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Food and Drug Administration
5630 Fishers Lane, Room 1061
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CITIZEN PETITION

ACTION REQUESTED

KV Pharmaceutical Company ("KV") respectfully submits this Citizen Petition under Section 505 of the Food, Drug and Cosmetic Act (generally codified at 21 U.S.C. § 355) and Section 10.30 of the Food and Drug Administration's implementing regulations (21 C.F.R. § 10.30). This petition requests that FDA: (1) relist U.S. Patent 5,246,714 (the '714 patent) in *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book") for 100 mg and 200 mg Toprol-XL (metoprolol succinate extended release) tablets, both approved drug products of AstraZeneca LP; (2) refrain from approval of any Abbreviated New Drug Application ("ANDA") for metoprolol succinate extended release100 mg and 200 mg tablets filed subsequent to KV's ANDA No. 76-640 for metoprolol succinate extended release 100 mg and 200 mg tablets until KV's 180-day exclusivity based on the '714 patent has expired; and (3) confirm that KV's right to 180-day exclusivity with regard to ANDA No. 76-640 has not been affected by FDA's earlier erroneous delisting of the '714 patent from the Orange Book.

The plain language of 21 U.S.C. § 355(j)(5)(B)(iv)(2002) establishes that KV is entitled to 180 days of marketing exclusivity for its generic drug product based on KV's paragraph IV certification of the '714 patent. KV's exclusivity should not be extinguished by FDA's erroneous delisting of the patent from the Orange Book. FDA's delisting was in error because the patent was delisted after KV filed its paragraph IV certification, after AstraZeneca did not file a corresponding infringement action, and after KV qualified for exclusivity. FDA's delisting was also in error because the '714 patent was delisted after it had been subject to a

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lawsuit. *See* 21 C.F.R. § 314.94(a)(12)(viii)(B). The plain language of the statute and court precedent compel FDA to preserve KV's exclusivity by relisting the '714 patent.

In view of the plain language of section 355(j)(5)(B)(iv), court precedent compelling FDA to preserve KV's exclusivity by relisting the '714 patent, and regulations prohibiting removal of the '714 patent from the Orange Book, KV petitions FDA to relist the '714 patent for Toprol-XL, maintain KV's exclusivity against subsequently filed ANDA applications, and confirm KV's right to its forthcoming exclusivity period.

STATEMENT OF GROUNDS

I. Background

In January 2003, KV submitted an Abbreviated New Drug Application (ANDA No. 76-640) for 200 mg metoprolol succinate tablets. KV's metoprolol succinate is a generic version of Toprol-XL, an approved drug of AstraZeneca LP. In July 2003, KV amended its ANDA No. 76-640 to also include 100 mg metoprolol succinate tablets.

As part of its ANDA, KV submitted paragraph IV certifications on all five patents listed by FDA as covering 100 mg and 200 mg Toprol-XL tablets in the then-current Orange Book. KV's paragraph IV certifications asserted that KV's proposed product did not infringe any of the listed patents and/or that the listed patents were invalid. The listed patents at that time included the '714 patent as well as U.S. Patent 4,927,640 (the '640 patent); U.S. Patent 4,957,745 (the '745 patent); U.S. Patent 5,001,161 (the '161 patent); and U.S. Patent 5,081,154 (the '154 patent). In fulfillment of its statutory requirement, KV notified the NDA holder (AstraZeneca LP) and patent owner (Aktiebolaget Hassle) of KV's paragraph IV certifications. KV believes it was the first applicant to file a substantially complete ANDA application on 100 mg and 200 mg metoprolol succinate tablets and was the first to submit paragraph IV certifications on each of the five listed patents.

AstraZeneca brought infringement actions against KV based on KV's certification of the '154 patent, the '161 patent and the '745 patent for 100 mg and 200 mg metoprolol

succinate.[1] AstraZeneca did not bring infringement actions based on KV's certification of the '714 patent or the '640 patent—presumably, having been satisfied that KV successfully designed around the remaining listed patents and that no infringement action legitimately could be brought on them.

Nevertheless, to establish KV's freedom to operate under the '714 patent and the '640 patent, KV filed declaratory judgment counterclaims on both remaining listed patents. KV filed its declaratory judgment counterclaims on 200 mg tablets on May 27, 2003. On August 11, 2003, the district court entered a consent order dismissing with prejudice KV's counterclaims on 200 mg tablets in view of AstraZeneca's covenant-not-to-sue on the '714 and '640 patents. KV filed declaratory judgment counterclaims on 100 mg tablets on September 11, 2003. On October 27, 2003, the district court likewise entered a consent order dismissing with prejudice KV's counterclaims on 100 mg tablets in view of AstraZeneca's covenant-not-to-sue on the '714 and '640 patents. AstraZeneca's covenants-not-to-sue again demonstrate that KV's extensive efforts to design around the'714 patent and the '640 patent were apparently successful.

