2014-1282, -1291

United States Court of Appeals for the Federal Circuit

APOTEX INC.,

Plaintiff-Appellant,

v.

DAIICHI SANKYO, INC., AND DAIICHI SANKYO CO., LTD.,

Defendants-Appellees,

and

MYLAN PHARMACEUTICALS INC.,

Movant-Cross-Appellant.

Appeals from the United States District Court for the Northern District of Illinois in Case No. 1:12-cv-09295, Judge Sharon Johnson Coleman

RESPONSE AND REPLY BRIEF FOR PLAINTIFF-APPELLANT APOTEX INC.

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September 29, 2014

CERTIFICATE OF INTEREST

Pursuant to FED. CIR. R. 47.4, counsel for Appellant Apotex, Inc. certifies the following:

1. The full name of every party represented by me is:

Apotex Inc.

2. The name of the real party in interest (if the party named in the caption is not the real party in interest) represented by me is:

The party named in the caption is the real party in interest.

3. All parent corporations and any publicly held companies that own 10% or more of the stock of the party represented by me are:

Apotex Pharmaceuticals, Inc. is the parent company of Apotex Inc.

4. The names of all law firms and the partners or associates that appeared for the party now represented by me in the trial court or agency or are expected to appear in this court are:

Steven E. Feldman, James P. White, and Sherry L. Rollo, all of Husch Blackwell LLP Chicago, Illinois.

/s/ Steven E. Feldman
an Attorney for Plaintiff-Appellant
Apotex Inc.

September 29, 2014
Date

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I. INTRODUCTION.

This appeal is about whether the Hatch-Waxman Act, which was enacted to promote generic competition, allows a subsequent ANDA filer, such as Apotex here, to challenge a patent that regardless of its disclaimed status retains its exclusionary effect absent a court decision that it is not infringed. As explained in our opening brief and further explained below, the MMA Amendments to the Hatch-Waxman Act and the Patent Statute itself expressly permit such declaratory judgment actions to obtain patent certainty.

In attempting to support the district court's dismissal for lack of subject matter jurisdiction, Daiichi tries to portray its patent as irrelevant and itself as an innocent bystander to these proceedings, arguing that its disclaimer of the '703 patent renders that patent non-existent and deprives the Court of subject matter jurisdiction to declare it unenforceable and not infringed. But if the '703 patent really never existed, it would not still be listed in the Orange Book, Mylan would not be eligible for any market exclusivity, and Apotex would have no need for the declaratory judgment that it seeks here. Because Daiichi did list the '703 patent in the Orange Book and because it remains listed there, Apotex requires a declaratory judgment that the patent is not infringed or invalid before FDA will

grant it final marketing approval to enable Apotex to compete on the first day that generic products are eligible to come to market.

Such a judgment will eliminate the continued exclusionary impact of the '703 patent and make it truly as if the '703 patent never existed. However, that is the last thing that Daiichi wants, because a judgment that the '703 patent is invalid or not infringed would subject it to not one, but two generic competitors when generic competition begins. How ironic it is for Daiichi to argue that its disclaiming of the patent should be why a court should not have jurisdiction to eliminate that disclaimed patent from inhibiting competition.

Accordingly, the Court should reverse the district court's dismissal of Apotex's complaint for lack of subject matter jurisdiction and put the final stake in the heart of a patent ("the '703 patent") that everyone agrees is no longer enforceable or infringed, but nevertheless continues to exclude competition in the market. The facts alleged demonstrate "there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment." *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 127 (2007). (citations omitted) (internal quotation marks omitted).

II. DAIICHI'S DISCLAIMER OF THE '703 PATENT DOES NOT NEGATE JURISDICTION.

The District Court and the opposing briefs in this action assert that there cannot be a cognizable controversy about infringement of a disclaimed patent. As stated in our opening brief (pp.18-20) these arguments focus solely on the status of the patent in the Patent Office and ignore the patent's continuing exclusionary effect on the market. Here, the controversy is that Daiichi's listing of the '703 patent in the Orange Book creates a barrier to regulatory approval of the Apotex ANDA Product and, therefore, can delay the competition with Daiichi that otherwise would result from market entry of that product. "It is well established that the creation of such barriers to compete [Forest's listing of the '941 patent-in-suit in the Orange Book] satisfies the causation requirement of Article III standing." *Caraco Pharm. Labs. v. Forest Labs., Inc.*, 527 F.3d 1278, 1293 (Fed. Cir. 2008)

The Daiichi's '703 patent, which is the only basis for any Mylan exclusivity period, remains listed in the Orange Book notwithstanding the disclaimer and its potential to exclude Apotex from the market remains. However, the noninfringement judgment sought in this action will remove that barrier. As the court stated in *Caraco*, "[t]his controversy is not premised only upon a threat of an infringement suit. A controversy also exists because Forest's

actions effectively prevent the FDA from approving Caraco's ANDA and thus exclude Caraco from the drug market." *Id.* at 1297.

A. DAIICHI'S DISCLAIMER IS ANALOGOUS TO A COVENANT NOT TO SUE, WHICH THIS COURT HAS REPEATEDLY FOUND TO BE INSUFFICIENT TO DEPRIVE THE COURT OF JURISDICTION IN THE HATCH-WAXMAN DECLARATORY JUDGMENT CONTEXT.

In the context of a Hatch-Waxman action, a disclaimer is no different than a covenant not to sue situation, which this Court has repeatedly held does not eliminate subject matter jurisdiction in the Hatch-Waxman context. Indeed, it made no difference that some of the patents in issue had been disclaimed in *Teva Pharmaceuticals USA, Inc. v. Eisai Co., Ltd.*, 620 F.3d 1341 (Fed. Cir. 2010), *vacated on other grounds, with instructions to dismiss as moot*, 131 S.Ct. 2991 (2011). There, the Court stated,

> Neither the statutory disclaimers nor Eisai's covenant-not-to-sue render this declaratory judgment action moot because the DJ patents remain listed in the Orange Book. *Caraco, 527 F.3d at 1296-97*. Thus, regardless of whether Eisai could bring an infringement action with respect to the DJ patents, under the Hatch-Waxman Act Teva still needs a court judgment of noninfringement or invalidity to obtain FDA approval and enter the market. *Id*.

Eisai, 620 F.3d at 1348 n.3.

The *Eisai* Court thus recognized that in the Hatch-Waxman context, a disclaimer is no different than a covenant not to sue. While it might render moot a typical noninfringement declaratory judgment action, it has no impact on jurisdiction in a declaratory judgment action to obtain patent certainty because it

has no impact on the Orange Book listing that is the source of such an action. *Dey Pharma. LP v. Sunovian Pharm., Inc.*, 677 F.3d 1158, 1164 (Fed. Cir. 2012); *Caraco*, 527 F.3d at 1297.

In attempting to draw a technical distinction between a disclaimer and a covenant not to sue outside the Hatch-Waxman context, Daiichi misses the larger jurisdictional point, which is that because the patent remains Orange Book listed, FDA requires a court judgment of invalidity or noninfringement before it will cease giving the patent exclusionary effect. Absent such a judgment, FDA will continue to give a patent exclusionary effect, because FDA admittedly "lacks expertise in patent matters" and does not engage in substantive review of a patent once listed to determine the propriety of such listing. 68 Fed. Reg. 36676, 36683 (June 18, 2003) ("In addition to the absence of any statutory basis for a substantive agency review of patents, we have long observed that we lack expertise in patent matters. An administrative process for reviewing patents, assessing patent challenges, and de-listing patents would involve patent law issues that are outside both our expertise and our authority."); *Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 132 S.Ct. 1670, 1677 (2012) (discussing 68 Fed. Reg. 36683 and FDA's lack of substantive review of patent listings in the Orange Book).

B. DAIICHI CONTINUES TO OBTAIN A SUBSTANTIAL EXCLUSIONARY BENEFIT FROM THE '703 PATENT DESPITE DISCLAIMING IT AT THE PATENT OFFICE.

In any event, if the '703 patent truly were nonexistent, why would Daiichi be so invested in this action that seeks a declaratory judgment that Apotex's generic product would not infringe a patent that Daiichi has disclaimed? The reason is simple. Daiichi is still benefiting from the ability of its '703 patent to limit generic competition. As Senator Kennedy explained in the legislative history of the MMA, "in recent years both brand-name and generic drug companies have exploited certain aspects of the Hatch-Waxman Act to delay generic competition. The changes to the …Act… will stop these abuses." 149 Cong. Rec. S15882 (Nov. 25, 2003 (remarks of Sen. Kennedy). The declaratory judgment and forfeiture provisions added in the MMA-Amendments were enacted, in part, 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." 149 Cong. Rec. S15746 (Nov. 24, 2003) (statement of Sen. Schumer). Daiichi (p.28) argues that "none of the alleged pre-MMA abuses Apotex describes have occurred here." This is wrong. Here, Daiichi has effectively "parked" Mylan's exclusivity to prevent increased generic competition during the 180-days after the '599 patent expires by refusing to agree to a "settlement order or consent decree" as expressly provided by subpart (BB) of 21

U.S.C. § 355 (j)(5)(C)(i)(I)(bb). This is no different than the situation described by Senator Kennedy during his remarks to Congress on the declaratory judgment provision added by the MMA-Amendments:

> [W]hen generic applicants are blocked by a first generic applicant's 180-day exclusivity, the brand drug company could choose not to sue those other generic applicants so as to delay a final court decision that could trigger the 'failure to market' provision and force the first generic to market.
>
> In… these… circumstances, generic applicants must be able to seek a resolution of disputes involving all patents listed in the Orange Book with respect to the drug immediately upon the expiration of the 45-day period. We believe there can be a case or controversy sufficient for courts to hear these cases merely because the patents at issue have been listed in the FDA Orange Book, and because the statutory scheme of the Hatch-Waxman Act relies on early resolution of patent disputes. The declaratory judgment provisions in this bill are intended to encourage such early resolution of patent disputes.

