in April 2011. *See* 9/4/08 Ltr. from G. Buehler to ANDA Applicant ("COSOPT® Solicitation") (attached as Complaint Exhibit 6).

Hi-Tech Pharmacal Co. ("Hi-Tech") submitted the first ANDA for generic COSOPT®. Its ANDA contained Paragraph IV certifications for all three listed patents. Merck sued Hi-Tech for infringing the '413 patent, and won its case. But Merck did not sue Hi-Tech for infringing the other challenged patents, and Hi-Tech for a time thus remained eligible for 180-day exclusivity based on its Paragraph IV certifications to those patents. In April 2006, however, Merck once again asked FDA to delist two of its patents (the '735 and '443 patents).

As it had in the acarbose case, FDA eventually established a docket and solicited public comments regarding Hi-Tech's continued eligibility for 180-day exclusivity. *See* COSOPT® Solicitation at 1. And as Teva had in the acarbose case, several companies submitted comments to FDA's public docket regarding the delisting trigger. *See* Docket, FDA 2008-N-0483 (attached as Complaint Exhibit 7). At least two of those submissions reiterated the same arguments that Teva previously had raised in the acarbose proceeding. *See, e.g.*, 9/19/08 Ltr. from A. Tsien to G. Buehler (attached as Complaint Exhibit 8).

Hi-Tech also filed a lawsuit in this Court seeking preemptively to secure a ruling that its exclusivity remained intact. *See Hi-Tech I*, 587 F. Supp. 2d at 6-7. Although the Court initially

denied Hi-Tech's request for a preliminary injunction, it required FDA to provide notice to the Court and the parties regarding Hi-Tech's potential forfeiture of exclusivity ***before*** the Court would permit the Agency to grant an effective approval to any other ANDA, and established a procedure under which the court would attempt to prevent FDA from depriving Hi-Tech of meaningful judicial review of the Delisting Rule. *Id*. at 13.

On October 28, FDA formally issued its predetermined decision that Hi-Tech had forfeited its exclusivity. *See* COSOPT® Letter Decision, FDA Docket No. 2008-N-0483 (Oct. 28, 2008) ("COSOPT® Dec.") at 14 (attached as Exhibit D). As Hi-Tech had predicted, FDA announced that it previously had rejected Hi-Tech's argument that the delisting trigger was limited to the delisting-counterclaim context, when it first promulgated the Delisting Rule in the acarbose case. *Id*. at 14 n.15 ("[A]s noted in the Acarbose Decision at pp. 8-9, we also have considered the argument that the forfeiture event described in section 505(j)(5)(D)(i)(I)(bb)(CC) of the Act applies only if the withdrawal of a patent is pursuant to the process described at section 505(j)(5)(C)(ii) of the Act."); *id*. at 14 ("We also have considered and rejected in both this case and in the matter described in the Acarbose Decision, the argument that eligibility for 180-day exclusivity following the NDA holder's voluntary withdrawal of its patent should be governed not by the MMA forfeiture provisions, but by the rule established in *Ranbaxy*.").

FDA simultaneously informed the parties and the Court that it was prepared immediately to approve other applicants' ANDAs for generic COSOPT®. Faced with an immediate commercial need to launch its product, and given the public's strong interest in immediate generic competition, Hi-Tech abandoned its efforts to secure a preliminary injunction barring FDA from divesting the company of its exclusivity. Instead, Hi-Tech later sought a permanent

injunction based on alternative grounds. *See Hi-Tech Pharmacal Co. v. FDA*, 587 F. Supp. 2d 13, 22 (D.D.C. 2008) ("*Hi-Tech II*").

D. Factual Background Relating To Losartan Potassium Drug Products

Losartan potassium is an angiotensin II receptor antagonist drug used primarily to treat hypertension. Merck holds two approved NDAs relating to losartan potassium: No. 02-0386 for losartan potassium tablets and No. 02-0387 for losartan potassium/hydrochlorothiazide tablets, which it commercially markets under the brand names Cozaar® and Hyzaar®, respectively. When Merck obtained FDA approval for Cozaar® and Hyzaar®, it listed the same three patents in the Orange Book for both drugs: U.S. Patent No. 5,138,069 ("the '069 patent"), which is scheduled to expire on August 11, 2009; U.S. Patent No. 5,153,197 ("the '197 patent"), which is scheduled to expire on October 6, 2009; and U.S. Patent No. 5,608,075 ("the '075 patent"), which is scheduled to expire on March 4, 2010. Because Merck subsequently conducted studies of its losartan-potassium products' safety and effectiveness for children, it earned an additional six-month period of "pediatric exclusivity" which prevents FDA from approving generic applications for these drugs for six months after the expiration of each patent. *See* 21 U.S.C. § 335a. Accordingly, these three patents together would have blocked any generic competition in the losartan-potassium market until September 4, 2014, when the pediatric exclusivity period attached to the '075 patent would expire.[2]

On December 18, 2003 (and thus after the MMA amendments to the Hatch-Waxman scheme became effective), Teva submitted the first ANDA seeking FDA approval to market a generic version of Cozaar® tablets in 25mg, 50mg and 100mg strengths. FDA accepted Teva's

