UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

HI-TECH PHARMACAL CO., INC., Plaintiff, v. U.S. FOOD AND DRUG ADMINISTRATION, Defendant, APOTEX, INC., Intervenor-Defendant.	)	Case No. 08-1495-JDB

MOTION OF TEVA PHARMACEUTICALS USA, INC. FOR LEAVE TO FILE A BRIEF *AMICUS CURIAE* IN SUPPORT OF HI-TECH PHARMACAL CO., INC.

For the reasons set forth in the accompanying Memorandum of Points and Authorities, Teva Pharmaceuticals USA, Inc. ("Teva") hereby seeks leave to file a brief *amicus curiae* in support of Plaintiff Hi-Tech Pharmacal Co., Inc. in the above-captioned action. A copy of the proposed brief *amicus curiae* is attached as Exhibit 1 to this motion.

Dated: October 24, 2008

Respectfully submitted,

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EXHIBIT 1

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

HI-TECH PHARMACAL CO., INC.,	)	
Plaintiff,	)	
v.	)	
U.S. FOOD AND DRUG ADMINISTRATION,	)	Case No. 08-1495-JDB
Defendant,	)	
APOTEX, INC.,	)	
Intervenor-Defendant.	)	

[PROPOSED] BRIEF *AMICUS CURIAE* OF TEVA PHARMACEUTICALS USA, INC. IN SUPPORT OF HI-TECH PHARMACAL CO., INC.

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INTRODUCTION

While FDA has not yet entered its final decision in this matter, at least part of that decision is a foregone conclusion. Just a few months ago, FDA held that Cobalt Laboratories had forfeited its right to 180-day exclusivity for generic acarbose tablets in part because Cobalt failed to begin marketing its generic products within 75 days of the date on which the acarbose brand manufacturer sought to delist the patent grounding Cobalt's claim to exclusivity. *See* Exh. 2 to Hi-Tech's Mot. for PI (Docket No. 4) at 7-9 (the "Acarbose Letter Decision"). As Teva explained in its submission to FDA's acarbose docket, that result cannot be squared with the statute's text, structure, or history: It is well-settled that brand manufacturers may not manipulate the exclusivity incentive by delisting a patent following the submission of an exclusivity-qualifying Paragraph IV certification, *Ranbaxy Labs. Ltd. v. FDA*, 469 F.3d 120, 126 (D.C. Cir. 2006), and nothing in the amended statute undermines that core principle of Hatch-Waxman law. Right or wrong, however, FDA's acarbose decision binds the Agency's hands in this case, and FDA thus is likely to hold that Merck lawfully delisted its COSOPT® patents such that Hi-Tech may have forfeited its exclusivity by failing to market its product within 75 days of the date Merck sought to delist its patents from the Orange Book.

If FDA rules against Hi-Tech on that basis, this Court should vacate FDA's decision and enjoin the Agency from approving other applicants until Hi-Tech's 180-day exclusivity period expires. Teva does not take this position lightly: Like intervenor Apotex, Teva has filed an ANDA seeking approval to market generic COSOPT®, and thus would be eligible to enter the market up to six months earlier if FDA holds (and this Court agrees) that Hi-Tech's exclusivity has been forfeited. Unlike Apotex, however, Teva is not willing to eviscerate Congress's exclusivity incentive over the long-run in exchange for short-term profits on a single product.

Make no mistake: that is exactly what FDA's current approach to patent delisting threatens to do. As *Ranbaxy* recognized, allowing brand manufacturers to delist patents in the face of an exclusivity-qualifying Paragraph IV certification—and thereby deprive the first generic applicant of exclusivity—puts the fox in charge of the henhouse, because it empowers brand manufacturers to undermine the very incentive Congress gave generic applicants to challenge brand-name patents. *Id*.; *see also Inwood Labs., Inc. v. Young*, 723 F. Supp. 1523, 1527 (D.D.C. 1989). Needless to say, Congress could not possibly have intended to put patent holders in charge of an incentive that rewards patent challengers, and the courts accordingly have rejected each of FDA's prior efforts to enable such manipulation. *Ranbaxy*, 469 F.3d at 126; *Mova Pharm. Corp. v. Shalala*, 140 F.3d 1060, 1069 (D.C. Cir. 1998); *Granutec, Inc. v. Shalala*, 139 F.3d 889, 1998 WL 153410, at *3 (4th Cir. 1998); *Inwood*, 723 F. Supp. at 1527.

