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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

MERCK & CO., INC. Plaintiff, v. APOTEX INC. and APOTEX CORPORATION Defendants.	**DOCUMENT ELECTRONICALLY FILED** **Civil Action Nos.** **06-5789 & 06-5791 (MLC)** (Consolidated)

MERCK'S REPLY MEMORANDUM OF LAW IN SUPPORT OF ITS MOTION TO DISMISS COUNTS IV-VII OF APOTEX'S COUNTERCLAIMS FOR LACK OF SUBJECT MATTER JURISDICTION

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GLOSSARY OF TERMS

ANDA	Abbreviated New Drug Application
Apotex	Apotex Inc. & Apotex Corp. – The defendants in suit
Apo. SJ Br.	Apotex Inc.'s Memorandum of Law in Support of Its Motion for Summary Judgment of Non-Infringement of U.S. Patent Nos. 6,248,735 and 6,316,443 (Docket Entry No. 35)
Apo. Opp. Br.	Apotex Inc's Brief in Opposition to Merck's Motion to Dismiss Counts IV-VII of Apotex Inc.'s Counterclaims for Lack of Subject Matter Jurisdiction (Docket Entry No. 46)
Alul Decl. __	The Declaration of Andrew M. Alul and corresponding exhibits filed in support of Apotex's Opposition Brief (Docket Entry No. 46)
FDA	United States Food & Drug Administration
Hi-Tech	Hi-Tech Pharmacal Co., Inc.
Hughes Exh. __	The Declaration of Heather M. Hughes and corresponding exhibits filed in support of Merck's Motion to Dismiss Counts IV-VII of Apotex Inc.'s Counterclaims for Lack of Subject Matter Jurisdiction. (Docket Entry No. 33)
Merck	Merck & Co., Inc. – The plaintiff in suit
Orange Book	The FDA's publication, *Approved Drug Products with Therapeutic Equivalence Evaluations*
USPTO	United States Patent and Trademark Office
Zogby Exh.__	The Declaration of Michael C. Zogby and corresponding exhibits filed in support of Merck's Memorandum of Law in Opposition to Apotex's Motion for Summary Judgment of Non-Infringement of U.S. Patent Nos. 6,248,735 and 6,316,443 (Docket Entry No. 45)
Zogby Second Decl., Exh. __	The Declaration of Michael C. Zogby and corresponding exhibits filed in support of this Reply Memorandum of Law

'413 Patent	U.S. Patent No. 4,797,413
'735 Patent	U.S. Patent No. 6,248,735
'443 Patent	U.S. Patent No. 6,316,443

I. INTRODUCTION

As the party asserting declaratory counterclaims, Apotex bears the burden of proving facts sufficient to establish jurisdiction. *See Indium Corp. v. Semi-Alloys, Inc.*, 781 F.2d 879, 883 (Fed. Cir. 1985). Apotex's counterclaims seek to have this Court do an impermissible act – render a judgment on the merits on an issue for which it has no subject matter jurisdiction. Lacking jurisdiction, the Court can only announce that fact and dismiss the claims. *See Local 1498, Am. Fed'n of Gov't Employees v. Am. Fed'n of Gov't Employees*, 522 F.2d 486, 492 (3d Cir. 1975) ("No matter how sympathetic we might be to plaintiffs' plight, where federal courts are without jurisdiction we are only to announce that fact and do no more.").

Apotex's counterclaims do not seek a construction of the claims of the disclaimed '735 and '443 patents, nor do they seek a determination that Apotex's product is outside the scope of those claims. Apotex's sole argument is that it does not infringe because the patents do not exist – an assertion that self-proves the absence of subject matter jurisdiction.

Finding itself with a position devoid of legal merit, Apotex tries to lead this Court into legal error by:

- Irresponsibly casting slurs on Merck, all of which are unsubstantiated and untruthful.

- Asserting blatant falsehoods that are contradicted by Apotex's own prior admissions.