[2] Merck also listed U.S. Patent No. 5,210,079 in connection with its Cozaar® NDA. That patent relates to a method of treatment for which Teva does not seek approval.

generic Cozaar® ANDA for filing on February 11, 2004 and docketed it as ANDA No. 07-6958. Teva's ANDA contained Paragraph III certifications to the '069 patent and the '197 patent, meaning that it would not seek to market its generic drug until the '197 patent and its associated period of pediatric exclusivity were scheduled to expire in April of 2010. Teva also submitted a Paragraph IV certification as to the '075 patent, claiming that that patent is invalid, unenforceable, and/or would not be infringed by Teva's proposed generic drug product. Teva was the first generic applicant to submit a substantially complete ANDA for Cozaar® for all three strengths that contained a Paragraph IV certification as to the '075 patent. *See* Marshall Decl. ¶ 7.

On May 24, 2004, Teva submitted an ANDA seeking FDA approval to market a generic version of Hyzaar® tablets in 50mg/12.5mg and 100mg/25mg strengths. FDA accepted Teva's generic Hyzaar® ANDA for filing on July 15, 2004 and docketed it as ANDA No. 07-7157. Teva's generic Hyzaar® ANDA contained the same patent certifications as its generic Cozaar® ANDA: Paragraph III certifications for the '069 and '197 patents, and a Paragraph IV certification for the '075 patent. Teva was the first generic applicant to submit a substantially complete ANDA for Hyzaar® for both strengths that contained a Paragraph IV certification as to the '075 patent. *See* Marshall Decl. ¶ 8.

Because Teva was the first generic applicant to submit substantially complete applications for generic Cozaar® and Hyzaar® that contained at least one Paragraph IV certification to at least a patent that Merck had listed in the Orange Book for those drugs, Teva became eligible for 180-day generic marketing exclusivity with respect to both drugs. *See* 21 U.S.C. § 355(j)(5)(B)(iv).

As required by Hatch-Waxman, Teva notified Merck of its Paragraph IV certifications to the '075 patent on February 23, 2004 (for Cozaar®) and July 15, 2004 (for Hyzaar®). Teva alleged that certain claims of the '075 patent were invalid based on prior art and that its generic losartan products did not infringe the patent's remaining claims under the doctrine of equivalents. Merck did not file a patent infringement claim against Teva based on those certifications. Instead, after Teva submitted its exclusivity-qualifying Paragraph IV certifications to the '075 patent, Merck yet again asked FDA to "delist" a patent from the Orange Book (the '075 patent).

By doing so, Merck essentially conceded that Teva's challenges to the '075 patent were so strong that Merck could not reasonably assert the '075 patent against any generic applicant for Cozaar® or Hyzaar®, and thus that Merck could not lawfully maintain its listing of the '075 patent in the Orange Book. Teva's Paragraph IV challenges to the '075 patent thereby accomplished precisely what Congress sought to reward with 180-day exclusivity: Teva identified a vulnerable—but competition-blocking—patent, invested the resources necessary to challenge that patent, and successfully removed that patent as a barrier to generic market entry.[3]

Despite that, FDA's Delisting Rule deprives Teva of its entitlement to the reward for risking fierce patent litigation and advancing the onset of generic market entry: 180-day exclusivity for its generic versions of Cozaar® and Hyzaar®. Instead, Merck's strategic behavior serves to discourage companies such as Teva from challenging its patents through

[3] Indeed, it bears note that when Merck later obtained FDA approval to market a 100mg/12.5mg strength of Hyzaar®—after Teva filed its Paragraph IV certifications to the '075 patent—Merck declined to list that patent in the Orange Book. On July 21, 2006, Teva amended its Hyzaar® ANDA to seek approval for 100mg/12.5mg generic Hyzaar®, but by virtue of Teva's prior Paragraph IV certifications to the '075 patent and Merck's resulting decision not to list that patent in connection with the new strength, exclusivity for this strength of Hyzaar® is not at issue here.

Paragraph IV certifications. That is so, pursuant to the Delisting Rule, because forfeiture events already have occurred under both prongs of the failure-to-market provisions of the MMA, long before Teva had any opportunity to go to market. As of August 12, 2006, thirty months had passed from the date Teva submitted its ANDA for generic Cozaar®. And as of January 16, 2007, thirty months had passed from the date Teva submitted its ANDA for generic Hyzaar®. These dates serve as the applicable dates in the (aa) subsection of the failure-to-market provision. *See* 21 U.S.C. § 355(j)(5)(D)(i)(I)(aa)(BB). And with respect to the (bb) subsection, well over 75 days now have passed from the date that Merck unilaterally asked FDA to delist the '075 patent from the Orange Book's patent listings for Cozaar® and Hyzaar®.[4]

Despite the fact that under a straightforward and undisputed application of the Delisting Rule Teva has already forfeited its right to 180-day exclusivity (and may have done so years ago), FDA's policy and practice of not publicizing exclusivity decisions until the date on which it grants final approval to ANDAs means that the Agency will not formally notify Teva of this decision until April 2010, when Teva—and, by virtue of the Delisting Rule, Teva's competitors—can (and will) launch generic losartan potassium products free-and-clear of any possible patent infringement claims by Merck or other regulatory barriers. By that time, however, Teva will not have an effective opportunity to challenge FDA's wrongful deprivation of Teva's 180-day exclusivity.