It is KV's understanding that well after KV notified AstraZeneca of its respective paragraph IV certifications on the '714 patent and subsequent to KV's filing of respective declaratory judgment counterclaims on the '714 patent, FDA removed ("delisted") the '714 patent from the Orange Book—presumably at the request of AstraZeneca.[2] KV respectfully submits FDA's delisting was erroneous in view of 21 U.S.C. § 355(j)(5)(B)(iv) and 21 C.F.R. § 314.94(a)(12)(viii)(B) because the delisting occurred after KV's paragraph IV certifications and after the filing of KV's declaratory judgment actions.

KV is aware of no reason why the '714 patent should rightfully have been delisted by FDA in the circumstances of this matter, or that AstraZeneca initially listed the '714 patent,

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[1] On May 6, 2003, AstraZeneca brought Civil Action No. 03-0592 in the District Court for the Eastern District of Missouri based on KV's ANDA with paragraph IV certifications on 200 mg metoprolol succinate. On August 22, 2003, AstraZeneca brought Civil Action No. 03-1169 in the same court based on KV's then-amended ANDA with paragraph IV certifications on 100 mg metoprolol succinate. On October 6, 2003 the actions were consolidated under Civil Action No. 03-0592.

[2] The '640 patent was not removed from the Orange Book.

which at least facially could apply to Toprol-XL, in error. *See* 21 C.F.R. § 314.53(b) and (f). AstraZeneca identified the '714 patent as covering Toprol-XL. KV subsequently devoted considerable resources to designing a generic drug product that does not infringe a valid claim of any patent then listed in the Orange Book for Toprol-XL. Subsequent to KV's paragraph IV certification, AstraZeneca chose not to bring an infringement action against KV on the '714 patent. Further, KV's ensuing declaratory judgment counterclaim to establish noninfringement was dismissed by stipulation. These facts demonstrate that KV's extensive efforts to design around the '714 patent were successful. KV's success in designing around the patent resulted in KV's statutory and regulatory eligibility for 180 days of marketing exclusivity for 100 mg and 200 mg metoprolol succinate tablets. *See* 21 U.S.C. § 355(j)(5)(B)(iv); 21 C.F.R. §§ 314.94(a)(12)(viii)(B) and 314.107(c).

II. The plain language of 21 U.S.C. § 355(j)(5)(B)(iv) provides KV with 180 Days of marketing exclusivity

Under the plain language of 21 U.S.C. § 355(j)(5)(B)(iv)(2002),[3] KV is entitled to 180 days of marketing exclusivity for 100 mg and 200 mg metoprolol succinate tablets based on the '714 patent because KV is apparently the first ANDA applicant on those drug products to file a paragraph IV certification on the '714 patent. That period has not been triggered because KV has not commercially marketed its product (and could not, since the ANDA has not yet been approved) and there has not been a court decision holding the '714 patent invalid or not infringed.[4] *See Ranbaxy Labs. Ltd. v. Leavitt*, No. 05-1838, 2006 U.S. Dist. LEXIS 24612, *28-

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[3] Because a paragraph IV certification was filed on metoprolol succinate 100 mg and 200 mg tablets before December 8, 2003, amendments to 21 U.S.C. § 355(j) found in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), Pub. L. No. 108-173 Sta. 2066 (Dec. 8, 2003), do not apply to the exclusivity determinations discussed herein. *See* MMA § 1102(b)(1).

[4] 21 U.S.C. § 355(j)(5)(B)(iv)(2002) reads:
If the application contains a certification described in subclause (IV) of paragraph (2)(A)(vii) and is for a drug for which a previous application has been submitted under this subsection [containing] such a certification, the application shall be made effective not earlier than one hundred and eighty days after--
(I) the date the Secretary receives notice from the applicant under the previous application of the first commercial marketing of the drug under the previous application, or

29 (D.D.C. May 1, 2006) *appeal pending , No. 06-5154 (D.C. Cir.)* (Attachment A). Absent a triggering court decision, a first-to-file applicant may enjoy its exclusivity so long as the patent is listed for an approved drug or approved method of using the drug and the patent does not expire. *See, e.g., Purepac Pharm. Co. v. Thompson*, 354 F.3d 877, 886-88 (D.C. Cir. 2003) (affirming FDA delisting of patent listed for method of treating epilepsy on drug not actually approved to treat epilepsy because successful ANDA applicant could never have exclusivity on a method that had never been approved); *Dr. Reddy's Labs., Inc. v. Thompson*, 302 F. Supp. 2d 340, 354 (D.N.J. 2003) (certification on patent that expired does not provide exclusivity). The statute bars approval of later-filed applications until the first-to-file applicant enjoys its period of exclusive marketing. *Ranbaxy Labs. Ltd.*, 2006 U.S. Dist. LEXIS 24612 at *26 (finding statutory bar of approval "generally undisputed").