- Concocting a "hard luck" story that Apotex is somehow being unfairly deprived of some purported right to usurp a prior generic certifier's claim to marketing exclusivity, when Apotex knew full well that it was precluded by that claim when it filed its ANDA.

Apart from the fact that they seek to mislead the Court, Apotex's misrepresentations and contrived posturing are irrelevant because, even if they were true, they would not alter the fact that there is no case or controversy between Apotex and Merck, because the subject patents no longer exist and Merck has not, and cannot, assert them against anyone.

II. FACTUAL SUMMARY

Because Apotex omits some facts and misstates others, Merck will briefly reprise the salient facts.

Hi-Tech, another generic company, filed an ANDA for a generic version of the COSOPT® product on October 7, 2005. (Zogby Exh. A, p. 7) Hi-Tech's ANDA and its subsequent notice letter to Merck challenged the enforceability of the '413 patent and the validity of the '735 and '443 patents (a "paragraph IV certification"). (Zogby Exh. B) In December 2005, the FDA website publicly announced that a paragraph IV certification had been filed, and on January 18, 2006, Merck sued Hi-Tech in this Court, asserting infringement of the '413 patent, but not the '735 or '443 patents. (Hughes Exh. 9)

Under the provisions of the Hatch-Waxman Act,[1] Hi-Tech, by making the first challenge to Merck's listed patents, became entitled to 180 days of marketing exclusivity over any subsequent challenger. 21 U.S.C. §§ 355(j)(5)(B)(iv). Because both the FDA website and Merck's complaint were public, Apotex was well aware that there was a prior generic challenger for the COSOPT® product months before it chose to file its own ANDA.

On April 18, 2006, Merck filed disclaimers of the '735 and '443 patents with the USPTO. (Hughes Exhs. 10 & 11) The legal effect of the disclaimers was that the claims of the patents were expunged, *nunc pro tunc*, as Apotex correctly stated in its opening summary judgment brief,[2]

> The Federal Circuit has interpreted the term 'considered as part of the original patent' in § 253 to mean that the patent is treated as though the disclaimed claims never existed. (Apo. SJ Br. at 11)

Further, Merck wrote to the FDA on April 26 and requested that the agency remove those patents from its "Orange Book". (Hughes Exh. 12)

On April 25, 2006, this Court denied Hi-Tech's motion to dismiss the complaint based on the '413 patent and granted Merck's cross-motion for

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[1] The Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984).

[2] Citing *Vectra Fitness Inc. v. TNWK Corp.*, 162 F.3d 1379 (Fed. Cir. 1998), *cert denied*, 526 U.S. 1160 (1999); *see also Guinn v. Kopf*, 96 F.3d 1419, 1422 (Fed. Cir. 1996) ("[T]he patent is viewed as though the disclaimed claims had never existed in the patent.").

judgment on the pleadings. *See Merck & Co., Inc. v. Hi-Tech Pharmacal Co., Inc.*, Nos. 06-266 and 06-268 (consolidated) (D.N.J. April 25, 2006).

Although Apotex asserts that it filed its ANDA before Merck made the disclaimers, it did not send a notice letter to Merck until October 23, 2006, six months after the disclaimers were filed. (Hughes Exh. 14) In that notice letter, Apotex parroted Hi-Tech's "unenforceability" defense to the '413 patent (even though it had already been adjudicated favorably to Merck) and cited and relied affirmatively on the disclaimers of the '735 and '443 patents saying, in part:

> Therefore, the effect of statutory disclaimer is that the claims are dedicated to the public and are not enforceable by the assignee, nor can the claims be infringed. (Hughes Exh. 14, p. 5)