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[4] FDA does not publicize the date on which it receives a delisting request from a brand manufacturer. However, the Agency's electronic Orange Book includes a notation—where applicable—that a delisting has been requested. In this case, the electronic Orange Book reflected no later than January 1, 2009 that Merck had asked FDA to delist the '075 patent from the Orange Book. *See* Electronic Orange Book, NDA 02-0386 (25mg) (accessed June 11, 2009) (attached as Complaint Exhibit 10).

LEGAL STANDARD

The legal standard governing motions for temporary injunctive relief is well-settled. To secure relief, the plaintiff must show that (1) there is a substantial likelihood of success on the merits; (2) the plaintiff would suffer irreparable injury if the requested injunction is denied; (3) an injunction will not substantially injure the opposing party or other third parties; and (4) the public interest will be furthered by the issuance of the injunction. *See Mova*, 140 F.3d at 1066. "These factors interrelate on a sliding scale and must be balanced against each other," *Davenport v. Int'l Bd. of Teamsters, AFL-CIO*, 166 F.3d 356, 360-61 (D.C. Cir. 1999), so that "[a]n injunction may be justified … where there is a particularly strong likelihood of success on the merits even if there is a relatively slight showing of irreparable injury." *CityFed Fin. Corp. v. OTS*, 58 F.3d 738, 747 (D.C. Cir. 1995); *see also Mova Pharm. Corp. v. Shalala*, 955 F. Supp. 128, 131 (D.D.C. 1997). Teva readily meets all four prongs of this standard.

ARGUMENT

I. TEVA IS LIKELY TO SUCCEED ON THE MERITS.

Teva is likely to succeed on the merits of its claim because the Delisting Rule is inconsistent with the text, structure, history, and purposes of the Hatch-Waxman Act. As the D.C. Circuit held in *Ranbaxy*, FDA may not effectuate a brand manufacturer's unilateral and voluntary request to delist a patent where the effect of that delisting would deprive the first generic applicant of its statutory right to 180-day exclusivity. 469 F.3d at 125-26. That is exactly what the Delisting Rule does.

Indeed, FDA's Delisting Rule is inconsistent with the statute for very same reasons that led the D.C. Circuit to invalidate FDA's pre-MMA delisting regulation at *Chevron* step one. *See id.* First, FDA's Delisting Rule allows brand manufacturers unilaterally and strategically to divest first applicants of 180-day exclusivity where (as here) a valid patent—in Hatch-Waxman

terms, a "blocking patent"—precludes the first applicant from marketing within 75 days of a delisting request. That was precisely the case in the acarbose and COPSOPT® matters, and it is here, too (because Merck asked FDA to delist the '075 patent more than 75 days before Teva could launch its products in April 2010). *See, e.g.*, Acarbose Dec. at 1 (delisting requested on April 16, 2007; blocking patent did not expire until May 7, 2008); COSOPT® Dec. at 2 (delisting requested on April 26, 2006; blocking patent did not expire until October 28, 2008). The Delisting Rule thus effectively writes the commercial marketing trigger out of the statute, by precluding applicants that otherwise would be entitled to exclusivity from triggering their exclusivity through a commercial launch.

In *Ranbaxy*, however, the D.C. Circuit expressly and unambiguously held that FDA may not rewrite the statute in a manner that effectively would eliminate the commercial-marketing trigger for initiating 180-day exclusivity. *See Ranbaxy*, 469 F.3d at 125 ("When the NDA holder asks the FDA to delist the patent …, the FDA's policy of acquiescence prevents the generic manufacturer that has filed an ANDA containing a paragraph IV certification from beginning its period of exclusivity [by marketing]."). If anything, the *Ranbaxy* court's concern about the commercial marketing trigger's vitality under FDA's pre-MMA delisting regulation is even more pertinent in the post-MMA world. After all, the MMA eliminated the court-decision trigger from the statute—and thereby made the commercial marketing trigger the ***only*** way a generic applicant can trigger its exclusivity period. *See* 21 U.S.C. § 355(j)(5)(B)(iv). Because FDA's Delisting Rule thus precludes otherwise eligible applicants from beginning their period of marketing exclusivity through the ***only*** pathway set forth in the statute, it is no less (and, indeed, is even more) "inconsistent with the structure of the statute" than the pre-MMA delisting regulation that *Ranbaxy* invalidated at *Chevron* step one. 469 F.3d at 125.

Second, FDA's post-MMA Delisting Rule—just like its pre-MMA delisting regulation—eviscerates the exclusivity reward at the heart of the statutory structure, because it "allows an NDA holder, by delisting its patent, to deprive the generic applicant of a period of marketing exclusivity" altogether. *Id*. at 126. Needless to say, that approach undermines the entire statutory scheme, because it allows patent-holding brand manufacturers to eliminate the very incentive Congress established in order to encourage generic applicants to challenge brand-name patents through Paragraph IV certifications in the first place. *Teva Pharms. USA, Inc.*, 548 F.3d at 106 ("The legislative purpose underlying paragraph IV is to enhance competition by encouraging generic drug manufacturers to challenge the patent information provided by NDA holders in order to bring generic drugs to market earlier."); *id*. at 104 ("Marketing exclusivity is valuable, designed to compensate manufacturers for research and development costs as well as the risk of litigation from patent holders.").