Unwilling to throw in the towel, FDA now seeks to evade these cases by asserting that Congress abrogated them when it added a series of "forfeiture triggers" to the statute as part of the Medicare Modernization Act (the "MMA"). Specifically, FDA has argued that the prior decisions were "'geared to the Act pre-MMA,'" Acarbose Letter Decision at 8 (quoting *Ranbaxy*, 469 F.3d at 122), while "[t]he effect of patent delisting on eligibility for 180-day exclusivity is expressly addressed by the plain language of section 505(j)(5)(D)(i)(I) of the [post-MMA] Act." *Id*. There's a kernel of truth in those claims: the existing cases do address the pre-MMA Act, and the MMA does provide that a generic applicant may "forfeit" exclusivity if it fails to enter the market within 75 days after "patent information submitted [to the FDA] is withdrawn by the holder of [an] approved NDA." 21 U.S.C. § 355(j)(5)(D)(i)(I)(bb)(CC) (2003) (the "delisting trigger"). But it simply does not follow that brand manufacturers now are free to delist patents in the face of an exclusivity-qualifying Paragraph IV certification simply because

the new statutory language "is broadly applicable to all patent withdrawals," and triggered "whenever a patent is withdrawn … by the NDA holder." Acarbose Letter Decision at 8.

To the contrary, FDA's superficial interpretation only begs the question. The issue here is not whether the delisting trigger is activated "***whenever***" a patent is delisted from the Orange Book. No one disputes that it is. Instead, the question here (as in *Ranbaxy*) is "***when***" a patent can be delisted from the Orange Book, such that the delisting trigger would be activated. The trigger itself does not remotely answer that question. It states only that an applicant might forfeit exclusivity ***if*** there is a delisting (and then only ***if*** the applicant fails to market within 75 days). But it says nothing about the circumstances under which such a delisting is permissible in the first place. As *Ranbaxy* made clear, the background rule at the time Congress added the delisting trigger was that brand manufacturers could not initiate a patent delisting when doing so would divest a first applicant of exclusivity, and nothing in the text, history, or structure of the MMA purports to abrogate that rule and open the doors to delistings at the brand manufacturer's whim.

To be sure, the MMA did make one change that sheds light on the question in this case. For the first time, it empowered generic applicants to force the delisting of a patent by filing a litigation counterclaim "seeking an order requiring the [NDA] holder to correct or delete the patent information submitted" for listing in the Orange Book. *See* 21 U.S.C. § 355(j)(5)(C)(ii)(I) (2003). Congress designed that provision to close a vexing loophole that previously allowed brand manufacturers to manipulate generic market entry by improperly listing patents in the Orange Book—that is, by listing patents that did not meet the criteria for listing. In essence, the scheme worked like this: On the eve of first generic approval, brand manufacturers would submit new patent information for listing in the Orange Book. FDA had long declined to second-guess a patent-listing requests, *e.g., Apotex, Inc. v. Thompson*, 347 F.3d 1335, 1349-50 (Fed. Cir. 2003), so it automatically would add the new patent to the Orange Book (making it a "later-listed

patent"). Because generic applicants must submit a certification to each listed patent (including later-listed patents), *Apotex Inc. v. FDA*, 414 F. Supp. 2d 61, 64 (D.D.C. 2006), FDA then would refuse to approve pending ANDAs until their sponsors certified to the later-listed patent.[1]