149 Cong. Rec. S15885 (Nov. 25, 2003) (remarks of Sen. Kennedy).

In response to these points Daiichi argues (p.37) that it had "no duty or obligation to enter a consent decree" and that "Apotex points to no authority that would support jurisdiction for the District Court to enter a consent decree concerning a disclaimed, and thus legally non-existent patent."[1] Here it does not matter whether Daiichi had a duty or obligation to enter into a settlement order or consent decree. The issue is whether Daiichi should continue to receive an exclusionary benefit from a patent that is not infringed. That Daiichi could have remedied the issue and chose not to only serves to highlight the value the disclaimed patent is continuing to provide Daiichi.

III. JANSSEN BY ITS OWN TERMS DOES NOT APPLY TO DECLARATORY JUDGMENT ACTIONS UNDER THE MMA-AMENDMENTS TO THE HATCH-WAXMAN ACT.

The opposition briefs rely predominantly on *Janssen Pharmaceutica, N.V. v. Apotex, Inc.*, 540 F.3d 1353 (Fed. Cir. 2008), to argue that jurisdiction over a subsequent ANDA's declaratory judgment action depends on whether the

[1] In fact, Apotex did provide (pp.18-19) authority supporting jurisdiction of a district court when the patent-at-issue is disclaimed. *See Eisai,* 620 F.3d at 1348n.3, *vacated with instructions to dismiss as moot,* 131 S.Ct. 2991 (2011); *Seattle Children's Hosp. v. Akorn, Inc.*, 2011 WL 6378838, *6 at n.3 (N.D. Ill. Dec.20, 2011); *Bone Care Int'l v. Anchen Pharms*., Case No. 09-CV-00285 (D.I.204) (D. Del. Oct. 31, 2011)(A227-30); *Bone Care Int'l v. Sandoz*, Case No. 09-CV-00524 (D.I.39) (D. Del. Oct. 6, 2011)(reinstating patent declaratory judgment claim on reconsideration of D.I.29 (Sept. 30, 2010).) (A346-52); (A211-20).

subsequent ANDA filer was challenging only the patent that was the basis for the potential 180-day exclusivity of the first ANDA filer, or also was challenging another patent listed by the new drug application ("NDA") filer in the Orange Book.[2] Notably, the district court did not base its jurisdictional ruling on *Janssen*.

In *Janssen*, this Court held that under the pre-MMA version of the Hatch-Waxman Act, a subsequent ANDA filer who had stipulated to the validity of an earlier to expire patent and challenged only the patent responsible for the first filer's exclusivity period to which it was then statutorily entitled, did not present a "cognizable Article III injury," but instead was *a* "result envisioned by the Hatch-Waxman Act" to protect the first ANDA filer's 180-day exclusivity period. 540 F.3d at 1361. Daiichi asserts that this stipulation in *Janssen* is indistinguishable from Apotex's paragraph III certification on the '599 patent and therefore,

[2] As explained in our opening brief (pp. 10-12), Daiichi listed U.S. Patent Nos. 5,616,599 ("the '599 patent") and 6,878,703 ("the '703 patent") in the Orange Book. Mylan's ANDA included Paragraph IV certifications of both patents. Daiichi and Mylan litigated the validity of the '599 patent, Mylan lost, and the Federal Circuit affirmed its validity. *Daiichi Sankyo Co. v. Matrix Labs.*, 619 F.3d 1346 (Fed. Cir. 2010). Because Mylan was unsuccessful in that litigation, the '599 patent is no longer a basis for any potential 180-day exclusivity period. With respect to the '703 patent that is the subject of this action, and in spite of Mylan's grandiose puffery about how it "blazed the path" and "assumed the risk" and "expense" of challenging the '703 patent, Mylan merely included a Paragraph IV certification in its ANDA. Mylan then declined to challenge the '703 patent in court and to remove it from the Orange Book. Daiichi also declined to litigate the '703 patent.

because Apotex is not presently challenging one of the Orange Book listing patents that it cannot obtain a judgment on the patent that it is challenging.[3]

Janssen can be distinguished because the 2003 Medicare Prescription Drug, Improvement, and Modernization Act ("MMA") changed the statutory provisions on which the *Janssen* decision was premised. The MMA changed that part of the statute to provide for forfeiture of that potential period of exclusivity in circumstances such as exist in this action. *Janssen* expressly stated the MMA-Amendments were "inapplicable to this case." *Id.* at 1357.

> Here, a generic pharmaceutical company, Teva Pharmaceuticals USA, Inc., filed the first Paragraph IV ANDA in 2002, before the December 2003 enactment of the MMA. Thus, the MMA amendments governing the commencement and forfeiture of the 180-day exclusivity period are inapplicable to this case.

Id.

The *Janssen* court further recognized that the MMA-Amendments were enacted to remedy issues relating to the 180-day exclusivity when a first Paragraph IV filer failed to launch its product in a timely manner, which is exactly the situation we have here.

[3] In fact a stipulation is different from a paragraph III certification. While a stipulation of validity forecloses the stipulating party's ability to challenge a patent in the future, a paragraph III certification does not. 21 C.F.R. §314.94(a)(12)(viii).

> In 2003, Congress replaced the provisions governing the triggering of the 180-day exclusivity period with a regime in which the 180-day exclusivity period could be ***forfeited for various reasons***, including the failure of the first Paragraph IV ANDA filer to launch its generic product within a certain time period.

Id. at 1357 n.2 (emphasis added) (citations omitted).

Nevertheless, the opposition briefs argue that under *Janssen* there could be jurisdiction in this action only if Apotex also challenged the '599 patent whose validity the Federal Circuit already has affirmed, but not if Apotex only challenged the disclaimed '703 patent, which is the only remaining basis for the potential 180-day exclusivity period. But this makes no sense under the MMA Amendments. Forfeiture is caused when a first filer fails to launch its product within 75-days after a court decision is rendered with respect to "each of the patents with respect to which the first applicant submitted **and lawfully maintained"** a paragraph IV certification that provides the basis for its first filer exclusivity – here, just the '703 patent. 21 U.S.C. § 355(j)(5)(D)(i)(I)(bb)(AA) (emphasis added).

Nowhere does Daiichi or Mylan attempt to reconcile the new statutory forfeiture provisions under the MMA with *Janssen's* underlying rationale. Instead they focus on the procedural aspects of whether it might have been easier or more difficult to file a declaratory judgment before or after the addition of an express statutory provision that grants a subsequent filer, who is not sued after

submitting a paragraph IV notice letter, the right to file a declaratory judgment to obtain patent certainty. Thus, Daiichi and Mylan fail to point to any textual support in the statute that would require a subsequent ANDA filer to challenge **all** Orange Book listed patents in order to cause forfeiture under the MMA-Amendments.

There is no dispute that Apotex is now challenging the sole patent that is the basis for Mylan's lingering eligibility for first filer exclusivity. The result "envisioned" by the MMA under these circumstances, unlike *Janssen*, is that if Apotex is successful in obtaining a judgment of noninfringement, it will cause Mylan to forfeit its eligibility to first filer exclusivity if it cannot launch its product in time. Thus, if anyone here is complaining about the results "envisioned" by the statute it is Daiichi and Mylan, not Apotex.

A. THE MMA-AMENDMENTS CREATED FORFEITURE PROVISIONS DESIGNED TO INCENTIVIZE SUBSEQUENT ANDA FILERS SUCH AS APOTEX TO CHALLENGE ORANGE BOOK PATENTS WHEN THE FIRST ANDA FILER IS NOT PREPARED TO GO TO MARKET.

As explained in our opening brief (pp. 29-32), under the old Hatch-Waxman Act a first generic filer arguably had a statutory entitlement to 180-days exclusivity that may or may not be triggered by subsequent events. Under the MMA provisions, they are merely eligible for first filer exclusivity, but can forfeit that exclusivity if they are unable or choose not to bring their product to market quickly and satisfy the underlying statutory purpose of getting generic products in

the hands of consumers as soon as possible. *Teva Pharms. USA, Inc. v. Novartis Pharms. Corp.*, 482 F.3d 1330, 1344 (Fed. Cir. 2007) ("A central purpose of the Hatch-Waxman Act and the subsequent ANDA declaratory judgment amendment to that Act is 'to enable competitors to bring cheaper, generic ... drugs to market as quickly as possible.'" [citing 149 Cong. Rec. S15885 (Nov. 25, 2003) (Statement of Sen. Kennedy)]).