This case perfectly illustrates the dilemma. Teva searched the Orange Book to determine which patents stood in the way of generic competition in the losartan potassium market. It saw that Merck had listed the '075 patent—titled "Polymorphs of losartan and the process for the preparation of form II of losartan"—as claiming its brand-name losartan potassium products. Teva's scientists began the arduous task of designing non-infringing losartan potassium products that would have the same therapeutic effect as Merck's brand-name products. And the company simultaneously engaged legal counsel to assess possible defenses to a potential patent infringement claim. Teva's patent counsel conducted an extensive prior-art search, and eventually developed a path-breaking challenge to the validity of the '075 patent under 35 U.S.C. § 102(b). And when Teva ultimately submitted its Paragraph IV challenge to the '075 patent and notified Merck that it had both engineered around the '075 patent's claims and developed a

powerful invalidity defense based on the prior art, Merck recognized that it could not in good faith assert the '075 patent against ***any*** generic applicant. Yet instead of simply conceding that Teva did not infringe its patent, Merck went on the offensive: It asked FDA remove the '075 patent from the Orange Book and thereby deprive Teva of the statutory reward for its efforts in this case—while discouraging Teva from engaging in future challenges to Merck's other brand-name products.

Nonetheless, Teva had succeeded in doing precisely what Congress intended the 180-day exclusivity incentive to reward: its challenge to the '075 patent removed a key barrier to generic drug competition. As a direct result of the company's decision to undertake the significant investments and risks necessary to challenge the '075 patent, Teva advanced the earliest possible date for generic market entry from September 2014 (when the pediatric-exclusivity period associated with the '075 patent otherwise would have expired) to April 2010 (when Merck's other patents and their associated periods of pediatric exclusivity will cease blocking generic competition). *See, e.g., Teva Pharms. USA, Inc.*, 548 F.3d at 106 ("The legislative purpose underlying paragraph IV is to enhance competition by encouraging generic drug manufacturers to challenge the patent information provided by NDA holders in order to bring generic drugs to market earlier."); *see also Serono Labs.*, 158 F.3d at 1326 ("The purpose of the Hatch-Waxman Amendments was, after all, to increase competition in the drug industry by facilitating the approval of generic copies of drugs. Congress expected that competition to make available more low cost generic drugs.") (citations and quotations omitted).

Thus, instead of rewarding Teva for making the investments and undertaking the risks necessary to provide consumers with more than four additional years of generic competition (and thereby creating literally ***billions of dollars*** in prescription-drug savings on these $1.5 billion per

year products), FDA's Delisting Rule effectively allows Merck to punish Teva for having challenged its patent by depriving Teva of the statutory reward for having done so. Indeed, the Agency's Delisting Rule puts the fox in charge of the henhouse. By allowing brand manufacturers to unilaterally delist patents and thereby divest applicants of their exclusivity, the Delisting Rule allows brand manufacturers to select who will and will not obtain the statutory reward. If a brand manufacturer wants to disadvantage a particular generic applicant—for instance, as punishment for prevailing in prior patent infringement litigation, or because a given generic applicant poses a greater threat to the brand company's strategic interests—it can simply delist patents challenged by that first applicant in the future. The Delisting Rule likewise allows brand manufacturers to leverage their bargaining power over generic manufacturers merely by signaling that it will deprive the first applicant of their statutory reward. Needless to say, Congress could not possibly have intended to "subject[] the exclusivity incentive to the caprices of the patent holder," *Inwood Labs., Inc. v. Young*, 723 F. Supp. 1523, 1527 (D.D.C. 1989), *appeal dismissed*, 43 F.3d 712 (D.C. Cir. 1994) (Table), and the Delisting Rule thus fundamentally undermines the statutory scheme. Again, as *Ranbaxy* recognized, "FDA may not … 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*. (quoting *MCI Telecomms. Corp. v. AT&T Co.*, 512 U.S. 218, 231 n.4 (1994)).

FDA simply ignored these points when it promulgated the Delisting Rule. According to FDA, the D.C. Circuit's analysis of the text, structure, and purposes of the statute in *Ranbaxy* does not apply here simply because *Ranbaxy* dealt with the pre-MMA version of the statute, while the MMA now "expressly addresse[s]" the "effect of patent delisting on eligibility for 180-

day exclusivity." Acarbose Dec. at 8; *see also* COSOPT® Dec. at 14 & n.15. Yet that analysis entirely misses the point. Of course it is true that *Ranbaxy* addressed the pre-MMA statute and that the MMA's new delisting trigger addresses "***the effect*** of patent delisting on eligibility for 180-day exclusivity." *Id*. (emphasis added). But the question of how a lawful patent delisting ***affects*** exclusivity only begs the question of ***when*** brand manufacturers lawfully may delist a patent, and thereby activate the delisting trigger, in the first place.