At first, generic manufacturers tried to evade that requirement by filing declaratory judgment actions seeking to compel the brand manufacturer to delist the later-listed patent. But the courts consistently held that neither Hatch-Waxman Act nor the patent laws authorized a "right of action for 'delisting.'" *See, e.g., Mylan Pharms. Inc., v. Thompson*, 268 F.3d 1323, 1332 (Fed. Cir. 2001). As a result, generic applicants had no choice but to submit a Paragraph IV certification to the later-listed patent—and at that point, brand manufacturers were home free: pre-MMA, the statute automatically stayed ANDA approval for 30 months whenever a brand manufacturer filed suit within 45 days of receiving notice that the applicant had filed a Paragraph IV certification (including to a later-listed patent), 21 U.S.C. § 355(j)(5)(B)(iii) (2002), and brand manufacturers thus were able to delay generic competition for another 30 months simply by filing suit based on the later-listed patent—no matter how meritless their claims.

After years of public criticism, Congress finally ended this form of brand-initiated manipulation with passage of the MMA. While brand manufacturers are still permitted to submit later-issued patents to the Orange Book, and generics are still required to certify to later-listed patents, the statute now provides that lawsuits based on Paragraph IV certifications to later-listed patents no longer give rise to an automatic 30-month stay. *Id*. § 355(j)(5)(B)(iii) (2003). And, as

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[1] To be clear, we use the term "later-listed patent" to refer to patents submitted to FDA after an ANDA has been filed but within 30 days of the date the patent has been issued. Where brand manufacturers obtain a new patent after the submission of an ANDA but fail to submit information about that patent to FDA within 30 days of its issuance, the patent is a "late-listed patent" for which no certification is required. *See* 21 C.F.R. § 314.94(a)(12)(vi) ("If a patent on the listed drug is issued and the holder of the approved application for the listed drug does not submit the required information on the patent within 30 days of issuance of the patent, an applicant who submitted an [ANDA] that contained an appropriate patent certification before the submission of the patent information is not required to submit an amended certification.").

noted above, where a brand manufacturer does initiate suit against a Paragraph IV applicant, the applicant now has the right to assert a counterclaim seeking a court order compelling the brand manufacturer to delist its patents from the Orange Book. *Id*. § 355(j)(5)(C)(ii)(I) (2003).

Against this backdrop, it is clear that the delisting forfeiture trigger was not remotely intended to abrogate—*sub silentio*—the *Ranbaxy* line of cases by permitting NDA holders to delist patents at-will and thereby divest first-filers of their exclusivity. Instead, it was intended simply to ensure that first applicants who succeed in securing a delisting order ***through the MMA's new delisting counterclaim action*** do not unduly delay market entry once the patent thicket is cleared. In that respect, the delisting forfeiture trigger is just like two other—parallel—forfeiture triggers that the MMA added to the same statutory subsection: one that applies where generic applicants fail to launch within 75 days of the date of a final court decision holding that the listed patents are invalid or not infringed, *id*. § 355(j)(5)(D)(i)(I)(bb)(AA) (2003), and one that applies where generic applicants fail to launch within 75 days of the date of a settlement order or consent decree conceding that the listed patents are invalid or not infringed. *Id*. § 355(j)(5)(D)(i)(I)(bb)(BB) (2003).

In other words, the statute's text and history show that the MMA's structurally linked delisting counterclaim and forfeiture trigger were designed to prevent brand manufacturers from manipulating the incentives for generics to challenge patents and to ensure that generics promptly enter the market—and thus that Congress intended the MMA to complement, rather than abrogate, *Ranbaxy*'s holding that brand manufacturers may not manipulate generic marketing incentives through patent delistings. The result of FDA's contrary interpretation thus is ironic. Rather than reading the MMA to close a loophole that brand manufacturers previously used to manipulate generic entry (by improperly listing patents), FDA has construed these loophole-closing provisions to open a new loophole for brands to manipulate generic market

entry (by improperly delisting patents). There is no evidence that Congress intended to take with one hand what it gave with the other, and any contrary decision should be vacated.