A. The NDA holder must list patents that cover the approved drug and ANDA applicants must rely on that listing

Applicants seeking approval from FDA to market a new drug product must file a New Drug Application (NDA). Applicants seeking approval to market a generic version of an already approved drug product must file an Abbreviated New Drug Application (ANDA). NDA holders approved to market a new drug product must submit information on patents that claim the drug or use of the drug for which the NDA was approved. 21 U.S.C. § 355(b)(1) and (c)(2); 21 C.F.R. § 314.53. This information is published by FDA in the Orange Book. 21 U.S.C. § 355(j)(7)(A)(iii).

Applicants for ANDAs are required to make certifications as to each patent listed in the Orange Book for a relevant drug product, or to state that a listed patent does not cover a use for which the ANDA applicant is seeking approval. 21 U.S.C. § 355(j)(2)(A)(vii-viii). Certifications must be made despite disagreement about the accuracy or relevance of the listed patent information. 21 C.F.R. §§ 314.53(f) and 314.94(a)(12)(vii). As such, ANDA applicants must rely on the NDA holder's good faith listing of patents when ANDA applicants set out to design a drug product that does not infringe a valid claim of any of the NDA holder's listed

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(II) the date of a decision of a court in an action described in clause (iii) holding the patent which is the subject of the certification to be invalid or not infringed[.]

patents.

B. First-to-file paragraph IV applicants that are not sued are eligible for exclusivity

An ANDA applicant that is first to file a paragraph IV certification asserting that a particular listed patent is invalid or not infringed by the applicant's ANDA is eligible for 180 days of marketing exclusivity for a generic version of that drug. Exclusivity begins on the day the applicant first commercially markets the drug or on the day a court finds the listed patent invalid or not infringed. *See* 21 U.S.C. § 355(j)(5)(B)(iv).[5]

C. KV is eligible for exclusivity because it was first to file and no court decision has been rendered

AstraZeneca listed the '714 patent in the Orange Book for Toprol-XL. KV filed an ANDA application seeking to market a generic version of Toprol-XL (100 mg and 200 mg) and was apparently the first-filer on these drug products. Along with its ANDA, KV filed a paragraph IV certification on the '714 patent. AstraZeneca subsequently did not bring an infringement action on the '714 patent. Therefore, to establish its freedom to operate, KV brought declaratory judgment actions on the '714 patent. The declaratory judgment actions were later dismissed based on AstraZeneca's covenants-not-to-sue.

The apparent result of AstraZeneca's decision not to sue KV and the parties' joint decision to stipulate to dismissal of KV's declaratory judgment counterclaims is that no court decision finding the '714 patent invalid or not infringed will trigger KV's exclusivity under 21 U.S.C. § 355(j)(5)(B)(iv). *See Apotex, Inc. v. Food & Drug Admin.*, 449 F.3d 1249, 1251, 1253 (D.C. Cir. 2006) (affirming FDA determination that a "stipulation and order" is insufficient to trigger 180-day exclusivity and refusing to enjoin FDA from providing exclusivity to first-to-file generic applicant). The plain language of 21 U.S.C. § 355(j)(5)(B)(iv), therefore, provides KV

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[5] A "court decision" for purposes of beginning an applicant's 180 days of marketing exclusivity does not include a stipulated dismissal of a declaratory judgment action for lack of subject matter jurisdiction such as the dismissal of KV's declaratory judgment counterclaim discussed herein. *See Apotex, Inc. v. Food & Drug Admin.*, 449 F.3d 1249, 1251, 1253 (D.C. Cir. 2006) (affirming a district court denial of a preliminary injunction against an FDA determination that a stipulated dismissal of a declaratory judgment action based on a promise not to sue did not trigger exclusivity).

with 180 days of marketing exclusivity beginning at KV's notification of the first commercial marketing of its drug products.