> **(D) Forfeiture of 180-day exclusivity period.—**
>
> > **(i) Definition of forfeiture event.—** In this subparagraph, the term "forfeiture event", with respect to an application under this subsection, means the occurrence of any of the following:
> >
> > > **(I) Failure to market.—** 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 and lawfully maintained a certification

> qualifying the first applicant for the 180-day exclusivity period under subparagraph (B)(iv), at least 1 of the following has occurred:
>
> > **(AA)** In an infringement action brought against that applicant with respect to the patent or in a declaratory judgment action brought by that applicant with respect to the patent, a court enters a final decision from which no appeal (other than a petition to the Supreme Court for a writ of certiorari) has been or can be taken that the patent is invalid or not infringed.
> >
> > **(BB)** In an infringement action or a declaratory judgment action described in subitem (AA), 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.

21 U.S.C. § 355(j)(5)(D)(i)(I) (emphasis added).

Under this part of the MMA, which indisputably is applicable in this action and which did not exist in the earlier version of the statute at issue in *Janssen*, Mylan is not ***entitled*** to a 180-day exclusivity period merely because it was the first ANDA filer. That potential exclusivity can be forfeited if one of several circumstances recited in the statute occurs including, as discussed in all of the briefs that have been filed, the circumstances that will occur if there is a declaratory judgment of noninfringement of the ’703 patent in this action,

To illustrate, in this case, Mylan filed a Paragraph IV certification to both the ’599 and ’703 patents and is believed to have been the first generic ANDA

filer with a certification on these patents. (A4.) However, when Mylan lost its litigation relating to the '599 patent its Paragraph IV certification as to the '599 patent was converted to a Paragraph III certification and Mylan was enjoined from launching its generic olmesartan product until the '599 patent expires. *Daiichi Sankyo*, 619 F.3d 1352; (A5; A49.) Had the '599 patent been the only patent listed in the Orange Book, Mylan would have lost its eligibility to the 180-day exclusivity at this point because to maintain Mylan's eligibility to the exclusivity period the statute says it must *maintain* a paragraph IV certification on at least one of the Orange Book listed patents. 21 U.S.C. § 355(j)(5)(B)(iv)(II)(bb) ("First applicant. As used in this subsection, the term "first applicant" means an applicant that, on the first day … submits a substantially complete application that *contains and lawfully maintains* a certification described in paragraph (2)(A)(vii)(IV) for the drug." (emphasis added)); (A50.) However, the '703 patent (although disclaimed), remained listed in the Orange Book and therefore at this time is the sole basis for Mylan's exclusivity eligibility.

Had Mylan decided to challenge through its own declaratory judgment action and won on the '703 patent while losing on the '599 patent, the statute provides that Mylan would have forfeited its own exclusivity because the injunction against it selling until the '599 patent expires would have precluded

Mylan from launching its product within the 75-day window required by the statute. 21 U.S.C. § 355(j)(5)(D)(i)(I)(bb). Therefore, despite Mylan's grandiose puffery about how it "blazed a path" by filing a paragraph IV certification on the '703 patent and its "remarkable success" that "ensures generic competition … more than five years before the '703 patent otherwise would have allowed," all that Mylan really did was hold the '703 patent in reserve in an effort to ensure that when generic competition does begin there will only be one generic on the market. Mylan Br. at 17, 50.

Daiichi for its part also declined to litigate the '703 patent, both here and in the Mylan case, or alternatively to provide a settlement judgment or consent decree with respect to the '703 patent because doing so would cause Mylan to forfeit exclusivity and result in additional generic competition sooner.

These tactical decisions by Mylan and Daiichi perhaps make sense from their own business standpoints, but in doing so they assumed the risk that a forfeiture event might occur in the meantime. In this regard, the purpose of the MMA was to emphasize that the statute does not envision the result of delaying the launch of the product of a subsequent ANDA filer, per se, but rather it envisions the promotion of opening markets to generic competition. The purpose and effect of the MMA is to emphasize that the 180-day exclusivity period is not an entitlement simply for being the first in line, but rather is a reward contingent

on the first filer getting its products to market fast – before a forfeiture event can occur. The express language of the MMA is that such forfeiture can occur through a declaratory judgment action like the instant action. As Senator Hatch explained:

> I think in the circumstances when the subsequent challenger has not been sued by the pioneer firm, that the first filer should at least forfeit its 180 days if it is not prepared to go to market in the 75-day grace period the new provision creates. This is good for the consumer and sound policy since the rationale behind the 180-day provision is to create an incentive for challenges to the pioneer's patents, not to create an entitlement to the first applicant to file a patent challenge with the FDA in the Parklawn Building.

149 Cong. Rec. S16105-06 (Dec. 9, 2003) (remarks of Sen. Hatch).

In light of these forfeiture provisions, exclusivity based on a disclaimed patent that Daiichi and Mylan both declined to litigate cannot possibly be the result envisioned by the revised statute as amended by the MMA. While the first filer's statutory entitlement under the old Act may have been a basis for holding that the subsequent filer's exclusion from the market was not a justiciable controversy in *Janssen*, that same rationale does not apply here. Under the MMA Mylan has eligibility for, but no entitlement to, exclusivity. It never will have entitlement if Apotex prevails in this appeal, and the present controversy is a justiciable one contemplated by the MMA as demonstrated by the remarks of Senator Hatch quoted above.

B. THIS COURT'S DECISION IN *CARACO* AND SUBSEQUENT CASES SUPPORT A FINDING THAT THE MMA AMENDMENTS REQUIRE JURISDICTION IN CASES WHERE A SUBSEQUENT ANDA FILER IS BEING PRECLUDED FROM THE MARKET.

Daiichi argues (p.13) that language from this Court's decisions in *Caraco* (decided before *Janssen* and applying pre-MMA law) and *Dey* (decided after *Janssen* and applying the MMA) support the notion that the MMA-Amendments do not affect the jurisdictional issues in this case and that *Janssen* controls. However, as noted above, *Janssen* itself says it is not construing the MMA-Amendments and recognizes that the MMA amendments were enacted to create events resulting in the forfeiture of the 180-day exclusivity.

Daiichi points to the following passage from *Caraco*, which discusses the legislative history of the MMA-Amendments when discussing "the need for broad federal jurisdiction over [civil actions to obtain patent certainty]" and the brand company's incentive to delay such decisions.

> Although the legislative discussion refers to the amended 180-day provisions, this distinction is inconsequential because under both the original and amended 180-day provisions, the ability of subsequent Paragraph IV ANDA filers to obtain FDA approval depends on the date of a final court decision holding the relevant Orange-Book-listed patents invalid or not infringed. Thus, Senator Kennedy's remarks concerning the brand name drug company's incentive to delay such court decisions are equally applicable to this case.

Caraco, 527 F.3d at n.4.

However, the applicability of Senator Kennedy's remarks, relating to a brand company's incentive to delay a subsequent generic filer's declaratory judgment action, to a pre-MMA case does not diminish the distinction of the present action over *Janssen* based on substantive additions of express forfeiture provisions under the MMA.

Similarly, in *Dey,* the Court only noted in the course of distinguishing *Janssen* that for purposes of the "issues in this case" it did not make a difference that an event that was a "trigger event" under the original statute was now a "forfeiture event" under the MMA-Amendments. *Dey*, 677 F.3d at 1160. Indeed in the subsequent paragraphs *Dey* addresses why the MMA-Amendments were enacted, namely to permit "a subsequent ANDA filer [to] independently trigger the first filer's exclusivity period through a declaratory judgment action leading to a final judgment of invalidity or noninfringement, thereby accelerating the second ANDA filer's ability to market its drug." *Dey*, 677 F.3d at 1160-61. Thus, there is no basis to construe *Dey* to require that *Janssen* continues to control the jurisdictional analysis as applied to the MMA-Amendments in this case. The distinction between the old Hatch-Waxman Act provisions and the MMA that Apotex draws here simply was never considered in *Dey* because it did not matter. The Court found that subject matter jurisdiction was present.

IV. THE CONSTITUTIONAL REQUIREMENTS FOR JURISDICTION ARE SATISFIED.

A. JURISDICTION DOES NOT DEPEND ON TENTATIVE APPROVAL.

Apotex's current absence of tentative approval does not preclude jurisdiction or make Apotex's claim too speculative. Such an argument is directly contrary to the declaratory judgment provisions of the MMA-Amendments and the Patent Act (35 U.S.C. § 271 (e)(5)), and was expressly rejected by the district courts in *Seattle Children's Hospital*, 2011 WL 6378838 at *8 and *Purdue Pharmaceutical Products, L.P. v. Actavis Elizabeth, LLC*, 2014 WL 1394178, *6 (D.N.J. Apr. 9, 2014) (unpublished).

