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Tips For Drafting Paragraph IV Notice Letters

By **Laura Lydigsen and Judy He** (May 16, 2023, 6:06 PM EDT)


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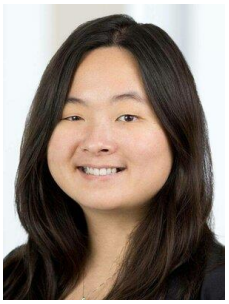
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The Hatch-Waxman Act established a pathway for drug companies to obtain regulatory approval for the commercial marketing of generic drug products by submitting an abbreviated new drug application, on ANDA.

Under Title 35 of the U.S. Code, Section 271(e)(2), an ANDA submission containing a Paragraph IV certification stating that a patent is invalid or not infringed under Title 21 of the U.S. Code, Section 355 (j)(2)(A)(vii)(IV), constitutes an artificial act of patent infringement that triggers several statutory deadlines for both brand and generic drug companies.

One of the most important deadlines for the generics during this process is the one for service of its statutorily required Paragraph IV notice letter.

In light of the U.S. District Court for the Northern District of West Virginia's March decision in Bausch Health Ireland v. Mylan Pharmaceuticals Inc., now is a good time for drug companies to revisit and consider some best practices.

Paragraph IV Notice Letter Background

Under the Hatch-Waxman Act, applicants who submit an ANDA must provide a certification with respect to each patent listed in the U.S. Food and Drug Administration's Orange Book in connection with the approved drug.

The fourth type of certification option — the Paragraph IV certification — requires the generic applicant to state that, "in the generic applicant's opinion and to the best of its knowledge," the listed patent is "invalid, unenforceable, or will not be infringed by the generic product."[1]

When an ANDA applicant submits a Paragraph IV certification, the applicant must notify any patent owners and holders of the new drug application for the brand name drug. This notice is called a Paragraph IV notice letter and must provide the factual and legal basis for the Paragraph IV certification.

Practice Tips

For decades, courts have wrestled with various issues relating to Paragraph IV notice letters. This article provides some practice tips from these cases for drug companies to consider and bear in mind as they

develop their litigation strategies:

1. Timing matters.

Notice letters should be sent within 20 days of receiving a Paragraph IV acknowledgment letter from the U.S. Food and Drug Administration and not before.[2] Absent that written acknowledgment, ANDA applicants should not serve their notice letters to brand companies.

In SB Pharmco Puerto Rico Inc. v. Mutual Pharmaceutical Co., in the U.S. District Court for the Eastern District of Pennsylvania, the submitter of an ANDA for generic Coreg CR filed a Paragraph IV certification for U.S. Patent No. 7,268,156 on Dec. 21, 2007.[3] On that same day, the defendants sent the plaintiffs a Paragraph IV notice letter even though the FDA had not yet accepted the ANDA for filing.[4]

The plaintiffs filed a declaratory judgment action seeking a determination that the Paragraph IV notice letter was improper and premature, and the court granted plaintiffs' motion for judgment on the pleadings under Rule 12(c).

The court found in 2008 that the applicable statute and regulations made clear that "the sending of notice of a Paragraph IV certification is expressly predicated upon the ANDA applicant receiving its own notice and acknowledgment from the FDA that the submitted ANDA has been received" and that this "sequence ensures that the statutory litigation triggers do not result in unnecessary patent infringement litigation initiated by incomplete ANDAs."[5]

2. Notice letters have been attached to public filings.

Generics should avoid to the extent possible disclosing any confidential information about their proposed ANDA product in the notice letter and detailed statement themselves.

The Hatch-Waxman statute includes a process for a generic to exchange the ANDA on a confidential basis, called an offer of confidential access.[6] Logically, the offer of confidential access should also protect the confidentiality of that same information about the ANDA product if it is also in the detailed statement — doing otherwise would undermine the purpose of the notice letter by discouraging full disclosures.

Nonetheless, because the notice letter and detailed statement are sent before the offer of confidential access exchange, some recipients have disclosed confidential information from them in public complaints and, in at least one instance, even wholesale attached the detailed statement to a complaint.[7]

Once information is publicly disclosed, it may be impossible to turn back the dial, and this is particularly true with complaints, which are often tracked by news services.

Thus, generics should be mindful that not all recipients will honor confidentiality markings and, to the extent possible, generics should avoid including confidential information about their ANDA product in the notice letter and attached detailed statement.

Confidentiality issues may be particularly tricky when a notice letter includes a noninfringement position. In such cases, the generic applicant faces the challenge of providing enough information in the notice letter to meet its statutory burden of disclosing its bases for asserting its product will not infringe,

while still maintaining the confidentiality of its noninfringement position from competitor companies.[8]

Often the generic can thread this needle by stating simply which limitations are not met by its product, as opposed to affirmatively stating what its product contains.