III. The '714 patent could not be delisted after AstraZeneca chose not to sue KV on the '714 patent

Despite KV's statutory eligibility for exclusivity based on the '714 patent, FDA apparently delisted the '714 patent in 2003 and may have concluded erroneously that KV is not entitled to 180 days of marketing exclusivity under the '714 patent. Despite FDA's erroneous delisting of the '714 patent, KV continues to be entitled to 180 days of marketing exclusivity in view of the District Court for the District of Columbia's recent decision in *Ranbaxy Labs. Ltd. v. Leavitt*. There, the district court established that FDA may not delist a patent after an ANDA applicant has already submitted a paragraph IV certification and become eligible for 180-day exclusivity based on the NDA holder's decision not to sue the ANDA applicant. *See* 2006 U.S. Dist. LEXIS 24612 at *28; *See* June 22, 2006 FDA Letter at 1-2, Docket Nos. 2005P-0008/CP1, 2005P-0046/CP1, and 2006P-0258/CP1 (June 22 FDA Letter) (Attachment B) (acknowledging court determination that it was impermissible for "FDA to remove [listed patents] at the request of [the NDA holder] when [ANDA] applicants had already submitted certification to those patents . . . and thus had become eligible for 180-day exclusivity . . . ."). The holding of that case directly controls the current matter and mandates that this Petition be granted.

In *Ranbaxy*, the district court enjoined FDA's erroneous delisting of patents for which ANDA applicants were first to file paragraph IV certifications but had not been sued by the NDA holder. The district court held that FDA could not treat first-to-file applicants that had not been sued by the NDA holder differently from first-to-file applicants that had been sued by the NDA holder because both types of applicants had been equally provided exclusivity under the statutory scheme. *See Ranbaxy Labs. Ltd.*, 2006 U.S. Dist. LEXIS 24612 at *28 ("If [the NDA holder] had sued plaintiffs because of their paragraph IV certifications, plaintiffs would have been in danger of losing their right to the 180-day exclusivity period upon final FDA approval only if the patents were found to be enforceable or infringed. In this case, however the FDA delisted the patents from the Orange Book, disregarding the plaintiffs' success in avoiding suit. That disparate treatment here contravened the plain and undisputed intent of Congress.")

(emphasis added).

A. Delisting is improper subsequent to a Paragraph IV certification to which exclusivity attaches

The court in *Ranbaxy* considered whether two ANDA applicants first to file paragraph IV certifications on particular dosages of simvastatin were entitled to exclusivity despite FDA's delisting of the paragraph-IV-certified patents. *See id.* at *13-16. The applicants had both filed paragraph IV certifications on two listed patents and paragraph III certifications on one listed patent that was soon to expire.[6] The NDA holder did not bring an infringement action against the applicants based on their paragraph IV certifications. *Id.* at *15. As such, the ANDA applicants were at that time entitled to exclusivity on their respective dosage forms of simvastatin. *See* 21 U.S.C. § 355(j)(5)(B)(iv); 21 C.F.R. § 314.107(c). Their respective applications, however, would not be given final approval until the paragraph-III-certified patent expired. *See Ranbaxy Labs. Ltd.*, 2006 U.S. Dist. LEXIS 24612 at *14.

Prior to expiration of the paragraph-III-certified patent, the NDA holder requested FDA delist the ANDA applicants' paragraph-IV-certified patents. *Id.* at *15-16. Under FDA's understanding of its regulations at that time, delisting of the patents would effectively eliminate the ANDA applicants' respective exclusivities.[7]

Nevertheless, at the request of the NDA holder, FDA delisted the paragraph-IV-certified patents and, in the mind of FDA, eliminated any exclusivity available on those patents. *See id.* at *16. The ANDA applicants filed respective citizen petitions to relist the patents—which FDA subsequently denied. *See id.* at *17. The ANDA applicants then brought actions to enjoin FDA to relist the patents and provide the exclusivity to which the applicants were entitled.

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[6] Paragraph III certifications seek approval only after expiration of the certified patent. *See* 21 U.S.C. § 355(j)(2)(A)(vii)(III).

[7] While the FDCA statute provides no express mechanism for removing a patent formerly listed in the Orange Book, FDA has interpreted the statute to afford the agency a ministerial role in listing and delisting patents. *See Ranbaxy Labs. Ltd.*, 2006 U.S. Dist. LEXIS 24612 at *10. If a listed patent is removed from the Orange Book, FDA has interpreted its regulations to require paragraph IV certifications to be amended to accurately reflect that the patent is no longer listed for the relevant drug product. *See* 21 C.F.R. § 314.94(a)(12)(viii). Applications that do not contain a paragraph IV listing are not subject to a delay in approval under 21 U.S.C. § 355(j)(5)(B)(iv) and, therefore, extinguish the first-to-file applicant's exclusivity. *See id.*

Id. at *20. The district court agreed with the applicants that FDA's delisting of the patents was erroneous and remanded to FDA to relist the patents and provide the applicants with their rightful exclusivity. *See id.* at *28-30.