Among other things, the NDA filer in *Seattle Children's* argued, just as Daiichi and Mylan do here, that any injury arising from the subsequent ANDA filer's inability to cause forfeiture of the first ANDA filer's exclusivity period could not be redressed by a favorable judgment because the later ANDA filer had "yet to receive 'tentative approval' of its ANDA and there [was] no telling if or when the FDA may approve [the later ANDA filer's] ANDA." *Seattle Children's*, 2011 WL 6378838 at *8. The *Seattle Children's* court rejected this argument on the basis that the "2003 amendments [to the Hatch–Waxman Act] created a civil action to obtain patent certainty ("CAPC") that could be brought by an ANDA applicant at a time when it likely would not have tentative approval." *Id.* As the court explained:

> Plaintiffs argue that there is no injury to **Akorn** and no controversy between **Akorn** and Plaintiffs over the '269 patent even if **Akorn** prevailed against Plaintiffs tomorrow, because **Akorn** has yet to receive "tentative approval" of its ANDA and there is no telling if or when the FDA may approve **Akorn's** ANDA. [footnote omitted] In other words, Plaintiffs argue that **Akorn's** absence of tentative approval from the FDA, not their conduct, precludes jurisdiction. However, this argument appears to conflict with certain rationales behind the 2003 amendments to the Hatch–Waxman Act. The 2003 amendments created a civil action to obtain patent certainty ("CAPC") that could be brought by an ANDA applicant at a time when it likely would not have tentative approval. An ANDA applicant may bring a CAPC when it notifies an NDA holder of its Paragraph IV ANDA and 45 days pass without the NDA holder suing. 21 U.S.C. § 355(j)(5)(C)(i)(II); Caraco, 527 F.3d at 1285.

Id.

This same argument also was recently rejected in *Purdue*, 2014 WL 1394178**, *6** (unpublished), which explained:

> Although TWi requires tentative approval from the FDA before it can trigger the first ANDA filer's 180–day exclusivity period, the statute does not explicitly require TWi to obtain tentative approval *before* seeking declaratory judgment of non-infringement with respect to any of the Orange Book patents for Intermezzo®. 21 U.S.C. § 355(j)(5)(D)(i)(I). More importantly, to require TWi to obtain tentative approval as a condition precedent to asserting jurisdiction over its counterclaims would undermine the Hatch–Waxman Act's policy of encouraging "early resolution of patent disputes." *See Caraco*, 527 F.3d at 1285.

Purdue, 2014 WL 1394178 at *6 [emphasis in original].

The *Purdue* court also pointed to Senator Kennedy's remarks in the MMA legislative history (also quoted in *Caraco*) to the effect that in circumstances in which a subsequent ANDA filer would be blocked by a first ANDA filer 180-day

exclusivity period, "generic applicants must be able to seek a resolution of disputes involving all patents listed in the Orange Book with respect to the drug immediately upon the expiration of the 45-day period [after the notification of the Paragraph IV certification]…. 149 Cong. Rec. S15885 (Nov. 25, 2003)." 2014 WL 1394178 at *7; *Caraco*, 527 F.3d at 1285-86.

Additionally, the *Purdue* court cited a letter from the Federal Trade Commission in the MMA legislative history that asserted that the right of a subsequent ANDA filer to seek declaratory judgment "also will allow for the simultaneous running of the periods for FDA approval and for the resolutions of patent infringement issues. 149 Cong. Rec. S15886." *Purdue*, at *7.

Therefore, the legislative history and the district court decisions negate the argument that tentative approval is a prerequisite for jurisdiction.

Mylan also cites *Mylan Pharms. v. United States FDA*, 789 F.Supp.2d 1 (D.D.C. 2011) and *Pfizer Inc. v. Shalala*, 182 F.3d 975 (D.C. Cir. 1999) to support its argument regarding lack of standing and ripeness based on the absence of tentative approval. However, the issue in those cases was standing to compel the FDA to take action with respect to a competitor's ANDA. *Mylan*, 789 F.Supp.2d at 2; *Pfizer*, 182 F.3d at 976. This is inapposite to this Court's jurisdiction over a civil action to obtain patent certainty as provided in 21 U.S.C. § 355(j)(5)(C), where Apotex seeks a declaratory judgment that it does not

infringe the '703 patent to eliminate a barrier to regulatory approval of its own ANDA.

Finally, Mylan repeatedly insinuates (Mylan Br. at 4, 39, 40, 57) that the absence of tentative approval must mean there is a deficiency with Apotex's ANDA. Mylan's speculation is unsupported by the record. The absence of tentative approval is simply a matter of waiting in the queue.[4] Apotex's ANDA has not been pending even that long.[5]

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[4] According to one report based on FDA statistics, the average time to tentative approval time for an ANDA as of June 2013 was about 36-months. *See* http://www.lachmanconsultants.com/june-approval-times-for-andas-a-snapshot-in-time.asp (June 2013).

[5] Mylan also erroneously asserts (p.46), again without support, that the declaratory judgment plaintiffs in *Caraco* and *Eisai* had tentative approval at the time they filed their complaint. In *Caraco*, the action was brought in February, 2002. *Caraco Pharm. Labs. v. Forest Labs. et al.*, 07-cv-10737 (E.D. Mich. Feb. 20, 2007) (Dkt. 1). Caraco did not receive tentative approval until November 29, 2002. *See excerpt from FDA Tenative Approvals, November 2007 available at http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Reports.TentativeApprovals.*

Drug Name and FDA Appl. #	Active Ingredients	Company	Tentative Approval Date
ESCITALOPRAM OXALATE (ANDA # 078219)	ESCITALOPRAM OXALATE	CARACO	11/29/2007

In *Eisai*, the declaratory plaintiff admitted that it did not have tentative approval at the time it filed its complaint in responding to Eisai's motion to dismiss. *Teva Pharms. v. Eisai Co. Ltd.*, 08-cv-02344-GEB-ES (DNJ) (Dkt. 31) at 18 ("The fact that the GATE ANDA has not yet received tentative approval does not change the conclusion that this declaratory judgment issue is ripe.")

B. APOTEX SATISFIES THE CAUSATION REQUIREMENT.

1. Apotex's Injury Is Being Caused By Daiichi's '703 Patent.

The opposition briefs assert that Apotex's injury is being caused by the Hatch-Waxman Act and its status as a subsequent ANDA filer, not by Daiichi's '703 patent. But the statute expressly permits Apotex to bring this action as a subsequent ANDA filer to obtain a declaratory judgment that this patent is not infringed and thereby put its ANDA product in a position to be approved for marketing on day one of generic competition. This is not a case of a plaintiff asserting a mere generalized interest or trying to invoke statutory provisions outside of its zone of interest. *E.g.*, *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 575 (1992); *Lexmark Intern., Inc. v. Static Controls. Components, Inc.*, 134 S.Ct. 1377, 1386 (2014). Apotex has filed an ANDA actively seeking FDA approval to get its product to market and is invoking statutory provisions that Congress has expressly granted to parties in its position. Of course, the circumstances that exist in this action might be different if there were a different statutory scheme or if Apotex were not a subsequent ANDA filer. However, the fact that circumstances might be different in a different universe does not diminish the traceability of Apotex's injury to Daiichi's listing of the '703 patent in the Orange Book. *Lexmark*, 134 S.Ct. at 1391 n.6 (2014) ("Proximate causation is not a requirement of Article III standing, which requires only that the plaintiff's injury be fairly

traceable to the defendant's conduct."); *Duke Power Co. v. Carolina Envtl. Study Group, Inc.*, 438 U.S. 59, 74-78, 81 n. 26 (1978).

The opposition briefs cite several Supreme Court cases regarding the general requirements for subject matter jurisdiction. The cited cases included *Steel Co. v. Citizens for a Better Environment*, 523 U.S. 83, 103 (1998), *Allen v. Wright*, 468 U.S. 737, 751 (1984), and *Linda R. S. v. Richard D.*, 410 U.S. 614 (1973). However, these cases all support the exercise of jurisdiction here. For example, in *Allen*, the Court said that the plaintiff's alleged injury would be "fairly traceable" to the alleged conduct by the defendant if that alleged conduct were sufficient "to make an appreciable difference" in the alleged injury. 468 U.S. at 758. In this action, it definitely would make an appreciable difference to Apotex's injury if Daiichi had not listed the '703 patent in the Orange Book. There would not be any injury.

In *S. v. D.*, the Court characterized the causation connection as "a logical nexus," and said that the plaintiff must show that he is "in danger of sustaining a direct injury as the result of" the defendant's conduct. 410 U.S. at 618. Again, Daiichi's listing of the '703 patent in the Orange Book will delay Apotex's ability to go to market after the '599 patent expires, and the statute expressly provides for Apotex to avoid that injury by a noninfringement declaratory judgment action against Daiichi.

