

More than One Year Later – MMA's Effect on Hatch-Waxman

The 2003 amendments to the Hatch-Waxman Act were enacted as part of the Medicare Modernization Act of 2003 ("MMA"). These amendments significantly changed the rules Specialty Pharma must follow in order to obtain FDA approval/entry into the marketplace for either AB-rated or branded generic products. In October 2004, FDA issued a guidance with the intention of clarifying how it viewed the changes made by MMA to the FDA review process for ANDA/505(b)(2) drug products. This article considers some of the important changes made with respect to 30-month stays of FDA approval, the requirements for notice of patent certifications, the awarding of 180-day exclusivity, and litigation strategies.

The changes made under MMA were quite significant indeed. Prior to enactment of MMA, it was possible that an ANDA or 505(b)(2) filer could be subjected to multiple 30-month stays of approval if a paragraph IV challenge was filed with respect to Orange Book-listed patents and a patent infringement litigation was then instituted by the NDA holder. Generally, under the MMA, it is no longer possible for an NDA holder to “stack” 30-month stays, i.e., obtain multiple 30-month stays by virtue of paragraph IV notifications filed against later-listed patents. MMA does not allow a 30-month stay of approval of an ANDA or 505(b)(2) based on patents which are submitted to the FDA Orange Book by the NDA holder (i) after August 18, 2003 and (ii) on or after the date which an ANDA or 505(b)(2) application was filed. Although a “late listed patent” can no longer be used to obtain a 30-month stay, the ANDA or 505(b)(2) filer is still obligated to file a certification to the patent, and is obligated to provide notice of a paragraph IV certification to the patent owner or NDA holder within 20 days of filing the paragraph IV certification.¹ If the NDA holder or patent owner initiates an action for patent infringement within 45 days of receiving notice of a paragraph IV certification, then the 30-month stay of approval is evoked.²

¹ The FDA Guidance of October 2004 clarifies that the new rule supercedes the Final (FDA) Rule which became effective on August 18, 2003.

² This 30-month stay may be shortened or lengthened by the court.

The FDA Guidance issued in October 2004 makes it clear that there are still some certain circumstances in which multiple 30-month stays are possible. One example provided in the Guidance concerns the situation where a first 30-month stay can be obtained against an ANDA or 505(b)(2) application containing a paragraph IV certification to a listed patent. If the same ANDA or 505(b)(2) application also contains a paragraph III certification for a different listed patent which was submitted before August 18, 2003 *and/or before the filing of the ANDA or 505(b)(2) application*, a second 30-month stay may be available against the ANDA or 505(b)(2) application if the paragraph III certification is amended to a paragraph IV certification.

The FDA Guidance of October 2004 further clarifies the impact of a district court decision concerning invalidity or non-infringement of an ANDA product with respect to the 30-month stay of approval and the trigger of 180-day exclusivity. A district court decision to that effect terminates the 30-month stay of approval, thus allowing FDA to render a final approval of an ANDA if it is otherwise ready for approval. On the other hand, 180-day exclusivity for an ANDA is not triggered until there is a final decision by the courts (e.g., by the Court of Appeals for the Federal Circuit, or an unappealed district court finding of invalidity and/or non-infringement).

Another landmark change in the law provided by the MMA concerns the awarding of 180-day exclusivity to the first ANDA filer who files a paragraph IV challenge to an Orange Book-listed patent. Under the old law, the FDA could not make the approval of subsequent ANDAs for the same drug product effective until the expiration of the “first-to-file” applicant’s 180-day exclusivity period. The 180-day exclusivity period was triggered by the earlier of (i) the commercial launch of the first-to-file applicant’s ANDA product, or (ii) the date of a decision of a court holding the challenged Orange Book patent(s) either invalid or not infringed. The old rules put the first-to-file applicant in the uncomfortable (and dangerous) position of having to launch after the first court decision in its favor (e.g., at the district court level) in order to take advantage of its 180-day exclusivity, because the clock was triggered by that first

decision. The old law allowed for “patent-based” 180-day exclusivity, whereby the exclusivity was attached to the first-to-file challenge to each Orange Book-listed patent. In circumstances where different applicants were the “first-to-file” challenges on different Orange Book-listed patents for the same drug product, FDA adopted a rather messy and difficult “shared exclusivity” approach under which each first-to-file applicant shared the 180-day exclusivity period.

The revised provisions under MMA provide “product-based” 180-day exclusivity. Exclusivity now attaches to the first-to-file challenger to any Orange Book patent on a particular drug product. In general, the only circumstance where there can be shared exclusivity is the case where more than one “substantially complete” ANDA application is filed on the same day (by more than one ANDA filer). First filers on subsequently (late) listed Orange Book patents do not have the opportunity to gain shared exclusivity, in contrast to the situation under the old rules.

To illustrate, imagine the circumstance where an NDA holder has listed two patents in the Orange Book as covering its (brand) product. The first company to file a patent challenge only challenges (i.e., files a paragraph IV certification) against one of the Orange Book-listed patents, and does not challenge the other Orange Book-listed patent (e.g., the first filer files a paragraph III certification stating that it will wait until that patent expires prior to marketing). Shortly thereafter, a second company files a patent challenge (paragraph IV certification) against both patents. Under the old rules, there would have been shared 180-day exclusivity as each company was the first to file a patent challenge to an Orange Book-listed patent. Under the new rules, only the first filer would be entitled to 180-day exclusivity (if at all).

The new rules also take into consideration many of the circumstances that happened under the old rules which resulted in delayed launch or no launch of a generic product due to the use of the old 180-day exclusivity provisions, including the example presented above. Specific forfeiture provisions now exist by virtue of the MMA³.