B. Improper to distinguish between paragraph IV certifications resulting in suit and paragraph IV certifications not resulting in suit

The court held that FDA could not delist paragraph-IV-certified patents upon which applicants had not been sued (thereby depriving applicants of exclusivity) while refusing to delist paragraph-IV-certified patents upon which applicants had been sued (thereby preserving exclusivity). *See Ranbaxy Labs. Ltd.*, 2006 U.S. Dist. LEXIS 24612 at *28. The statute clearly provides equal mechanisms providing exclusivity to those that are sued and those that are not sued. *See id.* at *26 ("[I]t is undisputed that Congress did not restrict this reward to only those ANDA holders who have been sued for infringement, or successfully defended such a suit, just as Congress did not restrict the reward to those ANDA holders who avoided suit by persuasion or effectively designing around the patent or otherwise."). As such, it was improper for FDA to favor "one of two equal statutory provisions over the other." *Id.* at *28.

The court found FDA's interpretation of its regulations allowing delisting of patents in one circumstance and not the other contravened "the plain and undisputed intent of Congress" because FDA's disparate delisting practice "effectively eliminates Congress's 'first commercial marketing' trigger, in violation of the clear command of Congress." *Ranbaxy Labs. Ltd.*, 2006 U.S. Dist. LEXIS 24612 at *28; *see also* 21 U.S.C. § 355(j)(5)(B)(iv) ("[T]he application shall be made effective not earlier than one hundred and eighty days after . . . the date the Secretary receives notice from the applicant under the previous application of the first commercial marketing of the drug under the previous application . . . .").

FDA should have provided exclusivity to the first-to-file applicants (whether sued or not) because Congress intended to reward both generic manufacturers that incur substantial risk and expense in defending infringement suits as well as generic manufacturers that incur substantial risk and expense in designing around patents. *Ranbaxy Labs. Ltd.*, 2006 U.S. Dist. LEXIS 24612 at *25-26. The citizen petitions to relist the patents should have been granted. *See id.* at *30.

C. FDA relisted the patents and confirmed exclusivities

In response to the district court's decision, FDA relisted the patents. June 22 FDA Letter at 2. In notifying interested parties of the patent relistings, FDA explained that the issue before the court was "whether it was permissible for FDA to remove [listed patents from the Orange Book], at the request of [the NDA holder] when [ANDA] applicants had already submitted certification to those patents . . . and thus had become eligible for 180-day exclusivity under section 505(j)(5)(B)(iv)." *Id.* at 1. FDA acknowledged that the court's order required "the patents be relisted, and that eligibility for 180-day exclusivity be determined based on the paragraph IV certification made to the patents." *Id.* at 2. As a result, absent an appellate court ruling to the contrary, the patents will remain listed until the ANDA applicants' respective periods of exclusivity have been triggered and have run. *Id.*

D. The '714 patent should likewise be relisted and KV's exclusivity confirmed

The '714 patent should likewise be relisted by FDA and FDA should confirm KV's entitlement to exclusivity based on the '714 patent. KV filed its ANDA application with paragraph IV certifications on the '714 patent well before the '714 patent was delisted. When KV filed its paragraph IV certifications and AstraZeneca did not subsequently file an infringement action, KV was entitled to 180 days of marketing exclusivity triggered either by a court decision or KV's first commercial marketing. KV's marketing exclusivity should not be eliminated or compromised simply because AstraZeneca did not sue KV on the '714 patent. Such an action would contravene "the plain and undisputed intent of Congress" and "effectively eliminate[] Congress's 'first commercial marketing' trigger, in violation of the clear command of Congress." *Ranbaxy Labs. Ltd.*, 2006 U.S. Dist. LEXIS 24612 at *28. Instead, the '714 patent should be relisted and KV should be provided the exclusivity to which it is entitled. *See id.* at *30.

IV. The '714 patent was erroneously delisted after KV filed its declaratory judgment counterclaim

As discussed above, prior to the district court's decision in *Ranbaxy Laboratories, Ltd.*, FDA's erroneous delisting of the'714 patent would have undermined KV's exclusivity. *See* 2006 U.S. Dist. LEXIS 24612 at *18-19. Nevertheless, even in the absence of the district court's

holding, FDA's own regulations expressly prohibited the delisting of the '714 patent and FDA should relist the patent until KV's exclusivity period has expired. *See Ranbaxy Labs. Ltd.*, 2006 U.S. Dist. LEXIS 24612 at *30 (finding FDA denial of citizen petitions requesting relisting of erroneously delisted patents contrary to the clear intent of Congress). FDA regulations expressly prohibited the delisting of the '714 patent because the patent was delisted after it was subject to a declaratory judgment action in an ANDA litigation. *See* 21 C.F.R. §§ 314.94(a)(12)(viii)(B) and 314.107(c).