The opposition briefs also assert that Apotex, not the '703 patent, is the cause of its injury because it did not file its ANDA until several years after Mylan. But that would be true of any ANDA filer that was not a first filer, and Apotex would be in the exact same position if it had filed one day after Mylan. It would render the statutory forfeiture provisions meaningless if a subsequent filer could not file a declaratory judgment action to obtain patent certainty. *See Seattle Children's*, 2011 WL 6378838 at *8 ("The case law and the expression of congressional intent recognized above, as well as the realities and time commitments associated with complex litigation, support **Akorn's** attempt to pursue tentative approval of its ANDA with the FDA while simultaneously seeking 'a favorable judgment in this action [to] eliminate the potential for the [listed] patent to exclude [**Akorn**] from the drug market.'" (quoting *Caraco*, 527 F.3d at 1293).) The plain language of the statute, which permits forfeiture events to be caused by the "first applicant or any other applicant," and the legislative history make clear that subsequent filers can cause forfeiture events by obtaining judgments of invalidity or noninfringement where a first filer is unable to get its product to market quickly enough. 21 U.S.C. § 355(j)(5)(D)(i)(I)(bb)(AA); 149 Cong. Rec. S16105-06 (Dec. 9, 2003) (Remarks of Sen. Hatch);) (discussed at p.31 of Apotex's opening brief.)

2. Declaratory Judgment Jurisdiction Does Not Require Daiichi's Listing Of the '703 Patent In The Orange Book To Have Been Wrongful.

The opposition briefs also argue that there is no jurisdiction because Daiichi allegedly did nothing "wrong" when it listed the '703 patent in the Orange Book. However, the issue is not whether Daiichi's conduct was "wrong" or "unlawful." Rather, it is whether the injury to Apotex is "fairly traceable" to listing of the '703 patent in the Orange Book.

The opposition briefs cited to *Allen v. Wright*, quoting from a sentence that states, "[a] plaintiff must allege personal injury fairly traceable to the defendant's allegedly ***unlawful conduct*** and likely to be redressed by the requested relief." 468 U.S. at 751 (emphasis added).

In the context of *Allen*, the plaintiff's alleged injury was a "personal injury," and the defendant's alleged conduct was "allegedly unlawful." However, those were not jurisdictional issues. In *Allen*, the issues were whether the plaintiff's injury was fairly traceable to the defendant's alleged conduct, and whether the requested relief would redress that injury. In general, jurisdiction does not require that the defendant's conduct have been "unlawful," just as it does not require that the plaintiff's injury have been a "personal injury" as opposed to a generalized grievance. *See Lexmark*, 134 S.Ct. at 1386 ("The plaintiff must have suffered or be imminently threatened with a concrete and particularized

"injury in fact" that is fairly traceable to the ***challenged action*** of the defendant and likely to be redressed by a favorable judicial decision." (emphasis added)); *Steel*, 523 U.S. at 103 ("[T]here must be causation—a fairly traceable connection between the plaintiff's injury and the ***complained-of conduct*** of the defendant." (emphasis added)).

Accordingly, there is jurisdiction for Apotex to bring a declaratory judgment action against Daiichi under 35 U.S.C. § 271 (e)(5), regardless of whether Daiichi did anything "wrong" when it listed the '703 patent in the Orange Book.

C. MYLAN'S ARGUMENT THAT *CARACO* WAS WRONGLY DECIDED LACKS MERIT.

Mylan's last ditch argument opposing jurisdiction is that Caraco was wrongly decided. (Mylan Bf. 53-59.) On this, Mylan stands alone. Neither the District Court nor Daiichi said that Caraco was wrong. And no case so holds.

Specifically, Mylan argues that the *Caraco* court was wrong when it held that:

> [I]f Forest had not listed its … patents in the FDA's Orange Book … then [Hatch-Waxman's exclusivity provision] would not independently delay Caraco's ANDA from being approved by the FDA. Such **but-for causation is sufficient** to satisfy the traceability requirement of Article III standing. *See Duke Power Co. v. Carolina Envtl. Study Group, Inc.*, 438 U.S. 59, 74-78, 81 n. 26, 98 S.Ct. 2620, 57 L.Ed.2d 595 (1978).

527 F.3d at 1292 (emphasis added). According to Mylan, "but for" causation is not enough. (Mylan Bf. 55-59.)

However, Mylan (p.55) omits *Caraco's* citation to *Duke Power* in its discussion. Indeed, Mylan does not discuss *Duke Power* anywhere in its brief.

In *Duke Power* a "but for" causal connection was sufficient for Article III standing. 438 U.S. at 74-78, 81 n.26. The Supreme Court determined that an environmental group had standing to challenge the constitutionality of the Price-Anderson Act, which limited the liability of nuclear power companies. The limited-liability provision of the Act was recognized to be a jurisdictionally sufficient "but for" cause of the construction of a nuclear power plant that allegedly would expose those living in the area to certain environmental changes and risks of injury, because without the liability limitations the construction would not be economically feasible. *Id.* at 74-75. Of course the Act did not itself construct and approve the plant for operation: those are events that are under the control of *Duke Power* and the Nuclear Regulatory Commission. Nevertheless, the future potential environmental harms alleged were deemed sufficiently traceable to the Act for the Court to exercise jurisdiction, even though the plant might never be completed or approved for operation for a variety of other reasons.

Duke Power is still good law. Two of the Supreme Court cases cited by Mylan predate *Duke Power* and so they can hardly be said to overrule it. *Pennsylvania v. New Jersey*, 426 U.S. 660 (1976); *Simon v. E. Ky. Welfare Rights Org.*, 426 U.S. 26 (1976). The three subsequent Supreme Court cases cited by Mylan do not discuss, much less overrule, *Duke Power*. *Clapper v. Amnesty Int'l USA*, 133 S.Ct. 1138 (2013); *Summers v. Earth Island Institute*, 555 U.S. 488 (2009); *Allen*, 468 U.S. 737.

Mylan speculates (p.56) that the *Caraco* court was following Sixth Circuit precedent, but says that here the Court should instead follow Seventh Circuit precedent. However, *Caraco* was following the Supreme Court's decision in *Duke Power*, not regional circuit law (no Sixth Circuit case is cited anywhere in *Caraco*). In addition, Mylan is wrong about Seventh Circuit case law. Mylan relies on the Seventh Circuit decision in *Parvati Corp. v. City of Oak Forest*, 630 F.3d 512 (7th Cir. 2010). *Parvati* does not discuss "but for" causation. However, it is clear that the Seventh Circuit considers "but for" causation to be sufficient for Article III standing. For example, in *Lac du Flambeau Band of Lake Superior Chippewa Indians v. Norton*, 422 F.3d 490 (7th Cir. 2005), the court held:

> While the Secretary may not be the only party responsible for the injury alleged here, a plaintiff does not lack standing merely because the defendant is one of several persons who caused the harm…. The Secretary's silent approval caused that potential [harm] to become a reality because, **but for** her approval [the harm could not occur].

Id. at 500-01 (emphasis added). Likewise, here Daiichi's listing of the '703 patent is a "but for" cause of Apotex's injury sufficient for Article III standing, even if Daiichi "may not be the only party responsible for the injury."

V. DAIICHI'S INABILITY TO UNILATERALLY CAUSE MYLAN TO LOSE EXCLUSIVITY BY DELISTING THE '703 PATENT FROM THE ORANGE BOOK DOES NOT AFFECT APOTEX'S ABILITY TO CAUSE FORFEITURE THROUGH A PATENT DECLARATORY JUDGMENT ACTION BECAUSE THE STATUTORY INCENTIVES AND PROVISIONS ARE DIFFERENT FOR GENERICS THAN FOR BRAND-SIDE COMPANIES.

The opposition briefs (Daiichi Br. at 35; Mylan Br. at 45) also argue that because the NDA holder Daiichi may not unilaterally delist the '703 patent and deprive Mylan of its potential 180-day period of excluding subsequent ANDA filers, there is no jurisdiction for Apotex's declaratory judgment seeking patent certainty under 35 U.S.C. § 271 (e)(5) and 21 U.S.C. § 355(j)(5)(C). That argument ignores that the same statute that provides for Mylan's exclusivity period under some circumstances, also provides for its forfeiture under other circumstances. As we explained in our opening brief (pp. 24-25), the policy that prevents a brand company from delisting a patent does not apply to generic competitors seeking to get their products to market by causing a forfeiture event. The rationale being that if a first ANDA filer is unable to get its product to market fast, a subsequent generic is entitled to cause a forfeiture of any exclusivity. *Dey*, 677 F.3d at 1160.

Thus, this action is not a case of a court acting on behalf of an ANDA holder to accomplish what the NDA holder may not do unilaterally. Rather, this is an action by a subsequent ANDA filer exercising its rights under 35 U.S.C. § 271(e)(5) and 21 U.S.C. § 355(j)(5)(C), to seek a declaratory judgment to obtain patent certainty in an effort to eliminate a barrier created by Daiichi's listing of the '703 patent in the Orange Book.