The answer to that question is the same post-MMA as it was pre-MMA. Nothing in the MMA eliminates the commercial marketing trigger, which was the key textual clause on which the *Ranbaxy* decision rested. Instead, as noted earlier, the commercial marketing trigger is even more important now than it was before the MMA because it is the only mechanism for initiating the exclusivity period. And nothing in the MMA diminishes the centrality of the exclusivity incentive to the statutory scheme and its purposes. Yet one can search in vain through FDA's decisions in the acarbose and COSOPT® cases for any reference to the commercial marketing trigger or to the *Ranbaxy* court's analysis of its structural significance to the statutory scheme—much less for some recognition that in light of the MMA's elimination of the court-decision trigger, FDA's new Delisting Rule is even more inconsistent with the text and structure of the statute than the pre-MMA delisting regulation invalidated by *Ranbaxy* at *Chevron* step one.

In short then, nothing in the MMA alters *Ranbaxy*'s holding that unilateral, exclusivity-divesting patent delistings are fundamentally inconsistent with both the text of the statute (*i.e.*, the commercial marketing trigger) and the incentive scheme at the heart of the statute's structure (*i.e.*, that such delistings altogether deprive applicants of their reward for doing exactly what Congress intended to encourage). And there certainly is nothing in the MMA's legislative history to suggest that Congress intended, *sub silentio*, to fundamentally alter the statutory

scheme by undermining this fundamental tenet of Hatch-Waxman recognized by *Ranbaxy* (and the long line of pre-MMA cases on which that decision was based, *see Mova*, 140 F.3d at 1069; *Granutec, Inc. v. Shalala*, 139 F.3d 889, 889 (4th Cir. 1998) (Table); *Inwood*, 723 F. Supp. at 1527).

To be sure, FDA is right that the delisting trigger makes clear that it now is possible in certain circumstances for a patent to be delisted despite a first applicant's exclusivity-qualifying certification to that patent. But when the delisting trigger is placed in its proper context, it is perfectly consistent with the D.C. Circuit's analysis of the previous statutory text, structure, and purposes, and *Ranbaxy*'s clear holding that brand manufacturers cannot effectuate exclusivity-divesting patent delistings. In particular, at the same time Congress added the delisting trigger to the statutory scheme, it added a delisting mechanism: a new provision that for the first time permitted generic applicants to seek a court order forcing brand manufacturers ***involuntarily*** to delist patents for which a generic applicant previously submitted an exclusivity-qualifying Paragraph IV certification. That provision of the statute now provides:

> If an owner of the patent or the holder of the [NDA] brings a patent infringement action against the [generic] applicant, the applicant may assert a counterclaim seeking an order requiring the holder to correct or delete the patent information submitted [to FDA] on the ground that the patent does not claim either the drug for which the application was approved or an approved method of using the drug.

21 U.S.C. § 355(j)(5)(C)(ii)(I) (internal enumeration omitted).

As set forth earlier, this provision and the corresponding modifications to the 30-month stay were a direct congressional response to years of anticompetitive manipulation by brand manufacturers who were listing sham patents in the Orange Book on the eve of generic approval and then "gaming" the 30-month stay provision in order to stall the onset of generic competition. *See, e.g., Closing The Gaps In Hatch-Waxman, Assuring Greater Access To Affordable Pharmaceuticals: Hearing Before The Committee On Health, Education, Labor, And Pensions* at

2, 107th Cong. (May 8, 2002) (statement of Sen. Kennedy) ("[Brand-name] pharmaceutical companies game the system by listing spurious patents with the FDA—patents on unapproved uses, unapproved compounds, or formulations that they don't even market. Then they get automatic 30-month stays delaying approval of generic drugs."). With this new delisting mechanism, generic applicants now can prevent brand manufacturers from manipulating the patent-listing process by pursuing a delisting cause of action that the courts never previously had allowed. *See aaiPharma*, 296 F.3d at 236; *Mylan*, 268 F.3d at 1332.

Given this clear statutory context and the obvious interplay between the MMA's new delisting counterclaim mechanism and its new delisting trigger, FDA is left to argue that because patent delistings after a Paragraph IV challenge now are possible in certain circumstances (namely, when a Paragraph IV applicant successfully obtains a ***court-ordered*** delisting, thus clearing the way for the applicant to go to market), patent delistings must be permissible in all circumstances (including cases—like this one—where the brand manufacturer's ***unilateral*** delisting would divest the first applicant of its exclusivity because the applicant cannot yet go to market). *See* Acarbose Dec. 8-9 (asserting that the delisting trigger "is not limited by its terms to a particular context in which the patent withdrawal occurs"); *see also* COSOPT® Dec. at 14 n.15 (citing Acarbose). But that simply isn't what Congress said in the MMA, and there's not a shred of evidence that Congress silently intended amendments ***designed to prevent*** brand manufacturers from manipulating the incentives for generic market entry (by improperly listing patents in the Orange Book) to instead ***authorize*** brand manufacturers to manipulate those incentives in an equally pernicious fashion (by delisting patents from the Orange Book, thereby depriving a first applicant of its exclusivity and discouraging future Paragraph IV challenges).