A. Patents that are subject to declaratory judgment actions may not be delisted

Section 314.94(a)(12)(viii)(B) of FDA's regulations establishes that "[a] patent that is subject of a lawsuit under § 314.107(c) shall not be removed from the [Orange Book] until FDA determines . . . that no delay in effective dates of approval is required under that section as a result of the lawsuit . . . ." *Id.* (emphasis added). FDA has at least once asserted that the lawsuit referenced in § 314.107(c) may include either an infringement action or a declaratory judgment action (such as the declaratory judgment action brought by KV on the '714 patent). *See* Brief For Appellants (FDA) at 32, *Ranbaxy Labs. Ltd. v. Leavitt*, No. 06-5154 (D.C. Cir. June 21, 2006) (relevant portions at Attachment C) ("Accordingly, when an NDA holder . . . delists a patent in the absence of patent infringement or declaratory judgment litigation (litigation referred to in 21 C.F.R. § 314.107(c)), ANDAs with paragraph IV certifications must be amended . . .") (emphasis added).[8] While FDA later reconsidered its own clear and unambiguous reading of these regulations, a review of the plain language of § 314.94(a)(12)(viii)(B) and § 314.107(c) makes apparent that FDA's position in the above-cited brief is the proper reading of the intersection between these two regulations.

[8] FDA later withdrew this position in the *Ranbaxy* appeal. *See* Reply Brief For The Appellants (FDA) at 35, *Ranbaxy Labs. Ltd. v. Leavitt*, No. 06-5154 (D.C. Cir. July 27, 2006) (relevant portions at Attachment D) ("Our reference to declaratory judgment actions on page 32 of our opening brief was inadvertent."). Nevertheless, a plain reading of the regulation (and its related statute) supports FDA's position in the original brief and FDA should embrace its original (and proper) appeal position.

1. A "court decision" under § 314.107(c) may arise from a declaratory judgment action

Section 314.94(a)(12)(viii)(B) expressly states a patent will not be delisted from the Orange Book if the patent is subject to a "lawsuit" under § 314.107(c) (unless no exclusivity is presently attached to the patent). The only reference in § 314.107(c) to any kind of "lawsuit" is a reference to a "decision of the court" that triggers exclusivity. *See* § 314.107(c)(ii) ("The date of a decision of the court holding the relevant patent invalid, unenforceable, or not infringed.") (emphasis added).[9]

FDA interprets exclusivity under § 314.107(c) to be triggered by a "decision of the court" in either an infringement action or a declaratory judgment action (in ANDA litigations) so long as the action results in an actual decision of invalidity, noninfringement or unenforceability that is clear on the face of the court's decision.[10] *See Apotex, Inc.*, 449 F.3d at 1251. The Court of Appeals for the D.C. Circuit has affirmed FDA's interpretation. *See id.* at 1253. A consistent interpretation of the "lawsuit" language found in § 314.107(c), therefore, would require that the "decision of a court" in § 314.107(c) be interpreted to encompass both infringement actions and declaratory judgment actions—since both are capable of producing a triggering "court decision." Likewise, a consistent interpretation of section 314.94(a)(12)(viii) prohibits the delisting of the '714 patent after it is subject to an infringement action or a declaratory judgment action.

Nevertheless, FDA has at times interpreted the "lawsuit under § 314.107(c)" to be solely a lawsuit initiated by an NDA holder or patent owner within forty-five days of notice of a paragraph IV certification rather than any ANDA litigation that may result in a "decision of a court." *See, e.g., Ranbaxy Labs. Ltd.*, 2006 U.S. Dist. LEXIS 24612 at *12 n.5 ("The FDA has interpreted the reference in 21 C.F.R. § 314.94(a)(12)(viii)(B) to a 'lawsuit under § 314.107(c)'

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[9] 21 C.F.R. § 314.107(c) interprets the exclusivity triggering language of 21 U.S.C. § 355(j)(5)(B)(iv).

