# A Clever Idea that Failed: An Unsolicited Covenant Not to Sue Does Not Deprive an ANDA Filer of Standing to Sue

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*The Hatch-Waxman Act* authorizes generic drug makes to submit an abbreviated new drug application ("**ANDA**") for drugs that are the bioequivalent of previously approved drugs. When the approved drug is protected by unexpired patents listed in the Orange Book, the ANDA filer may file a Paragraph IV certification, declaring that the listed patents are invalid. This declaration is an act of infringement, enabling either party to commence an infringement suit. The first person to file a reasonably complete ANDA filing with a Paragraph IV certification will eventually obtain a 180-day right to be the only generic maker of that drug. The 180 period commences upon the first to occur of (i) the commercial marketing of the generic drug, (ii) a court determination of patent invalidity, and (iii) the expiration of the patents.

Brand drug makers will sometimes craft strategies intended to cause the first ANDA filer's actions to create a logjam that will prevent subsequent ANDA filers from coming to market for an extended period of time. For example, brand drug companies have sometimes paid the first ANDA filer to stay out of the market, a practice that the FTC has attacked as recently as February 2008, with mixed success.

Brand drug makers have also simply not commenced an infringement action against the ANDA filer, leaving the filer with no standing (until recently) to sue for a declaratory judgment, and no way to commercialize the generic drug without running the risk of infringement. This strategy was foreclosed by a 2003 amendment to the Federal Food, Cosmetic and Drug Act granting standing to the first ANDA filer to file a declaratory judgment action. Although some ANDA filers still encountered standing issues, *MediImmune v. Genentech*, 127 S. Ct. 764 (2007) laid them to rest. Brand drug makers refined their strategies by suing for infringement on one of the patents listed in the Orange Book, but not on the others. Recent court cases have eliminated this as a viable strategy. See *Teva Pharmaceuticals v. Novartis*, 482 F.3d 1330, 1342 (Fed. Cir. 2007).

In *Caraco Pharmaceutical Laboratories Ltd. v. Forest Laboratories Inc.*, (Fed Cir. April 1, 2008) (No. 2007-1404), the Federal Circuit was faced with a novel approach. That case involved Lexapro, which is covered by two patents listed in the Orange Book. The first ANDA filing was made by Ivax Pharmaceuticals. Before the *MediImmune* decision was rendered, Forest Labs sued Ivax for infringement of one of the two patents, and was successful. Caraco Pharmaceutical filed a second ANDA certification and sued for a declaratory judgment that both of the Lexapro patents were invalid. Forest tried to thwart Caraco with respect to one of the patents by granting Caraco (but not Ivax) an unsolicited covenant not to sue. Forest then argued that Caraco lacked standing to litigate the validity of that patent because there was no case or controversy, and thus no jurisdiction under Article III of the Constitution. The three-judge panel of the Federal Circuit, in a divided opinion, disagreed.

The Federal Circuit panel, in a divided opinion, viewed *MediImmune* as authority to look at the totality of the circumstances to determine whether there was a case or controversy. The panel explained why Caraco's ability to proceed to market with its generic drug would be thwarted absent a ruling concerning both patents. According to the panel, Caraco would in any event have to await the expiration Ivax's 180-day period of exclusivity, which as a practical matter could not commence absent a court ruling concerning both patents. Since substantial rights depend on that resolution, and since Caraco had joined the issue with its ANDA filing, the panel found there to be a case or controversy.

The implications of this case might be limited to situations involving second ANDA filers who are trying to

clear a logjam presented by a stalemate involving the first ANDA filer. But this case may also have implications for first ANDA filers because brand manufacturers will not be able to deprive them of the ability to obtain a judicial resolution of all patents listed in the Orange Book simply by providing a covenant not to sue.

The stakes in these cases are high, giving rise to substantial strategic creativity. One more arrow has been removed from the quiver of the brand manufacturers. They will without doubt create others.