These statutory provisions also refute Daiichi's argument (p.35) that Apotex's "real dispute is with FDA" and that this "is not a patent dispute." The relief that Apotex is seeking here is a declaratory judgment that Daiichi's '703 patent is not infringed by Apotex's ANDA product. While a consequence of that judgment will be to enable Apotex to obtain final FDA marketing approval for its generic olmesartan product sooner than it otherwise would, Apotex's dispute here is squarely with Daiichi who owns that '703 patent, listed it in the Orange Book and continues to benefit from the exclusionary effects of that listing.

CROSS-APPEAL SUMMARY OF THE ARGUMENT

The district court's denial of Mylan's motion for intervention and to file its own motion to dismiss as moot once it granted Daiichi's motion to dismiss should be affirmed. This is a patent case and Mylan is neither patentee nor the accused infringer. Nothing in Mylan's brief changes the fact that there is no meaningful relief this Court can grant it on appeal or that the district court can grant it if this case is reversed remanded with instructions for the district court to enter judgment of noninfringement in Apotex's favor. *CE Design, Ltd. v. Cy's Crab House North, Inc.*, 731 F.3d 725, 730 (7th Cir. 2013) ("If we cannot grant any relief, our jurisdiction ceases.").

VI. THE DISTRICT COURT'S DENIAL OF MYLAN'S MOTIONS SHOULD BE AFFIRMED.

Regarding the jurisdictional issues in this appeal, Mylan's interests are adequately protected by Daiichi, which makes largely all of the same substantive arguments that Mylan makes on the jurisdictional issues. Mylan and Daiichi also share the same competitive interests in maintaining Mylan's eligibility to 180-exclusivity period and stand to benefit from no additional generic competition for those 180-days if the district court's jurisdictional ruling is upheld. *Shea v. Angulo*, 19 F.3d 343, 347 (7th Cir.1994) ("Where a prospective intervenor has the same goal as the party to a suit, there is a presumption that the representation in

the suit is adequate."); *Wolfsen Land & Cattle Co. v. Pac. Coast Fed'n of Fishermen's Ass'ns*, 695 F.3d 1310, 1317 (Fed. Cir. 2012) (denying prospective intervenor's appeal from order denying intervention because, *inter alia*, the prospective intervenor "can show no divergence in either motivations or approaches between itself and [the defendant] as to this case…").

The regulatory interest that Mylan asserts it is seeking to protect through intervention – namely, protecting its eligibility to first generic filer exclusivity – is not being decided in this patent declaratory judgment action, where the Court is limited to deciding whether Apotex's product infringes Daiichi's patent. While a noninfringement judgment is a predicate to forfeiture of Mylan's eligibility to first filer exclusivity, the actual forfeiture decision ultimately will be made by FDA. *Cf. Minnesota Mining and Mfg. v. Barr Labs.*, 289 F.3d 775, 780 (Fed. Cir. 2002) ("Under the Hatch-Waxman Amendments we cannot enforce the requirements of paragraph IV certifications in an infringement suit.").

In any event, the relief for which Mylan seeks intervention – dismissal of Apotex's declaratory judgment complaint against patentee Daiichi for lack of subject matter jurisdiction – already was granted by the district court on Daiichi's own motion. While Mylan claims that it might be adversely affected if Apotex's generic product gets to market and competes with Mylan's product, that has never been enough to allow intervention in a patent case where neither the proposed

intervenors' patents nor their products are actually at issue in the case. *Cf. Chapman v. Manbeck*, 931 F.2d 46 (Fed. Cir. 1991) (affirming the district court's denial of an alleged infringer's motion to intervene as a third-party in a patentee's suit against the Commissioner of Patents for reinstatement of his patent because the court action in which the alleged infringer seeks to intervene "does not impair [his] ability to litigate its rights fully elsewhere.")

CONCLUSION

For the reasons described above, the court should reverse the judgment of the district court and find that there is subject matter jurisdiction over Apotex's declaratory judgment action.

Respectfully Submitted,

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STATUTORY ADDENDUM

21 U.S.C. §355. New drugs

* * * * *

(j) Abbreviated new drug applications

(1) Any person may file with the Secretary an abbreviated application for the approval of a new drug.

(2)(A) An abbreviated application for a new drug shall contain—

(i) information to show that the conditions of use prescribed, recommended, or suggested in the labeling proposed for the new drug have been previously approved for a drug listed under paragraph (7) (hereinafter in this subsection referred to as a "listed drug");

(ii)(I) if the listed drug referred to in clause (i) has only one active ingredient, information to show that the active ingredient of the new drug is the same as that of the listed drug;

(II) if the listed drug referred to in clause (i) has more than one active ingredient, information to show that the active ingredients of the new drug are the same as those of the listed drug, or

(III) if the listed drug referred to in clause (i) has more than one active ingredient and if one of the active ingredients of the new drug is different and the application is filed pursuant to the approval of a petition filed under subparagraph (C), information to show that the other active ingredients of the new drug are the same as the active ingredients of the listed drug, information to show that the different active ingredient is an active ingredient of a listed drug or of a drug which does not meet the requirements of section 321(p) of this title, and such other information respecting the different active ingredient with respect to which the petition was filed as the Secretary may require;

(iii) information to show that the route of administration, the dosage form, and the strength of the new drug are the same as those of the listed drug referred to in clause (i) or, if the route of administration, the dosage form, or the strength of the new drug is different and the application is filed pursuant to the approval of a petition filed under subparagraph (C), such information respecting the

route of administration, dosage form, or strength with respect to which the petition was filed as the Secretary may require;

(iv) information to show that the new drug is bioequivalent to the listed drug referred to in clause (i), except that if the application is filed pursuant to the approval of a petition filed under subparagraph (C), information to show that the active ingredients of the new drug are of the same pharmacological or therapeutic class as those of the listed drug referred to in clause (i) and the new drug can be expected to have the same therapeutic effect as the listed drug when administered to patients for a condition of use referred to in clause (i);

(v) information to show that the labeling proposed for the new drug is the same as the labeling approved for the listed drug referred to in clause (i) except for changes required because of differences approved under a petition filed under subparagraph (C) or because the new drug and the listed drug are produced or distributed by different manufacturers;

(vi) the items specified in clauses (B) through (F) of subsection (b)(1) of this section;

(vii) a certification, in the opinion of the applicant and to the best of his knowledge, with respect to each patent which claims the listed drug referred to in clause (i) or which claims a use for such listed drug for which the applicant is seeking approval under this subsection and for which information is required to be filed under subsection (b) or (c) of this section—

(I) that such patent information has not been filed,

(II) that such patent has expired,

(III) of the date on which such patent will expire, or

(IV) that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted; and

(viii) if with respect to the listed drug referred to in clause (i) information was filed under subsection (b) or (c) of this section for a method of use patent which does not claim a use for which the applicant is seeking approval under this subsection, a statement that the method of use patent does not claim such a use.

The Secretary may not require that an abbreviated application contain information in addition to that required by clauses (i) through (viii).

(B) Notice of opinion that patent is invalid or will not be infringed.—

(i) Agreement to give notice.—An applicant that makes a certification described in subparagraph (A)(vii)(IV) shall include in the application a statement that the applicant will give notice as required by this subparagraph.

(ii) Timing of notice.—An applicant that makes a certification described in subparagraph (A)(vii)(IV) shall give notice as required under this subparagraph—

(I) if the certification is in the application, not later than 20 days after the date of the postmark on the notice with which the Secretary informs the applicant that the application has been filed; or

(II) if the certification is in an amendment or supplement to the application, at the time at which the applicant submits the amendment or supplement, regardless of whether the applicant has already given notice with respect to another such certification contained in the application or in an amendment or supplement to the application.

(iii) Recipients of notice.—An applicant required under this subparagraph to give notice shall give notice to—

(I) each owner of the patent that is the subject of the certification (or a representative of the owner designated to receive such a notice); and

(II) the holder of the approved application under subsection (b) of this section for the drug that is claimed by the patent or a use of which is claimed by the patent (or a representative of the holder designated to receive such a notice).

(iv) Contents of notice.—A notice required under this subparagraph shall—

(I) state that an application that contains data from bioavailability or bioequivalence studies has been submitted under this subsection for the drug with respect to which the certification is made to obtain approval to engage in the commercial manufacture, use, or sale of the drug before the expiration of the patent referred to in the certification; and

(II) include a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed.

(C) If a person wants to submit an abbreviated application for a new drug which has a different active ingredient or whose route of administration, dosage form, or strength differ from that of a listed drug, such person shall submit a petition to the Secretary seeking permission to file such an application. The Secretary shall approve or disapprove a petition submitted under this subparagraph within ninety days of the date the petition is submitted. The Secretary shall approve such a petition unless the Secretary finds—

(i) that investigations must be conducted to show the safety and effectiveness of the drug or of any of its active ingredients, the route of administration, the dosage form, or strength which differ from the listed drug; or

(ii) that any drug with a different active ingredient may not be adequately evaluated for approval as safe and effective on the basis of the information required to be submitted in an abbreviated application.