Indeed, the statutory text helps underscore what otherwise is obvious from the structural interplay between the delisting counterclaim and the delisting trigger—namely, that Congress intended the delisting trigger to apply only where patents are delisted following a successful delisting-counterclaim challenge. Specifically, the (bb) subsection of the failure-to-market forfeiture clause, which includes the delisting trigger, provides that exclusivity may be forfeited if certain events occur "***with respect to*** the first applicant or any other applicant [that has obtained tentative approval]." 21 U.S.C. § 355(j)(5)(D)(i)(I)(bb) (emphasis added). Yet none of the events that follow—(1) the entry of a court decision holding that a challenged patent is invalid or not infringed, (2) the entry of a settlement order or consent decree that includes a finding of invalidity or non-infringement, or (3) a patent delisting—can occur "with respect to [an] applicant" outside the context of litigation between a generic applicant and the brand manufacturer. *Id*. § 355(j)(5)(D)(i)(I)(bb)(AA)-(CC). The first two events necessarily relate to litigation, and ***unilateral*** patent delistings outside the litigation context do not, by definition, occur "with respect to [an] applicant." After all, an NDA holder's unilateral request for delisting outside the litigation context is communicated only ***to FDA***, which then publishes a notice of the delisting in the Orange Book for the public's benefit. By contrast, where a delisting occurs in response to a court order compelling the brand manufacturer to delist a challenged patent, the resulting delisting unquestionably takes place "with respect to [an] applicant" because a particular applicant secured that delisting through the statute's counterclaim right of action. Nonetheless, FDA's Delisting Rule pays no heed to this statutory language, and instead reads that language (along with the commercial marketing trigger) out of the statute.

FDA's only remaining argument reflects its stubborn approach to this issue. The Agency ultimately asserts that "it seems unlikely that NDA holders would engage in a concerted practice

to divest first applicants of exclusivity by delisting patents, because NDA holders lose less market share if there is a 180-day exclusivity period in which they share the market with only the first applicant, as opposed to facing competition from all approvable ANDA applicants." COSOPT® Dec. at 14. But FDA raised ***this exact*** argument in *Ranbaxy* (using virtually the same words), and the D.C. Circuit rejected it. *See* Brief of Appellants, No. 06-5154, 2006 WL 1757180 (D.C. Cir. June 21, 2006), at 37-38 ("[I]t is unlikely that an NDA holder would delist ... because an NDA holder would ordinarily prefer generic competition to be limited to one generic for the 180-day period, since prices fall further when additional competitors enter the market") (excerpt attached as Exhibit E). As the D.C. Circuit recognized in *Ranbaxy*, FDA's argument fundamentally misunderstands the economic principles that govern incentives—which necessarily seek to affect future conduct over the long-run—by myopically focusing on the near-term. In short, regardless of whether it would behoove a brand manufacturer to preserve the first applicant's exclusivity and therefore face less competition ***in a particular case***, brand manufacturers have a long-term economic interest in reducing the incentive for generic manufacturers to file future patent-challenging certifications ***in all future cases***. If brand manufacturers can reduce the likelihood that a patent challenge will result in exclusivity over the long-run, as the Delisting Rule permits, that is exactly what they will do: they will delist patents and thereby "diminish[] the incentive for a manufacturer of generic drugs to challenge a patent" in the future. *Ranbaxy*, 469 F.3d at 126.

At the end of the day, FDA's new Delisting Rule simply loses sight of the fact that Teva did exactly what Congress intended to reward when it created the 180-day exclusivity period. Teva challenged Merck's patents and has cleared the path for generic competition to begin more than four years earlier than it otherwise would. Teva has not sat on its rights, "parked" its

exclusivity by refusing to launch its product, or done anything else to forfeit its 180 days of exclusivity. Again, as a direct result of Teva's efforts, consumers now will have access to generic Cozaar® and Hyzaar® products years earlier than they otherwise would, which is exactly what Congress sought to reward when it created 180-day exclusivity: it will "'get generic drugs into the hands of patients at reasonable prices—fast.'" *Andrx Pharms., Inc. v. Biovail Corp. Int'l*, 256 F.3d 799, 809 (D.C. Cir. 2001) (quoting *In re Barr Labs., Inc.*, 930 F.2d 72, 76 (D.C. Cir. 1991)). FDA's Delisting Rule fundamentally undermines this comprehensive statutory scheme, and this Court should have no more trouble invalidating the Delisting Rule than both it and the D.C. Circuit did last time FDA sought to undermine the exclusivity incentive by permitting unilateral, exclusivity-divesting patent delistings.