Merck sued Apotex in this Court for infringement of the '413 patent, but did not assert either the '735 or '443 patents. (Hughes Exh. 3) Apotex agreed to be bound by the appellate decision on the '413 patent in the Hi-Tech case (Hughes Exh. 17), and, on March 29, 2007, the appeals court affirmed this Court's decision favorable to Merck. *See Merck & Co., Inc. v. Hi-Tech Pharmacal Co., Inc.*, 2007 WL 926284 (Fed. Cir. March 29, 2007). This Court then entered judgment for Merck in this case for that patent, leaving only Apotex's counterclaims on the disclaimed patents for disposition. (Docket Entry No. 39)

As a result of Merck's lawful assertion of the '413 patent and its disclaimers of the '735 and '443 patents:

- Hi-Tech will be free of all patent barriers to its marketing of a generic version of the COSOPT® product on October 28, 2008.[3]

- Apotex will be free of all patent barriers and Hi-Tech's marketing exclusivity 180 days after Hi-Tech begins selling its product. 21 U.S.C. § 355(j)(5)(B)(iv).

In short, Apotex has obtained every marketing right to which it is legally entitled and its goal here is not to preserve any of its rights, but rather to obtain a fictitious judgment on the merits on non-existent patents as a device to circumvent the statutory scheme and deprive Hi-Tech, the more diligent ANDA filer, of its right of marketing exclusivity.

III. ARGUMENT

A. Apotex's Attacks On Merck Are Irresponsible and Baseless

Throughout its opposition brief, Apotex makes totally unfounded and irresponsible attacks on Merck. For example,

> "[Merck's] subsequent gaming of the legislative and regulatory scheme… to delay generic competition." (Apo. Opp. at 1)
>
> "Merck's transparent attempt to manipulate this Court's jurisdiction and continue delaying Apotex's approval." (Apo. Opp. at 2)
>
> "Merck blatantly attempts to manipulate this Court's jurisdiction…" (Apo. Opp. at 11)

[3] That reflects the expiration of the patent on April 28, 2008 plus six months of additional exclusivity earned by Merck by conducting FDA-requested pediatric clinical studies.

While counsel may be expected to exhibit litigious zeal, those comments are totally out of line and baseless. What Merck did – and all that it did – was to disclaim two patents that, if asserted, could have provided it exclusivity until 2011, thus removing any patent barrier to generic marketing after the '413 patent expires, and then twice requested that the FDA remove the disclaimed patents from its Orange Book. (Hughes Exhs. 12 & 16) Merck made the disclaimers and requested the FDA to "delist" the patents months before it was aware of any ANDA filed by Apotex or by any other entity. That is the antithesis of "gaming the legislative and regulatory scheme."

Apotex repeatedly chides Merck for declining to accede to Apotex's demand that Merck enter into a consent judgment on the merits. (Apo. Opp. at 2, 12, 17, 19, 22, 25). For example,

> To resolve this matter amicably, Apotex requested a consent judgment of non-infringement to clear the way for approval. (Alul Decl. Tab G) But Merck refused and revealed its true intent here: to continue using its '735 and '443 patents to block Apotex's approval indefinitely. (Apo. Opp. at 12)

Apart from the facts that Merck is not "using" the disclaimed patents, has no such "intent", and Apotex's approval is not blocked "indefinitely", what Apotex asked Merck to do was join with it in leading this Court into legal error. Because the Court lacks subject matter jurisdiction, it cannot enter a judgment on the merits, no matter how much one party wants it, or even if both parties consent to it. *See*

Merck & Co., Inc. v. Apotex, Inc., No. 06-230 (D. Del. April 10, 2007) (granting plaintiff's motion to dismiss for lack of subject matter jurisdiction). Indeed, if Merck had joined Apotex in requesting that impermissible result, it would have been incumbent on the Court *sua sponte* to examine its jurisdiction and it would necessarily have concluded it could not give the requested judgment. *See Amusement & Music Operators Assoc. v. The Copyright Royalty Tribunal*, 636 F.2d 531, 533 (D.C. Cir. 1980) ("[P]arties cannot by mutual consent confer subject matter jurisdiction where it does not otherwise exist; the Court, sua sponte, must consider jurisdictional difficulties that it perceives.").