³ Id. at subparagraphs (D)(i) and (D)(ii)

Furthermore, if the first applicant forfeits the 180-day generic exclusivity under any of these specific forfeiture provisions of the MMA, no subsequent ANDA applicant will be eligible for 180-day exclusivity.⁴ Also, the Act clarified that the 180-day period starts upon marketing the ANDA or the NDA product, eliminating situations where the ANDA filer marketed the brand product and the 180-day exclusivity period never began (thereby blocking final approval of subsequent ANDAs). The FDA Guidance of October 2004 clarifies that the new provisions relating to 180-day exclusivity govern only ANDAs filed after the date of enactment of the MMA (December 8, 2003) that reference a listed drug for which no paragraph IV certification was made in any ANDA before that date, except that the new provisions concerning forfeiture of the 180-day exclusivity and the triggering of the exclusivity period by judicial action apply for earlier ANDAs.

There are six grounds for forfeiture listed in the Act. The first ground is failure of the first filer to market its generic product by the *later* of one of a number of possible occurrences: (1) the *earlier* of the date that is 75 days after the date on which approval of its ANDA is made effective; or 30 months after the date of submission of its ANDA; (2) 75 days after (i) a final decision (from which no appeal can be taken, other than a petition to the Supreme Court for a writ of certiorari) is entered by a court in an infringement action to the effect that, as to each of the patents challenged by the first filer (paragraph IV certification), each patent is invalid or not infringed; or (ii) 75 days after 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; (3) the first filer withdraws the application or the application is considered to have been withdrawn because it does not meet the requirements for approval; (4) the first filer amends or withdraws its paragraph IV certification for all of the patents with respect to which its claim to 180-day exclusivity was based; (5) the first filer fails to obtain tentative approval of the application within 30 months after the application filing date (thereby coinciding with the end of the 30-month stay); (6) the first filer enters into an agreement with another applicant, 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), and the Federal Trade Commission or the

⁴ Id. at subparagraph (D)(iii)

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 antitrust laws⁵; or (7) expiration of all patents which the first filer submitted a paragraph IV certification.

Considering my previous illustration, the first filer could eventually forfeit exclusivity if, for example, it obtained a final court decision of patent invalidity or non-infringement based on the first patent, but could not launch its generic product within 75 days of that decision is entered by the court (e.g., because the second patent was still in existence). Once the first filer is deemed to have forfeited its 180-day exclusivity, any subsequent ANDA filer could expect to launch its generic product immediately upon resolution of any patent issues and receiving final FDA approval.

To date, there have not been many published court decisions dealing with 180-day exclusivity under the new rules. One significant decision does stand out. In Teva Pharm. v. F.D.A., 2004 U.S. Dist. Lexis 26233, Teva and Purepak were awarded 180-day exclusivity to market generic versions of gabapentin, which is marketed by Pfizer under the brand Neurontin[®]. During the 180-day exclusivity, Pfizer launched a generic version of gabapentin. Since the Hatch-Waxman Act did not prevent the NDA holder from marketing a generic, Teva's petition to prevent Pfizer's generic gabapentin was denied by the Court. Although this decision dealt with an ANDA filed prior to 2003 MMA, this outcome flies in the face of the legislative intent to give incentive to paragraph IV patent challengers with 180-day exclusivity if successful. Nevertheless, this situation is not addressed in the new rules.

Prior to the new rules, even if the NDA holder/patent owner did not bring suit against an ANDA filer based on Orange Book-listed patents, the ANDA nevertheless faced the uncertainty of going through the entire FDA review and possibly launching its

⁵ As defined in section 1 of the Clayton Act (15 U.S.C. 12) and section 5 of the Federal Trade Commission Act (15 U.S.C. 45) to the extent that section applies to unfair methods of competition.

generic product without knowing if an infringement suit would be brought at a later time. MMA created a mechanism by which ANDA applicants can bring a declaratory judgment action against the NDA holder if the NDA holder does not sue within its 45-day window after receiving notification of a paragraph IV certification. Basically, in order to take advantage of this mechanism, the paragraph IV notification to the NDA holder/patent owner would have to be accompanied by an offer of confidential access to the ANDA application. The document providing the offer can contain restrictions as to persons entitled to access. If this offer is made, the ANDA filer can initiate a declaratory judgment action asking a court to determine whether the patent(s) is valid and/or infringed if an infringement action is not brought against the ANDA filer.

While this provision may look appealing to some, the MMA does not provide automatic standing for paragraph IV patent challenger to obtain a declaratory judgment of non-infringement or invalidity. Apotex, Inc. v. Pfizer, Inc., 2004 U.S. Dist. Lexis 26232. In that case, the Court held that although the 2003 MMA provides for a paragraph IV patent challenger to file for a declaratory judgment action of non-infringement or invalidity if NDA holder chose not to sue within 45 days after receiving the paragraph IV notification from the patent challenger, the patent challenger still must show both prongs of the “reasonable apprehension” test to be considered to have standing - first, a case or controversy jurisdiction in patent infringement must exist, and second, there must be a reasonable apprehension of patent litigation.

Conclusion

Although the MMA provided more certainty with respect to many of the issues concerning the 30-month stay and 180-day exclusivity provisions of the previous version of the Hatch-Waxman Act, an ANDA or 505(b)(2) filer must carefully consider the ramifications of the new rules in plotting its strategy in bringing a generic or branded generic product to market. In general, one should be aware of the fact that notice is required with respect to all paragraph IV certifications (regardless of when filed). Careful planning should take place with respect to first patent challengers entitled to 180-

day exclusivity under the new rules to ensure that this very valuable prize is not forfeited by virtue of any of the now-specified forfeiture conditions of the MMA.

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