II. TEVA WILL SUFFER IRREPARABLE HARM WITHOUT THE ENTRY OF IMMEDIATE INJUNCTIVE RELIEF.

Teva will be irreparably harmed unless this Court immediately vacates the Delisting Rule and enjoins the Agency from divesting Teva of its hard-won exclusivity for generic losartan potassium drug products based on that Rule. As noted above, FDA has adopted a post-*Ranbaxy* practice of withholding the formal issuance of its determination that a first applicant is not entitled to 180-day exclusivity under the Delisting Rule until the Agency is ready to—and in fact simultaneously does—approve a competing generic manufacturer's product. *See* Acarbose Dec. at 1 n.1; COSOPT® Dec. at 1 n.1. Because it is virtually impossible for a first applicant to obtain effective judicial relief after FDA approves competing generic products for commercial marketing, *Sandoz*, 439 F. Supp. 2d at 32 ("'Once the statutory entitlement has been lost, it cannot be recaptured.'") (quoting *Apotex*, 2006 WL 1030151 at *17), FDA has to date successfully shielded the Delisting Rule from judicial review. Indeed, in each of the prior cases in which FDA has applied the Delisting Rule, FDA's procedural approach has caused the

aggrieved parties to abandon their efforts to obtain meaningful judicial relief. *See Cobalt Labs., Inc. v. FDA*, No. 08-798-RBW (lawsuit voluntarily dismissed); *Hi-Tech I*, Case No. 08-1495-JDB (sought only permanent injunction following issuance of FDA's letter decision).

Yet FDA's Delisting Rule already has harmed Teva by divesting the company of its right to 180-day exclusivity in clear violation of the statute. Barring immediate injunctive, that harm will be irreparable. 180-day generic marketing "exclusivity typically gives the first generic entrant a permanent advantage over subsequent entrants, because that officially sanctioned "head start" permits first entrants to secure distribution channels and access to customers; enter into long-term sales agreements; increase sales across all of its product lines; and retain greater market share in the long-run." Marshall Decl. ¶ 11. Because the Delisting Rule has stripped Teva of its exclusivity, however, "Teva has lost its officially sanctioned head start, impairing its access to customers for generic losartan potassium tablets, decreasing its opportunities to strengthen market position on other product lines, and diminishing Teva's ability to establish and retain long-term market share for generic products containing losartan potassium. *Id*. ¶ 15.

Short of an injunction that would prevent the Delisting Rule's application, there is no way to remedy those losses. "Because a given prescription can be filled only once, it is impossible to 'make up' for a lost sale by filling a subsequent prescription." Marshall Decl. ¶ 17. It thus should come as no surprise that courts have repeatedly recognized that lost generic marketing exclusivity is a form of irreparable injury sufficient to ground preliminary injunctive relief against FDA. *See*, *e.g.*, *Mova*, 140 F.3d at 1066 n.6; *Sandoz*, 439 F. Supp. 2d at 32 (citing *Apotex*, 2006 WL 1030151 at *17).

Moreover, the loss of exclusivity will in this case cost Teva literally hundreds of millions of dollars in lost revenues. In the 12-month period ending March 31, 2009, Merck sold a

combined 848 million tablets of Cozaar® and Hyzaar®, with a market value exceeding $1.5 ***billion*** dollars. Marshall Decl. ¶ 4. With its statutorily-entitled period of exclusivity intact, Teva's lower-priced generic versions of these drugs will allow it to command a significant percentage of this market. Absent exclusivity, however, Teva will sell approximately 50-60 percent fewer losartan potassium tablets and will lose hundreds of millions of dollars in net revenues. *Id*. ¶ 15. While those losses are a form of "economic" harm, they are truly irreparable—and thus capable of grounding injunctive relief—because the government's sovereign immunity would preclude Teva from recovering damages in the event this Court later overturns the Delisting Rule. *See, e.g.*, *Brendsel v. Office of Fed. Hous. Enter. Oversight*, 339 F. Supp. 2d 52, 66 (D.D.C. 2004); *see also Entergy Ark., Inc. v. Nebraska*, 210 F.3d 887, 899 (8th Cir. 2000); *cf. CSX Transp., Inc. v. Williams*, 406 F.3d 667, 674 n.7 (D.C. Cir. 2005).

Finally, it bears emphasis that Teva will suffer irreparable harm unless this Court acts immediately. The launch of a generic drug takes months of planning and preparation, and the resources needed for an exclusive launch and a non-exclusive launch vary greatly. Marshall Decl. ¶ 19. To prepare for an exclusive launch, Teva would have to begin the manufacturing process (which includes several months of preparing and validating sample batches, followed by approximately six months of commercial production) ***this month***. The Marshall Declaration explains this process in detail:

- "Given the losartan potassium market's vast size, it will take at least six months for Teva to manufacture enough losartan potassium product to satisfy the market's demand in the event of an exclusive product launch. But Teva cannot begin the commercial manufacturing process until several other steps are completed." *Id*. ¶ 20.

- "First, Teva must prepare validation batches of its generic Cozaar® and Hyzaar® products so that its commercial manufacturing process can be confirmed as producing a drug with the correct properties and specifications. Multiple validation batches must be prepared for each strength of each drug (five strengths

in total). Teva cannot commence manufacturing losartan potassium products on a commercial scale until the validation process has been completed. This entire process takes several months to complete." *Id.* ¶ 21.