(D)(i) An applicant may not amend or supplement an application to seek approval of a drug referring to a different listed drug from the listed drug identified in the application as submitted to the Secretary.

(ii) With respect to the drug for which an application is submitted, nothing in this subsection prohibits an applicant from amending or supplementing the application to seek approval of a different strength.

(iii) Within 60 days after December 8, 2003, the Secretary shall issue guidance defining the term "listed drug" for purposes of this subparagraph.

(3)(A) The Secretary shall issue guidance for the individuals who review applications submitted under paragraph (1), which shall relate to promptness in conducting the review, technical excellence, lack of bias and conflict of interest, and knowledge of regulatory and scientific standards, and which shall apply equally to all individuals who review such applications.

(B) The Secretary shall meet with a sponsor of an investigation or an applicant for approval for a drug under this subsection if the sponsor or applicant makes a reasonable written request for a meeting for the purpose of reaching agreement on the design and size of bioavailability and bioequivalence studies needed for approval of such application. The sponsor or applicant shall provide

information necessary for discussion and agreement on the design and size of such studies. Minutes of any such meeting shall be prepared by the Secretary and made available to the sponsor or applicant.

(C) Any agreement regarding the parameters of design and size of bioavailability and bioequivalence studies of a drug under this paragraph that is reached between the Secretary and a sponsor or applicant shall be reduced to writing and made part of the administrative record by the Secretary. Such agreement shall not be changed after the testing begins, except—

(i) with the written agreement of the sponsor or applicant; or

(ii) pursuant to a decision, made in accordance with subparagraph (D) by the director of the reviewing division, that a substantial scientific issue essential to determining the safety or effectiveness of the drug has been identified after the testing has begun.

(D) A decision under subparagraph (C)(ii) by the director shall be in writing and the Secretary shall provide to the sponsor or applicant an opportunity for a meeting at which the director and the sponsor or applicant will be present and at which the director will document the scientific issue involved.

(E) The written decisions of the reviewing division shall be binding upon, and may not directly or indirectly be changed by, the field or compliance office personnel unless such field or compliance office personnel demonstrate to the reviewing division why such decision should be modified.

(F) No action by the reviewing division may be delayed because of the unavailability of information from or action by field personnel unless the reviewing division determines that a delay is necessary to assure the marketing of a safe and effective drug.

(G) For purposes of this paragraph, the reviewing division is the division responsible for the review of an application for approval of a drug under this subsection (including scientific matters, chemistry, manufacturing, and controls).

(4) Subject to paragraph (5), the Secretary shall approve an application for a drug unless the Secretary finds—

(A) the methods used in, or the facilities and controls used for, the manufacture, processing, and packing of the drug are inadequate to assure and preserve its identity, strength, quality, and purity;

(B) information submitted with the application is insufficient to show that each of the proposed conditions of use have been previously approved for the listed drug referred to in the application;

(C)(i) if the listed drug has only one active ingredient, information submitted with the application is insufficient to show that the active ingredient is the same as that of the listed drug;

(ii) if the listed drug has more than one active ingredient, information submitted with the application is insufficient to show that the active ingredients are the same as the active ingredients of the listed drug, or

(iii) if the listed drug has more than one active ingredient and if the application is for a drug which has an active ingredient different from the listed drug, information submitted with the application is insufficient to show—

(I) that the other active ingredients are the same as the active ingredients of the listed drug, or

(II) that the different active ingredient is an active ingredient of a listed drug or a drug which does not meet the requirements of section 321(p) of this title,

or no petition to file an application for the drug with the different ingredient was approved under paragraph (2)(C);

(D)(i) if the application is for a drug whose route of administration, dosage form, or strength of the drug is the same as the route of administration, dosage form, or strength of the listed drug referred to in the application, information submitted in the application is insufficient to show that the route of administration, dosage form, or strength is the same as that of the listed drug, or

(ii) if the application is for a drug whose route of administration, dosage form, or strength of the drug is different from that of the listed drug referred to in the application, no petition to file an application for the drug with the different route of administration, dosage form, or strength was approved under paragraph (2)(C);

(E) if the application was filed pursuant to the approval of a petition under paragraph (2)(C), the application did not contain the information required by the Secretary respecting the active ingredient, route of administration, dosage form, or strength which is not the same;

(F) information submitted in the application is insufficient to show that the drug is bioequivalent to the listed drug referred to in the application or, if the application was filed pursuant to a petition approved under paragraph (2)(C), information submitted in the application is insufficient to show that the active ingredients of the new drug are of the same pharmacological or therapeutic class as those of the listed drug referred to in paragraph (2)(A)(i) and that the new drug can be expected to have the same therapeutic effect as the listed drug when administered to patients for a condition of use referred to in such paragraph;

(G) information submitted in the application is insufficient to show that the labeling proposed for the drug is the same as the labeling approved for the listed drug referred to in the application except for changes required because of differences approved under a petition filed under paragraph (2)(C) or because the drug and the listed drug are produced or distributed by different manufacturers;

(H) information submitted in the application or any other information available to the Secretary shows that (i) the inactive ingredients of the drug are unsafe for use under the conditions prescribed, recommended, or suggested in the labeling proposed for the drug, or (ii) the composition of the drug is unsafe under such conditions because of the type or quantity of inactive ingredients included or the manner in which the inactive ingredients are included;

(I) the approval under subsection (c) of this section of the listed drug referred to in the application under this subsection has been withdrawn or suspended for grounds described in the first sentence of subsection (e) of this section, the Secretary has published a notice of opportunity for hearing to withdraw approval of the listed drug under subsection (c) of this section for grounds described in the first sentence of subsection (e) of this section, the approval under this subsection of the listed drug referred to in the application under this subsection has been withdrawn or suspended under paragraph (6), or the Secretary has determined that the listed drug has been withdrawn from sale for safety or effectiveness reasons;

(J) the application does not meet any other requirement of paragraph (2)(A); or

(K) the application contains an untrue statement of material fact.

(5)(A) Within one hundred and eighty days of the initial receipt of an application under paragraph (2) or within such additional period as may be agreed upon by

the Secretary and the applicant, the Secretary shall approve or disapprove the application.

(B) The approval of an application submitted under paragraph (2) shall be made effective on the last applicable date determined by applying the following to each certification made under paragraph (2)(A)(vii):

(i) If the applicant only made a certification described in subclause (I) or (II) of paragraph (2)(A)(vii) or in both such subclauses, the approval may be made effective immediately.

(ii) If the applicant made a certification described in subclause (III) of paragraph (2)(A)(vii), the approval may be made effective on the date certified under subclause (III).

(iii) If the applicant made a certification described in subclause (IV) of paragraph (2)(A)(vii), the approval shall be made effective immediately unless, before the expiration of 45 days after the date on which the notice described in paragraph (2)(B) is received, an action is brought for infringement of the patent that is the subject of the certification and for which information was submitted to the Secretary under subsection (b)(1) or (c)(2) of this section before the date on which the application (excluding an amendment or supplement to the application), which the Secretary later determines to be substantially complete, was submitted. If such an action is brought before the expiration of such days, the approval shall be made effective upon the expiration of the thirty-month period beginning on the date of the receipt of the notice provided under paragraph (2)(B)(i) or such shorter or longer period as the court may order because either party to the action failed to reasonably cooperate in expediting the action, except that—

(I) if before the expiration of such period the district court decides that the patent is invalid or not infringed (including any substantive determination that there is no cause of action for patent infringement or invalidity), the approval shall be made effective on—

(aa) the date on which the court enters judgment reflecting the decision; or

(bb) the date of a settlement order or consent decree signed and entered by the court stating that the patent that is the subject of the certification is invalid or not infringed;

(II) if before the expiration of such period the district court decides that the patent has been infringed—

(aa) if the judgment of the district court is appealed, the approval shall be made effective on—

(AA) the date on which the court of appeals decides that the patent is invalid or not infringed (including any substantive determination that there is no cause of action for patent infringement or invalidity); or

(BB) the date of a settlement order or consent decree signed and entered by the court of appeals stating that the patent that is the subject of the certification is invalid or not infringed; or

(bb) if the judgment of the district court is not appealed or is affirmed, the approval shall be made effective on the date specified by the district court in a court order under section 271(e)(4)(A) of title 35;

(III) if before the expiration of such period the court grants a preliminary injunction prohibiting the applicant from engaging in the commercial manufacture or sale of the drug until the court decides the issues of patent validity and infringement and if the court decides that such patent is invalid or not infringed, the approval shall be made effective as provided in subclause (I); or

(IV) if before the expiration of such period the court grants a preliminary injunction prohibiting the applicant from engaging in the commercial manufacture or sale of the drug until the court decides the issues of patent validity and infringement and if the court decides that such patent has been infringed, the approval shall be made effective as provided in subclause (II).

In such an action, each of the parties shall reasonably cooperate in expediting the action.

