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April 4, 2007

VIA E-FILING

The Honorable Gregory M. Sleet
United States District Court
Federal Building
844 North King Street
Wilmington, DE 19801

Re: *Merck & Co., Inc. v. Apotex, Inc.*
C.A. No. 06-230

Dear Judge Sleet:

Apotex's letter of yesterday under Local Rule 7.1.2(c) calls the Court's attention to the very recent Federal Circuit case of *Teva Pharmaceuticals USA, Inc. v. Novartis Pharmaceuticals Corp.*, No. 06-1181 (Fed. Cir. March 30, 2007). In that case, the Federal Circuit recognized that the Supreme Court's decision in *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. ____, 127 S.Ct. 764 (2007) overruled the Federal Circuit's apprehension of suit test for declaratory judgment jurisdiction in favor of the broader principles of an actual justiciable controversy in earlier Supreme Court precedent.

Neither the *Teva* case nor *MedImmune* itself supports the notion that Apotex may maintain a declaratory judgment action in the face of the comprehensive covenant not to sue that Merck has given to Apotex. There is no suggestion in either case that the well established rule of *Super Sack Mfg. Corp. v. Chase Packaging Corp.*, 57 F.3d 1054 (Fed. Cir. 1995) is in any way altered. In fact, as elaborated below, *Teva* confirms that *Super Sack* is still the law.

Apotex's summary of the facts of the *Teva* case is selective and incomplete. In that case, Novartis sued on the first-to-expire of five Orange Book patents covering the drug FAMVIR[®] or its mode of use. This placed Teva at risk under the first "composition" patent and procured a 30 month stay against approval of Teva's ANDA. The remaining four method of use patents still presented a threat to Teva if the first action was unsuccessful. The Teva court specifically noted that Novartis declined to give Teva a covenant not to sue. Teva's declaratory judgment action was instituted against the four withheld patents under the provisions of 21 U.S.C. § 355(j)(5)(C). Under this provision, if the patentee or NDA holder does not sue on an

Orange Book patent after receiving notice of a Paragraph IV certification, the ANDA applicant may bring a declaratory action to obtain “patent certainty.”

Consequently the statute contemplated a declaratory judgment solution for exactly the situation in which Novartis placed Teva. As the Federal Circuit said, “Novartis has tried to simultaneously leverage the benefits under the Hatch-Waxman Act [the 30-month stay] and avoid the patentee’s accompanying responsibilities.” *Teva* at 16. And the legislative history of § 355(j)(5)(C) cited in *Teva* acknowledges that a covenant not to sue (which was not involved in the *Teva* case) abrogates the right to bring a declaratory judgment:

The provision [a "civil action to obtain patent certainty"] . . . is intended to clarify that Federal district courts are to entertain such suits for declaratory judgments so long as there is a "case or controversy" under Article III of the Constitution. We fully expect that, in almost all situations where a generic applicant has challenged a patent [by filing an ANDA with a paragraph IV certification] and not been sued for patent infringement, a claim by the generic applicant seeking declaratory judgment on the patent will give rise to a justiciable "case or controversy" under the Constitution. **We believe that the only circumstance in which a case or controversy might not exist would arise in the rare circumstance in which the patent owner and brand drug company have given the generic applicant a covenant not to sue, or otherwise formally acknowledge that the generic applicant's drug does not infringe.**

Teva, at 17 (emphasis added).

The essential element of federal jurisdiction is a controversy or dispute that is “definite and concrete, touching the legal relations of parties having *adverse legal* interests.” See *MedImmune* at 7-8, *Teva* at 6. As the legislative history of the very provision on which Teva brought its declaratory actions makes clear, a covenant not to sue removes the basis of any such controversy between the parties. Likewise, in the present case, Merck’s covenant not to sue has removed any adversary character from the legal relationship between Merck and Apotex concerning the patents in suit.

The parties who will be most affected if Apotex is successful in provoking a “triggering event” under the Hatch-Waxman Act are Teva Pharmaceuticals and Barr Laboratories, not Merck. Teva and Barr were the first filers of ANDAs directed to FOSAMAX® for the treatment for osteoporosis and Paget’s disease, and were the first to challenge Merck’s patents. Although Merck is uncertain about the relative rights of Teva and Barr, they currently have or share a statutorily mandated marketing exclusivity as against all other generic drug manufacturers for a period of 180 days after the expiration of Merck’s acknowledged exclusivity to market once weekly doses of FOSAMAX®. That is the same drug as to which Apotex is

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seeking rights in this case. What Apotex is admittedly attempting to do in this case is to destroy that 180-day exclusivity period of others by insisting on a merits litigation on patents for which it has a covenant not to sue. If the Court is concerned about the implications of the unusual issues of this case and their impact on the parties, Merck suggests that Teva and Barr at least be invited to be heard as interested third parties with respect to Apotex's effort to create a triggering event to unseat the 180-day exclusivity of Teva or Barr (or both).

MedImmune, Teva and *Super Sack* make it clear that declaratory judgment jurisdiction requires a concrete dispute regarding the subject matter of the litigation that affects the legal relationship *between the parties*. Merck has no patent controversy with Apotex about the patents in this case. Hence, Merck's motion to dismiss should be granted.

Respectfully,

/s/ Mary B. Graham

Mary B. Graham (#2256)

MBG/dam

cc: Clerk of the Court (via hand delivery)
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