BACKGROUND

A. Statutory and Regulatory Overview

The Food, Drug, and Cosmetic Act (the "FDCA" or "statute"), as modified by the Hatch-Waxman Act and MMA, establishes the procedure for obtaining approval to market pharmaceuticals in the United States. *See* 21 U.S.C. § 355.[2] Under the statute, brand-name drug manufacturers obtain approval by filing a New Drug Application ("NDA") that, among other things, contains clinical data demonstrating the safety and efficacy of the proposed new drug. *See id*. § 355(b)(1). Prior to Hatch-Waxman, generic manufacturers generally had to complete a full NDA in order to obtain approval—even though generics contain the same active ingredients and provide the same therapeutic value as their brand-name equivalents. Generic market entry thus was cost-prohibitive, and patients lacked widespread access to generic medicines. In 1984, Congress enacted Hatch-Waxman to remove those barriers, increase competition, and thereby reduce the cost of pharmaceuticals. *See* Pub. L. No. 98-417, 98 Stat. 1585 (1984).

To accomplish those goals, Hatch-Waxman permits generic companies to obtain approval if they can show that the proposed generic drug is bioequivalent to a brand-name drug that FDA already has approved. Generic applicants do so by submitting an Abbreviated NDA ("ANDA") that, among other things, establishes the proposed generic's chemical and bioequivalence to the previously approved drug. 21 U.S.C. § 355(j). Provided the ANDA does so, its sponsor need not repeat prior safety or efficacy studies conducted on the brand-name drug. *Id.* § 355(j)(2)(A).

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[2] Because the issues in this case turn on the interplay between the Hatch-Waxman Act and the MMA, we denote the version of the statute to which we refer when necessary—(2002) for Hatch-Waxman citations, and (2003) for MMA citations. Where the two versions are identical, or alterations immaterial, we omit such references.

To balance the 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 then 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 the Orange Book.

Because the Agency lacks patent-law expertise, it plays only a "ministerial role" in maintaining the Orange Book. *See, e.g.*, *Apotex*, 347 F.3d at 1349-50; *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. 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. *See* 35 U.S.C. § 271(e); *see also Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 678 (1990).

To encourage 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.*, *Purepac Pharm. Co. v. Thompson*, 354 F.3d 877, 879 (D.C. Cir. 2004). Under the original statute, that 180-day period began to run on the earlier of (a) the date on which the first applicant first began to market 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 first applicant's first commercial marketing. 21 U.S.C. § 355(j)(5)(B)(iv) (2003).

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

Three problems commonly arose under Hatch-Waxman. First, brand manufacturers often attempted to manipulate generic marketing rights by improperly seeking to delist 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 practice in court, and the D.C. Circuit reversed FDA's delisting policy at *Chevron* step one. *Ranbaxy*, 469 F.3d at 125-26. As the appellate court explained, FDA's delisting policy 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." *Id*. 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 policy 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*.

In addition to manipulatively seeking to ***delist*** challenged patents, brand manufacturers attempted to manipulate generic market entry by improperly ***listing*** new patents in the Orange

Book—in some cases submitting new patents that plainly did not qualify for Orange-Book listing under the statute and FDA regulations. Such anticompetitive patent listings were particularly troubling to first applicants that were prepared to go to market, since brand manufacturers were able to exploit the 30-month stay to delay generic approvals. *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").

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 late-listing patents, 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) (2003). Moreover, Congress empowered generic applicants who are sued for patent infringement to force brand manufacturers to delist improperly submitted patents through a new counterclaim right of action "seeking an order requiring the [NDA] holder to correct or delete the patent information submitted" to the Orange Book. *Id*. § 355(j)(5)(C)(ii)(I) (2003).

Finally, 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 often were able to delay full generic competition 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., Inc. v. FDA*, No. 08-1495-JDB, ___ F. Supp. 2d ___, 2008 WL 4531774 *2 (D.D.C. Oct. 10, 2008) (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) … 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) (2003).