(iv) 180-day exclusivity period.—

(I) Effectiveness of application.—Subject to subparagraph (D), if the application contains a certification described in paragraph (2)(A)(vii)(IV) and is for a drug for which a first applicant has submitted an application containing such a certification, the application shall be made effective on the date that is 180 days after the date of the first commercial marketing of the drug (including the commercial marketing of the listed drug) by any first applicant.

(II) Definitions.—In this paragraph:

(aa) 180-day exclusivity period.—The term "180-day exclusivity period" means the 180-day period ending on the day before the date on which an application submitted by an applicant other than a first applicant could become effective under this clause.

(bb) First applicant.—As used in this subsection, the term "first applicant" means an applicant that, on the first day on which a substantially complete application containing a certification described in paragraph (2)(A)(vii)(IV) is submitted for approval of a drug, submits a substantially complete application that contains and lawfully maintains a certification described in paragraph (2)(A)(vii)(IV) for the drug.

(cc) Substantially complete application.—As used in this subsection, the term "substantially complete application" means an application under this subsection that on its face is sufficiently complete to permit a substantive review and contains all the information required by paragraph (2)(A).

(dd) Tentative approval.—

(AA) In general.—The term "tentative approval" means notification to an applicant by the Secretary that an application under this subsection meets the requirements of paragraph (2)(A), but cannot receive effective approval because the application does not meet the requirements of this subparagraph, there is a period of exclusivity for the listed drug under subparagraph (F) or section 355a of this title, or there is a 7-year period of exclusivity for the listed drug under section 360cc of this title.

(BB) Limitation.—A drug that is granted tentative approval by the Secretary is not an approved drug and shall not have an effective approval until the Secretary issues an approval after any necessary additional review of the application.

(C) Civil action to obtain patent certainty.—

(i) Declaratory judgment absent infringement action.—

(I) In general.—No action may be brought under section 2201 of title 28 by an applicant under paragraph (2) for a declaratory judgment with respect to a

patent which is the subject of the certification referred to in subparagraph (B)(iii) unless—

(aa) the 45-day period referred to in such subparagraph has expired;

(bb) neither the owner of such patent nor the holder of the approved application under subsection (b) of this section for the drug that is claimed by the patent or a use of which is claimed by the patent brought a civil action against the applicant for infringement of the patent before the expiration of such period; and

(cc) in any case in which the notice provided under paragraph (2)(B) relates to noninfringement, the notice was accompanied by a document described in subclause (III).

(II) Filing of civil action.—If the conditions described in items (aa), (bb), and as applicable, (cc) of subclause (I) have been met, the applicant referred to in such subclause may, in accordance with section 2201 of title 28, bring a civil action under such section against the owner or holder referred to in such subclause (but not against any owner or holder that has brought such a civil action against the applicant, unless that civil action was dismissed without prejudice) for a declaratory judgment that the patent is invalid or will not be infringed by the drug for which the applicant seeks approval, except that such civil action may be brought for a declaratory judgment that the patent will not be infringed only in a case in which the condition described in subclause (I)(cc) is applicable. A civil action referred to in this subclause shall be brought in the judicial district where the defendant has its principal place of business or a regular and established place of business.

(III) Offer of confidential access to application.—For purposes of subclause (I)(cc), the document described in this subclause is a document providing an offer of confidential access to the application that is in the custody of the applicant under paragraph (2) for the purpose of determining whether an action referred to in subparagraph (B)(iii) should be brought. The document providing the offer of confidential access shall contain such restrictions as to persons entitled to access, and on the use and disposition of any information accessed, as would apply had a protective order been entered for the purpose of protecting trade secrets and other confidential business information. A request for access to an application under an offer of confidential access shall be considered acceptance of the offer of confidential access with the restrictions as to persons entitled to access, and on the use and disposition of

any information accessed, contained in the offer of confidential access, and those restrictions and other terms of the offer of confidential access shall be considered terms of an enforceable contract. Any person provided an offer of confidential access shall review the application for the sole and limited purpose of evaluating possible infringement of the patent that is the subject of the certification under paragraph (2)(A)(vii)(IV) and for no other purpose, and may not disclose information of no relevance to any issue of patent infringement to any person other than a person provided an offer of confidential access. Further, the application may be redacted by the applicant to remove any information of no relevance to any issue of patent infringement.

(ii) Counterclaim to infringement action.—

(I) In general.—If an owner of the patent or the holder of the approved application under subsection (b) of this section for the drug that is claimed by the patent or a use of which is claimed by the patent brings a patent infringement action against the applicant, the applicant may assert a counterclaim seeking an order requiring the holder to correct or delete the patent information submitted by the holder under subsection (b) or (c) of this section on the ground that the patent does not claim either—

(aa) the drug for which the application was approved; or

(bb) an approved method of using the drug.

(II) No independent cause of action.—Subclause (I) does not authorize the assertion of a claim described in subclause (I) in any civil action or proceeding other than a counterclaim described in subclause (I).

(iii) No damages.—An applicant shall not be entitled to damages in a civil action under clause (i) or a counterclaim under clause (ii).

(D) Forfeiture of 180-day exclusivity period.—

(i) Definition of forfeiture event.—In this subparagraph, the term "forfeiture event", with respect to an application under this subsection, means the occurrence of any of the following:

(I) Failure to market.—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 and lawfully maintained a certification qualifying the first applicant for the 180-day exclusivity period under subparagraph (B)(iv), at least 1 of the following has occurred:

(AA) In an infringement action brought against that applicant with respect to the patent or in a declaratory judgment action brought by that applicant with respect to the patent, a court enters a final decision from which no appeal (other than a petition to the Supreme Court for a writ of certiorari) has been or can be taken that the patent is invalid or not infringed.

(BB) In an infringement action or a declaratory judgment action described in subitem (AA), 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 holder of the application approved under subsection (b) of this section.

(II) Withdrawal of application.—The first applicant withdraws the application or the Secretary considers the application to have been withdrawn as a result of a determination by the Secretary that the application does not meet the requirements for approval under paragraph (4).

(III) Amendment of certification.—The first applicant amends or withdraws the certification for all of the patents with respect to which that applicant submitted a certification qualifying the applicant for the 180-day exclusivity period.

(IV) Failure to obtain tentative approval.—The first applicant fails to obtain tentative approval of the application within 30 months after the date on which the application is filed, unless the failure is caused by a change in or a review of the requirements for approval of the application imposed after the date on which the application is filed.

(V) Agreement with another applicant, the listed drug application holder, or a patent owner.—The first applicant enters into an agreement with another applicant under this subsection for the drug, the holder of the application for the listed drug, or an owner of the patent that is the subject of the certification under paragraph (2)(A)(vii)(IV), the Federal Trade Commission or the Attorney General files a complaint, and there is a final decision of the Federal Trade Commission or the court with regard to the complaint from which no appeal (other than a petition to the Supreme Court for a writ of certiorari) has been or can be taken that the agreement has violated the antitrust laws (as defined in section 12 of title 15, except that the term includes section 45 of title 15 to the extent that that section applies to unfair methods of competition).

(VI) Expiration of all patents.—All of the patents as to which the applicant submitted a certification qualifying it for the 180-day exclusivity period have expired.

(ii) Forfeiture.—The 180-day exclusivity period described in subparagraph (B)(iv) shall be forfeited by a first applicant if a forfeiture event occurs with respect to that first applicant.

(iii) Subsequent applicant.—If all first applicants forfeit the 180-day exclusivity period under clause (ii)—

(I) approval of any application containing a certification described in paragraph (2)(A)(vii)(IV) shall be made effective in accordance with subparagraph (B)(iii); and

(II) no applicant shall be eligible for a 180-day exclusivity period.

* * * * *

United States Court of Appeals
for the Federal Circuit

Apotex Inc. v. Daiichi Sankyo, Inc., 2014-1282, -1291

CERTIFICATE OF SERVICE

I, Elissa Matias, being duly sworn according to law and being over the age of 18, upon my oath depose and say that:

Counsel Press was retained by HUSCH BLACKWELL LLP, Attorneys for Appellant to print this document. I am an employee of Counsel Press.

On **September 29, 2014** counsel has authorized me to electronically file the foregoing **Response and Reply Brief for Plaintiff-Appellant** with the Clerk of Court using the CM/ECF System, which will serve via e-mail notice of such filing to all counsel registered as CM/ECF users, including any of the following:

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Paper copies will also be mailed to the above principal counsel at the time paper copies are sent to the Court.

Upon acceptance by the Court of the e-filed document, six paper copies will be filed with the Court, via Federal Express, within the time provided in the Court's rules.

September 29, 2014

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CERTIFICATE OF COMPLIANCE

Undersigned counsel certifies that:

This brief complies with the type-volume limitation of Federal Rule of Appellate Procedure 32(a)(7)(B). The brief contains **8175** words, excluding the parts of the brief exempted by Federal Rule of Appellate Procedure 32(a)(7)(B)(iii) and Federal Circuit Rule 32(b).

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Date: September 29, 2014

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