- "Teva must acquire significant quantities of raw and other materials in order to begin manufacturing losartan potassium products on a commercial scale subsequent to completion of validation. Needless to say, Teva will need to acquire significantly more component materials if it is preparing for an exclusive launch than if it is preparing for a non-exclusive launch. Because Teva's manufacturer of active pharmaceutical ingredient (API) can only produce a limited amount of API each month, Teva must ask its API manufacturer to begin producing API far sooner for an exclusive launch than for a non-exclusive launch, so that its API supplier can commit adequate human and physical resources to producing losartan potassium API. In this case, Teva would need to immediately place an order for API with significant quantities of material to be delivered beginning no later than August 2009." *Id.* ¶ 22.

- "Teva also would have to purchase far greater quantities of other materials in connection with an exclusive product launch, including non-active ingredients, bottles and packaging materials. These materials must be ordered and produced on roughly the same schedule as the API to ensure the manufacturing process can begin on schedule and proceed in a coordinated fashion." *Id.* ¶ 23.

- "Finally, Teva must make an appropriate allocation of its own human resources and manufacturing capacity as soon it begins receiving API and other materials from its suppliers. Again, greater plant capacity and a greater commitment of human resources are necessary if Teva will be producing generic Cozaar® and Hyzaar® for an exclusive commercial launch than if not. These decisions, too, must be made imminently so that appropriate resources will be in place and 'ready to go' as soon as Teva begins receiving API and other raw materials from its suppliers." *Id.* ¶ 24.

As the foregoing timeline illustrates, these things cannot be done in the days or weeks that immediately precede Teva's planned commercial launch in April 2010. To the contrary, Teva must start making decisions about manufacturing losartan potassium ***immediately***, and the decisions it now must make have significant consequences. If Teva prepares for an exclusive launch, only to discover that it forfeited its exclusivity years ago because the Delisting Rule is lawful, it will have wasted considerable resources producing products it cannot sell. *Id.* ¶ 27. If, on the other hand, Teva prepares for a non-exclusive launch, only to have this Court invalidate the Delisting Rule on the eve of Teva's launch, then Teva will not have sufficient product on

hand to satisfy the market's demand for these widely prescribed products—resulting in lost sales and loss of goodwill from customers that cannot purchase sufficient product quantities from Teva. *Id*. ¶ 26. Consumers, too, will suffer: many will not be able to obtain affordable generic alternatives to brand-name Cozaar® and Hyzaar® for months following the end of Merck's monopoly in April 2010. *Id*. ¶ 26.

In short, Teva needs to know ***now*** whether its exclusivity remains intact (because the Delisting Rule is invalid) or has been forfeited (because the Delisting Rule is valid).

III. THE BALANCE OF HARDSHIPS AND PUBLIC INTEREST FAVOR THE ENTRY OF IMMEDIATE INJUNCTIVE RELIEF.

The final equitable factors—the balance of hardships and public interest—likewise favor granting immediate injunctive relief. With respect to the former, FDA is a federal agency and cannot seriously claim that it would be harmed by an injunction requiring it to apply Hatch-Waxman Act in a manner consistent with Congress's intent and the D.C. Circuit's decision in *Ranbaxy*. Nor will any private party suffer significant harm from an injunction. Merck will not be harmed, because it will face generic competition regardless of the outcome here. And while a declaration that the Delisting Rule is unlawful may have some ancillary impact on the other generic applicants (because it will clear the way for Teva's exclusivity), any harm to those companies vastly would be outweighed by the harm Teva would suffer absent injunctive relief. After all, Teva claims the exclusive right to market generic losartan potassium tablets for 180 days, while its competitors seek only the right to be one of many companies that would enter the market during that period. As a result, the costs of denying injunctive relief will be borne singularly by Teva, while any costs to the subsequent applicants from the entry of an injunction would be shared across the industry.

Finally, it bears note that the generic drug industry as a whole ultimately stands to benefit from a decision invalidating the Delisting Rule. At some point, every member of the generic industry is likely to be a first-filer on one or more future products, and thus would benefit from a decision that fully preserves the value of exclusivity for those who undertake the significant risks inherent in submitting the first Paragraph IV certification.

But make no mistake: it is the public that stands to lose the most if this Court declines to vacate the Delisting Rule. If generic companies cannot be sure that FDA and the courts will protect their right to 180-day exclusivity when it matters most, they will be less likely to challenge patents by filing Paragraph IV certifications in the future—slowing the onset of generic competition, and ultimately increasing prices for patients and insurers. That result would directly undermine the basic purpose of the Hatch-Waxman Act, which is to "'get generic drugs into the hands of patients at reasonable prices—fast.'" *Andrx*, 256 F.3d at 809 (quoting *In re Barr Labs.*, 930 F.2d at 76). By contrast, injunctive relief would foster that basic goal by preserving the incentive scheme Congress established in the Hatch-Waxman Act, and this Court should act quickly to restore the integrity of the Hatch-Waxman regime and protect Teva's statutory reward for advancing the onset of generic competition in the losartan potassium market by well over four years.

CONCLUSION

For the foregoing reasons, Teva respectfully requests that this Court grant its motion for a preliminary injunction.

Dated: June 19, 2009

Respectfully submitted,

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CERTIFICATE OF SERVICE

The undersigned certifies that on this 19th day of June, 2009, he caused a copy of the foregoing **MEMORANDUM OF POINTS AND AUTHORITIES** to be served upon the following attorneys by electronic mail:

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