C. Abbreviated Factual Background

In August 2005, Hi-Tech filed the first ANDA seeking FDA approval to market generic COSOPT®. At the time Hi-Tech filed its application, brand manufacturer Merck had listed three patents for COSOPT® in the Orange Book, and Hi-Tech's ANDA included Paragraph IV certifications to all three patents. In January 2006, Merck sued Hi-Tech for infringing one of

those patents. Merck did not, however, assert either of the other two listed patents against Hi-Tech. Instead, it disclaimed those patents in April 2006, and soon asked FDA to delist those patents from the Orange Book. Merck later prevailed in its litigation against Hi-Tech. Because the patent at issue in that litigation does not expire until October 28, FDA has not yet approved Hi-Tech's ANDA and Hi-Tech thus has not begun to market its generic COSOPT® products. *See Hi-Tech Pharmacal Co.*, 2008 WL 4531774 at *3-*4. Under FDA's decision in the acarbose case, Hi-Tech's failure to enter the market within 75 days of Merck's delisting request activates the delisting clause of the forfeiture trigger set forth in 21 U.S.C. § 355(j)(5)(D)(i)(I).[3]

ARGUMENT

FDA'S POST-MMA APPROACH TO PATENT DELISTING IS INCONSISTENT WITH THE TEXT, STRUCTURE, AND HISTORY OF THE STATUTE.

FDA's post-MMA approach to patent delisting is inconsistent with the text, structure, and history of the statute, and provided that the Agency holds that Hi-Tech has forfeited its exclusivity in part because it failed to launch its generic COSOPT® products within 75 days of the brand manufacturer's delisting request, this Court should both vacate that decision and enjoin the Agency from approving subsequent generic COSOPT® applications—including Teva's—until Hi-Tech's 180-day exclusivity period ends.

The argument here is straightforward: FDA's post-MMA approach to patent delisting presents the precise structural inconsistencies that led the D.C. Circuit to invalidate FDA's pre-MMA delisting policy at *Chevron* step one. First, FDA's post-MMA approach to delisting—which allows brand manufacturers to divest first applicants of 180-day exclusivity where (as

[3] Even under FDA's view of the law, that does not mean that Hi-Tech necessarily has forfeited its exclusivity: as FDA recognized in the granisetron case, the statute requires FDA to determine "the later of" two events—and delisting is just one of the events that goes into that calculus. We take no position here with respect to Hi-Tech's claims that the other events have not occurred.

here) a valid blocking patent precludes the first applicant from marketing within 75 days of a delisting request—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. *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, this concern is even greater post-MMA than it was pre-MMA, since the MMA eliminated the court-decision trigger—meaning that the commercial marketing trigger is now the ***only*** way a generic can trigger its exclusivity period. *See* 21 U.S.C. § 355(j)(5)(B)(iv) (2003). Because FDA's post-MMA policy on delistings thus precludes otherwise eligible applicants from beginning their periods of marketing exclusivity through the only pathway provided in the statute, it is no less (and, indeed, is even more) "inconsistent with the structure of the statute" than the pre-MMA delisting policy that *Ranbaxy* invalidated at *Chevron* step one. 469 F.3d at 125.

Far more important, FDA's post-MMA delisting policy—just like its pre-MMA delisting policy—eviscerates the exclusivity reward at the heart of the statute, because "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 gave generic applicants to challenge brand-name patents in the first place. *See Inwood*, 723 F. Supp. at 1527 (holding that Congress could not have intended to "subject[] the exclusivity incentive to the caprices of the patent holder"). As *Ranbaxy* recognized, however, "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's only response to these straightforward points is that *Ranbaxy* "did not purport to render a decision on patent delisting and exclusivity under the MMA," which now "expressly addresse[s]" the "effect of patent delisting on eligibility for 180-day exclusivity." Acarbose Letter Decision at 8. That, of course, is true. Ranbaxy did address the pre-MMA statute, and section 505(j)(5)(D)(i)(I) of the statute does address "***the effect of*** patent delisting on eligibility for 180-day exclusivity." *Id*. (emphasis added). But the question of how a delisting ***affects*** exclusivity is entirely different from the question of ***whether*** (as FDA held in the acarbose case) brand manufacturers may manipulate the exclusivity incentive by initiating a delisting whenever they choose. FDA cites nothing in the MMA or its legislative history that would suggest Congress intended, *sub silentio*, to fundamentally alter the statutory scheme by undermining the central premise of *Ranbaxy* (and the long line of cases on which that decision was based, *see Mova*, 140 F.3d at 1069; *Granutec*, 139 F.3d at 889; *Inwood*, 723 F. Supp. at 1527), and there is none. *Cf. City of New York v. FCC*, 486 U.S. 57, 67-68 (1988) (finding it "quite significant that nothing in the … Act or its legislative history indicates that Congress explicitly … intended to overturn … decade-old policy without discussion or even any suggestion that it was doing so").