Apotex urges, as "evidence" of Merck's purported motive, Apotex's counsel's self-serving, litigation-motivated email diatribe (Alul Decl., Tab G), conveniently omitting mentioning that Merck, in response, (i) pointed out the fatal jurisdictional defect and (ii) offered to stipulate to the facts and enter into the same form of stipulation of dismissal that Apotex's counsel had agreed to in a prior case. (Zogby Second Decl., Exh. 1)

B. Apotex Misstates The Facts Of This Case

Repeatedly, Apotex seeks to mislead this Court by mischaracterizing the facts of this case, as shown below.

Apotex's Mischaracterization

> The '735 and '443 patents pose two very significant obstacles for Apotex and its proposed generic product. The first,

> of course, is potential infringement liability, both for Apotex and its prospective customers. (Apo. Opp. at 1-2)[4]

The Correct Facts

Apotex's assertions that it and its customers face infringement risks are plainly disingenuous. As Apotex has previously admitted:

> On or about April 18, 2006, Merck submitted to the PTO a Statutory Disclaimer, disclaiming the entire interest in claims 1-27 of the '735 patent. ... In view of the Statutory Disclaimer described above and because claims 1-27 of the '735 patent have been disclaimed, they cannot be infringed. (Hughes Exh. 14, p. 17)

> On or about April 18, 2006, Merck submitted to the PTO a Statutory Disclaimer, disclaiming the entire interest in claim 1-17 of the '443 patent. ... In view of the Statutory Disclaimer, claims 1-17 of the '443 patent cannot be infringed. (Hughes Exh. 14, p. 22)

Apotex's Mischaracterization

> Whether the patents are enforceable due to a disclaimer is a question to be decided on the merits as part of Apotex's pending motion for summary judgment of non-infringement...." (Apo. Opp. at 19)

The Correct Facts

There is no "question" about whether the disclaimed patents are unenforceable. Again, the best evidence is Apotex's own words:

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[4] Similarly: "Apotex's harm includes both potential infringement liability...." (Apo. Opp. at 17); "...the parties have clear and adverse legal interests regarding infringement of the patent-in-suit" (Apo. Opp. at 18); "such a decision would not only give Apotex and, just as importantly, its customers, patent certainty...." (Apo. Opp. at 23)

> Once a patent term has ended a patent is no longer enforceable and an ANDA applicant risks no liability to the patent holder. (Hughes Exh. 14, p. 1) (emphasis added)
>
> As noted, a patent can be statutorily disclaimed by the assignee. By doing so, the assignee relinquishes legal rights to the patent, including the right to enforce said patent. Therefore, the effect of a statutory disclaimer is that the claims are dedicated to the public, are not enforceable by the assignee... (Hughes Exh. 14, p. 5) (emphasis added)

Apotex's Mischaracterization

> The second and more important [obstacle] here, however, is that Apotex cannot even obtain FDA approval to market a competing generic product in the first place without obtaining a declaratory of non-infringement and/or invalidity in its favor. ... Apotex's harm includes not only potential infringement liability, but its inability to obtain approval of its non-infringing generic product and to compete in the market in the first place. ... The purported disclaimer does nothing to alleviate the harm caused by Apotex's inability to obtain the approval needed to enter the market in the first instance with a competing generic product, as it is entitled to do. (Apo. Opp. at 2)[5]

The Correct Facts

Provided Apotex satisfies the FDA that its ANDA meets the agency's technical requirements (which so far it has not done), Apotex will get its regulatory approval immediately after the expiration of Hi-Tech's 180 days of marketing exclusivity. It does not need a judgment here to obtain that. That barrier to

[5] Similarly: "Apotex can obtain approval of its ANDA and compete in the dorzolamide hydrochloride/timolol maleate ophthalmic solution market only by obtaining a judgment of non-infringement on the '735 and '443 patents." (Apo. Opp. at 11)

Apotex's marketing is the one that Congress created and results from the fact that Hi-Tech pursued its ANDA more diligently than Apotex did. Apotex is not "entitled" either to circumvent the statutory scheme or deprive Hi-Tech of the benefit that Congress decreed.