The Biologics Price Competition and Innovation Act presents one additional wrinkle in the debate about the confidentiality of Hatch-Waxman notice letters.

The BPCIA dispenses with some of the complexity of the Hatch-Waxman Act's offer of confidential access process and simply states that confidentiality protections "shall apply to the exchange of information described in this subsection," making clear that information contained in the notice letter exchange is protected in addition to the application itself.[9]

Whether the BPCIA's clarification on confidentiality weighs in favor of construing the Hatch-Waxman Act similarly has not been addressed by the courts.

3. Invalidity and noninfringement defenses can be developed beyond notice letters.

Another reason why generics should avoid disclosing too much in their Paragraph IV notice letters is that they will have the opportunity to further develop their defenses during litigation.

Numerous courts have rebuffed plaintiffs' attempts to limit ANDA submitters to only the defenses in their notice letters.[10] The most recent decision in this vein comes from the Northern District of West Virginia in the Bausch case.[11]

The plaintiffs filed a motion for judgment on the pleadings as to infringement on the basis that, while Mylan's answer had denied all infringement allegations, Mylan "cannot deviate from the defenses asserted in its Paragraph IV notice letter, which did not include non-infringement arguments for every asserted claim of the patents-in-suit."[12]

The court denied the plaintiffs' motion and found that "it possesses no authority to penalize any perceived deficiencies in Mylan's Paragraph IV notice letter under the Hatch-Waxman Act" and, as a result, "it will not limit Mylan to the theories raised in therein."[13]

As such, "Mylan may develop its non-infringement contentions in the ordinary course of this litigation."[14]

There are also downsides to saying too much in a notice letter. The more defenses a generic company raises in a notice letter, the greater the possibility that one of the defenses may conflict with another Paragraph IV submitter's position.

In 2008, in Takeda Chemical Industries Ltd. v. Mylan Labs, the U.S. Court of Appeals for the Federal Circuit affirmed an award of $16.8 million in attorney fees against generic litigants when they had "changed the focus of their invalidity arguments from those in their certification letters."[15]

For one generic, the Federal Circuit found that the district "court methodically examined a number of shortcomings in [its] Paragraph IV letter, which were made obvious by [its] constantly shifting set of arguments, that supported the finding that the certification was baseless."

For another generic, the Federal Circuit found that its "invalidity argument in its certification letter appear[ed] even more baseless."[16] The risks of shifting positions can be minimized by crafting letters to cover only the generic's best, most firm defenses. Other defenses can always be added.

Conclusion

Drafting Paragraph IV notice letters and getting them served within 20 days of receiving a Paragraph IV acknowledgment letter from the FDA can be challenging.

While applicants are required to provide a full and detailed explanation of the factual and legal basis for its invalidity or noninfringement positions, there is not a lot of guidance in the rules and regulations as to what satisfies that standard.[17]

Generics need not disclose every defense possible, as there is opportunity to develop additional defenses during litigation, and should be careful to avoid defenses that may force them to take inconsistent positions in subsequent litigation with other ANDA applicants.

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[1] https://www.fda.gov/drugs/abbreviated-new-drug-application-anda/patent-certifications-and-suitability-petitions.

[2] 21 C.F.R. §314.95(b).

[3] 552 F. Supp. 2d 500, 503 (E.D. Pa. 2008).

[4] Id. at 503-04.

[5] Id. at 507-08.

[6] 21 CFR 314.95(c)(8).

[7] E.g., Nycomed U.S. Inc. v. Tolmar Inc., 10-2635 KSH, 2011 WL 1675027, at *1 (D.N.J. Apr. 28, 2011).

[8] See, e.g., Yamanouchi Pharm. Co. v. Danbury Pharmacal, Inc., 231 F.3d 1339, 1347-48 (Fed. Cir. 2000) (affirming district court's award of attorney fees after finding that defendants made a baseless Paragraph IV certification).

[9] 21 U.S.C. §262(l)(A).

[10] E.g., Bausch Health Ireland Ltd. et al. v. Mylan Pharmaceuticals Inc., No. 1:22CV20, 2023 WL 2726432, at *3 (N.D.W. Va. Mar. 30, 2023); Abbott Labs. v. Lupin Ltd., No. 09-152-LPS, 2011 WL 1897322, at *7 (D. Del. May 19, 2011); Abbott Labs., Inc. v. Apotex Inc., 725 F. Supp. 2d 724, 728 (N.D. Ill. 2010).

[11] Bausch, 2023 WL 2726432.

[12] Id.

[13] Id.

[14] Id.

[15] E.g., Takeda Chem. Indus., Ltd. v. Mylan Labs., Inc., 549 F.3d 1381, 1384 (Fed. Cir. 2008) (affirming district court's award of attorney fees where defendants "each changed the focus of their invalidity arguments from those in their certification letters").

[16] Id. at 1387, 1389.

[17] 21 CFR 314.95(c)(7).