[10] FDA has asserted that a "decision of the court" under § 314.107(c)(ii) is a decision with an "actual holding evidenced by language on the face of the court's decision showing that the determination of invalidity, noninfringement, or unenforceability has been made by the court." *Apotex, Inc.*, 449 F.3d at 1251 *citing* FDA Letter from Gary Buehler, Dir., Office of Generic Drugs, to Tammy McIntire, Apotex Corp. at 2 (Apr. 11, 2006) (Attachment E).

to refer to a lawsuit brought against an ANDA applicant within the first 45 days after the patent owner and the NDA holder received notice.") A plain reading of FDA's definition of "a court decision," however, renders FDA's interpretation erroneous because the only reference to litigation in § 314.107(c) encompasses any ANDA litigation (whether an infringement action or a declaratory judgment action) where a court may render a decision of invalidity, noninfringement or unenforceability. *See Apotex, Inc.*, 449 F.3d at 1251; 21 C.F.R. § 314.107(c). Further, the regulation in its present form makes no mention of a lawsuit that is initiated by an NDA holder or a patent owner within forty-five days. *See* 21 C.F.R. § 314.107(c)(2006); *Ranbaxy Labs. Ltd.*, 2006 U.S. Dist. LEXIS 24612 at *12 n.5 ("This definition of litigation appeared in the version of § 314.107(c) before it was amended to remove the 'successful defense' requirement."). It would be improper for FDA to restrict "a lawsuit under § 314.107(c)" to a specific kind of lawsuit not even mentioned in the regulation.

2. An interpretation of "lawsuit" based on the 1994 version of § 314.107(c) would be erroneous.

FDA has argued, however, that its interpretation of § 314.107(c) is based on the regulation as it existed prior to amendments in 1998—and based on language that was expressly repealed in 1998. *See* 63 FR 59710, Nov. 5, 1998; 21 C.F.R. § 314.107(c) (2000); *Ranbaxy Labs. Ltd.*, 2006 U.S. Dist. LEXIS 24612 at *12 n.5. An interpretation based on language that has been expressly repealed from a regulation is simply not supportable and should be rejected by FDA as an improper and unreasonable interpretation.

The repeal of the relevant language in 1998 was necessitated by a court decision finding the regulation contrary to statute. *See Mova Pharm. Corp. v. Shalala*, 140 F.3d 1060, 1076 (D.C. Cir. 1998). The regulation was contrary to statute because it required an ANDA applicant to successfully defend a patent infringement action brought by an NDA holder or patent owner within forty-five days of notification of a paragraph IV certification before the applicant could be eligible for exclusivity. *Mova Pharm. Corp.*, 140 F.3d at 1076 ("We find that the FDA exceeded its statutory authority in imposing the successful-defense requirement as a prerequisite to the invocation of the 180-day exclusivity . . . ."). The statute, on the other hand, provides "first applicants the 180-day exclusivity period even if they have not been sued."

Purepac Pharm. Co. v. Freidman, 162 F.3d 1201, 1205 (D.C. Cir. 1998) (emphasis added); *Mova Pharm. Corp.*, 140 F.3d at 1076. After the court decision in *Mova Pharmaceuticals Corp.*, FDA amended the regulation to remove the "successful defense" requirement along with any mention of litigation brought within forty-five days of paragraph IV notification. *See* 63 FR 59710, Nov. 5, 1998.

The current version of § 314.107(c), therefore, has no reference to litigation initiated within forty-five days. *See* 21 C.F.R. § 314.107(c) (2006). In fact, as discussed above, the current version's only reference to litigation is to a "court decision." FDA's interpretation of a "court decision" in § 314.107(c) as set forth in *Apotex, Inc*, (encompassing both infringement actions and declaratory judgment actions) cannot be reconciled with FDA's assertion that patents may be delisted under § 314.94(a)(12)(viii) only when litigation is initiated within forty-five days of notification of a paragraph IV certification. Instead, FDA's opposite assertion that patents may only be delisted "in the absence of patent infringement or declaratory judgment litigation" is the proper and reasonable interpretation of the regulations and should be applied to the '714 patent. *See* Brief For Appellants (FDA) at 32, *Ranbaxy Labs. Ltd. v. Leavitt*, No. 06-5154 (D.C. Cir. June 21, 2006).

3. The statute does not differentiate between infringement actions and declaratory judgment actions

FDA's position can likewise not be reconciled with statute. In describing lawsuits brought following a paragraph IV certification, Congress expressly contemplated that an applicant might file a declaratory judgment action if the NDA holder or patent owner did not bring an infringement action within forty-five days. *See* 21 U.S.C. § 355(j)(5)(B)(iii) ("Any action brought under [the declaratory judgment statute] shall be brought in the judicial district where the defendant has its principal place of business . . . ."). Attempts by FDA to distinguish between types of lawsuits that are both clearly authorized by Congress and both clearly trigger exclusivity through a "court decision" demonstrate a failure of the interpretation to find statutory authority. Because the plain language of the regulations demonstrates that the "court decision" of § 314.107(c) encompasses declaratory judgment actions and because the statute makes no distinction (as to exclusivity) between declaratory judgment actions and infringement actions, a

proper interpretation of § 314.94(a)(12)(viii) requires that patents upon which a declaratory judgment action has been initiated (by an ANDA applicant) not be removed from the Orange Book until the applicant's exclusivity has expires. *See* 21 C.F.R. § 314.94(a)(12)(viii).