Apotex's Mischaracterization

> Apotex intends to market its generic product before expiration of '413, '735 and '443 patents; to that end, after Merck listed those patents, Apotex filed its ANDA and included a Paragraph IV Certification to the '413, '735 and '443 patents, stating that these patents are invalid, unenforceable, and/or not infringed by Apotex's proposed generic dorzolamide/timolol ophthalmic solution. (Apo. Opp. at 10)

The Correct Facts

Apotex cannot market a generic product prior to the expiration of the '413 patent. It stands enjoined by this Court in a non-appealable order until that patent and Merck's pediatric exclusivity expire on October 28, 2008. (Docket Entry No. 39)

Apotex's Mischaracterization

"The purported disclaimer of ... the '735 patent and ... the '443 patent ..." (Apo. Opp. at 1, 2 (two occurrences), 12, 18, 19, 21)

The Correct Facts

There is nothing "purported" about the disclaimers. They are real, final and irrevocable. As Apotex said in its notice letters, "To protect the public, ...

disclaimers are final and irrevocable. Indeed, 35 U.S.C. § 253 does not include a mechanism for withdrawal or amendment of a … disclaimer." (Hughes Exh. 14, p. 2) And, as noted above, the effect of those disclaimers is, in Apotex's own words "as though the disclaimed claims never existed." (Apo. SJ Br. at 11)

Apotex's Mischaracterization

> A real and immediate controversy exists between adverse parties because Merck's conduct creates a bottleneck that delays Apotex from receiving FDA approval, just as assuredly as if Merck had successfully enforced the '735 and '443 patents against Apotex. (Apo. Opp. at 17) … FDA approval of Apotex's ANDA will not be made effective until 180-days after that first commercial marketing of the first filer's generic COSOPT®, which will likely not occur until sometime after October 28, 2008 … if at all, as settlement between brand name drug companies and first filers that keep the first filer off the market in order to 'park' a 180-day exclusivity period have been found by the Federal Trade Commission to be a real tactic used by the brand name drug companies. (Apo. Opp. at 22)[6]

The Correct Facts

First, if Merck had "successfully enforced the '735 and '443 patents against Apotex", Apotex would be barred from marketing until 2011, but because of the disclaimers, Apotex will be free to sell in 2009.

Second, the argument that Hi-Tech may not sell when it has the right to do so, and the suggestion that Merck may have a settlement that will delay Hi-Tech's

[6] Similarly: "The harm to Apotex of indefinite delay in approval" (Apo. Opp. at 22); "Otherwise the approval of Apotex's competing generic product will be delayed indefinitely." (Apo. Opp. at 25)

marketing are contrived strawmen. Hi-Tech litigated vigorously and there is no rational reason why it would forgo the benefit of its marketing exclusivity as soon as it is able to sell. Nor does Apotex cite any factual basis for the "settlement" speculation – because there is none. Apotex thus relies on alleged delays and schemes for which there is no evidence at all and which, in any event, could not be the source of any "immediate" or "imminent" harm to Apotex, which, under this Court's existing injunction, is foreclosed from marketing prior to October 2008.[7]

Apotex's "indefinite delay" argument is contrived and baseless.

C. Apotex's Contrived "Hard Luck" Story

Apotex complains of the fact that it will not be able to sell until Hi-Tech has enjoyed its 180 days of marketing exclusivity. That is not an unusual result, nor is it an unfair one. Hi-Tech completed its ANDA and filed it many months before Apotex did. That marketing exclusivity is the lawful result ordained by Congress for a first certifier.