To be sure, the delisting trigger does make clear that it now is possible—in certain circumstances—for a patent to be delisted despite the existence of an exclusivity-qualifying certification based on that patent. But that is so only because Congress amended the counterclaim provisions of the statute to authorize generic applicants (for the first time) 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) (2003) (internal enumeration omitted). As set forth above, 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.").

Given this clear statutory context, FDA is left to argue that because post-Paragraph IV patent delistings are now possible in certain circumstances (namely, when a Paragraph IV applicant obtains a court order requiring the brand manufacturer ***involuntarily*** to delist a patent), post-Paragraph IV delistings must be permissible in all circumstances (including cases—like this one—where the brand manufacturer's ***voluntary*** delisting would divest the first applicant of its exclusivity). But that simply isn't what Congress said in the MMA, and there's not a shred of evidence to think that Congress intended that amendments ***designed to prevent*** brand manufacturers from manipulating the incentives for generic market entry would instead be interpreted to ***authorize*** brand manufacturers to manipulate those incentives in an equally pernicious fashion.

FDA's only remaining argument misses the point entirely. We fully agree that the delisting trigger "is not limited by its terms to a particular context in which the patent withdrawal occurs" and thus "applies whenever an NDA holder withdraws a patent." Acarbose Letter Decision at 8-9. But again, the question here is not when the delisting trigger applies—it applies every time there is a delisting—but when brand manufacturers can carry out a delisting that would activate that trigger. As set forth above, the MMA authorizes delistings only in the context of a counterclaim action seeking to compel such a delisting, and the *Ranbaxy* decision and remainder of the statutory scheme make clear (at *Chevron* step one) that brand-initiated delistings outside that context are fundamentally inconsistent with the text, structure, and history of the Act.

At the end of the day, FDA's approach to delisting simply loses sight of the fact that Hi-Tech did exactly what Congress intended to reward when it created the 180-day exclusivity period. Hi-Tech set about to bring consumers affordable, generic COSOPT®. It looked in the Orange Book and saw that Merck had listed three patents. It undertook the expense and effort of evaluating those patents, invested the resources necessary to develop a challenge to those patents, and then assumed the risk of costly patent infringement litigation by filing Paragraph IV certifications to those patents. Merck in fact sued Hi-Tech for infringing one of those patents—but Merck also waived the white flag in response to Hi-Tech's powerful challenge to the other two patents, and conceded that those patents never should have been listed in the Orange Book. As a result of Hi-Tech's efforts, consumers now will have access to generic COSOPT® years earlier than they otherwise would, which is exactly the result 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 post-MMA approach

to delisting fundamentally undermines that scheme, and this Court should set aside FDA's delisting policy aside.

CONCLUSION

For the foregoing reasons, this Court should vacate any decision predicated on FDA's post-MMA approach to patent delisting and enjoin the Agency from approving subsequent applicants for generic COSOPT® pending the expiration of Hi-Tech's 180-day period of marketing exclusivity.

Dated: October 24, 2008

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on October 24, 2008, I caused the foregoing **MOTION FOR LEAVE TO FILE A BRIEF *AMICUS CURIAE*** to be served upon the following attorneys by e-mail and dispatched hard copies for Monday delivery *via* Federal Express:

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