B. KV is entitled to exclusivity because § 314.94(a)(12)(viii) prohibits delisting of the '714 patent

KV brought its counterclaim for a declaratory judgment of noninfringement by its 200 mg tablets on May 27, 2003. KV brought its counterclaim for a declaratory judgment of noninfringement by its 100 mg tablets on September 11, 2003. Because FDA apparently delisted the '714 patent after KV brought its respective declaratory judgment actions, the delisting of the '714 patent was in error. It is FDA's practice, upon learning of an erroneously delisted patent, to relist the patent and to determine eligibility for exclusivity based on paragraph IV certifications made to that patent. *See* June 22 FDA Letter at 2 ("The court found that FDA's delisting . . . was inconsistent with congressional intent regarding eligibility for exclusivity. The Agency believes that the order effectively requires that the patents be relisted, and that eligibility for 180-day exclusivity be determined based on the paragraph IV certifications made to the patents."). As such, the erroneously delisted '714 patent should be relisted and KV's exclusivity should be maintained. *See Ranbaxy Labs. Ltd.*, 2006 U.S. Dist. LEXIS 24612 at *30; *see also Purepac Pharm. Co.*, 162 F.3d at 1205 (affirming FDA's action withholding final approval of an ANDA application pending first-to-file ANDA applicants first commercial marketing of the generic drug product).

V. Conclusion

KV has invested considerable time and resources developing a formulation for its metoprolol succinate 100 mg and 200 mg tablets. In doing so, it designed around the '714 patent. In view of KV's successful design of a noninfringing product, AstraZeneca chose not to sue KV directly and additionally stipulated to dismissal of KV's declaratory judgment counterclaims. Subsequent to KV's successful paragraph IV certifications and declaratory judgment actions, however, AstraZeneca presumably requested FDA delist the patent. FDA apparently agreed and erroneously delisted the patent.

A patent upon which a paragraph IV certification has been filed and by which an ANDA applicant has become eligible for 180 days of exclusivity may not be delisted. *See Ranbaxy Labs. Ltd.*, 2006 U.S. Dist. LEXIS 24612 at *28; June 22 FDA Letter at 1-2. Likewise, a patent upon which a declaratory judgment action has been initiated may not be delisted. *See* 21 C.F.R. § 314.94(a)(12)(viii)(B). Had AstraZeneca sued KV, FDA would not have delisted the '714 patent at AstraZeneca's request. The fact that AstraZeneca did not sue KV on the '714 patent should not influence KV's entitlement to exclusivity. *See Ranbaxy Labs. Ltd.*, 2006 U.S. Dist. LEXIS 24612 at *28.

By filing a paragraph IV certification, KV has exposed itself to costly patent litigation and has availed itself of the 180-day marketing exclusivity provided in 21 U.S.C. § 355(j)(5)(B)(iv). FDA should not deprive KV of the 180-day exclusivity to which it is entitled under the plain language of the statute by delisting the patent in a manner that extinguishes KV's exclusivity before that exclusivity has run. FDA's erroneous delisting of the '714 patent does not impair the agency's ability to relist the patent for the period necessary to recognize KV's exclusivity. As such, KV petitions FDA to (1) relist the '714 patent, (2) refrain from approval of all ANDAs for metoprolol succinate 100 mg and 200 mg tablets filed subsequent to KV's ANDA, and (3) confirm KV's continuing eligibility for exclusivity.

ENVIRONMENTAL IMPACT

The relief requested by this petition would result in the recognition of a 180-day period of exclusivity for an ANDA application. Because the grant of the petition would not have an effect on the environment, no environmental assessment is required. 21 C.F.R. § 25.31(a) (2004).

ECONOMIC IMPACT

Information on the economic impact of the action requested by this petition will be submitted if requested by the Commissioner.

CERTIFICATION

The undersigned certifies that, to the best of his knowledge and belief, this petition includes all information and views on which the petition relies, and includes representative data and information known to him that are unfavorable to the petition.

Respectfully submitted,

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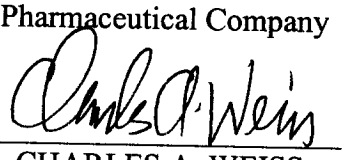
By: 
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