Apotex chose to take advantage of the liberalized ANDA procedures established by the Hatch-Waxman Act, allowing it to avoid doing expensive clinical studies and rely on Merck's data. With those advantages come

[7] If there were any basis for subject matter jurisdiction (and there is not), the absence of any imminent harm and Apotex's speculation of what might happen in late 2008 would justify the Court's exercise of discretion to decline it. *See Zimmerman v. HBO Affiliate Group*, 834 F.2d 1163, 1170 (3d Cir. 1987).

concomitant restrictions. When Apotex filed its ANDA, it was fully cognizant that it was not the first certifier and well aware of the consequences of being second. Although Apotex asserts it is "entitled" to get FDA approval (Apo. Opp. at 2) and it is subject to a generic "bottleneck" that contravenes Congress's intent (Apo. Opp. at 7, 8 & 11), those assertions are 180° out of congruence with reality. In fact, it is Hi-Tech, not Apotex, that is "entitled" to earlier marketing, and that result is precisely what Congress intended when it created the incentive of marketing exclusivity for early patent challenges. Apotex nowhere justifies its attempts to trample on Hi-Tech's rights and, as noted above, it provides not a shred of evidence that Hi-Tech intends to "park" those rights or that there is any other "abuse" that might justify such a result.

If Apotex is unhappy with the statutory scheme, its remedy is to petition Congress to change it. If it is unhappy that the FDA declined Merck's two requests to remove the disclaimed patents from the Orange Book, its remedy is to petition and, if it thinks justified, sue the agency. But it is not entitled to ask this Court to do an act that is precluded by its jurisdictional restrictions.

D. The Recent Supreme Court And Federal Circuit Decisions Do Not Undo The Constitutional Restriction On Jurisdictions

Apotex cites the recent decisions in *MedImmune*, *SanDisk*, and *Teva Pharm.*[8] and argues they signaled the death knell of the "reasonable apprehension of suit" test for declaratory judgment jurisdiction. (Apo. Opp. at 12-16)

Merck discussed each of those decisions in detail in its opening brief on its motion to dismiss (at pages 7-9) and respectfully invites the court's attention to that discussion. By way of summary, the common thread of all those cases was the existence of live patents under which the declaratory plaintiff faced an ongoing risk of infringement. By contrast, here, neither of the subject patents is alive and, contrary to Apotex's fruitless attempts to contradict its own prior admissions, no one – not Apotex, not its customers, not anyone else – has any potential liability for infringement.

Apotex argues that it meets the criteria for declaratory relief because:

> "This dispute is ripe because Merck's conduct causes immediate injury to Apotex. … Apotex continues to suffer an actual and imminent injury-in-fact. ... Apotex is suffering: the inability to promptly launch its generic [product]." (Apo. Opp. at 17-18)

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[8] *MedImmune, Inc. v. Genentech, Inc.*, 594 U.S. __, 127 S. Ct. 764 (2007); *SanDisk Corp. v. STMicroelectronics, Inc.*, 2007 WL 881008 (Fed. Cir. March 26, 2007); *Teva Pharm. USA, Inc. v. Novartis Pharm. Corp.*, 2007 WL 942201 (Fed. Cir. March 30, 2007).

Merck's conduct has not caused any injury to Apotex, much less "immediate" or "imminent" injury. Because Apotex has been adjudged an infringer of the lawfully asserted, valid, enforceable '413 patent, even apart from Hi-Tech's marketing exclusivity, Apotex is enjoined from selling before October 28, 2008.

IV. CONCLUSION

Apotex's slurs, mischaracterizations and hard luck story are contrived, but are an irrelevant smokescreen. The single operative fact is that this Court cannot give a judgment on the merits on patents that do not exist and that Merck does not, and cannot, seek to enforce. There is no live case or controversy between Apotex and Merck, hence no subject matter jurisdiction for Apotex's counterclaims, which should simply be dismissed on that basis.

Respectfully submitted,

Dated: May 17, 2007

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