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REPORT

Patents

Medicare Act Increases Risk of Declaratory Judgment Actions Against Innovators

By Brian McCormick and Meredith Manning

Although not widely publicized, several provisions of the Medicare Prescription Drug, Modernization, and Improvement Act (the Medicare Act) may prove important to innovator pharmaceutical companies. Specifically, the new law seeks to encourage generic drug applicants to bring declaratory judgment actions against innovators for patent invalidity and/or noninfringement, and establishes a counterclaim for the correction of patent listings.[1] Although the impact of the provisions remains unclear, innovators should bear them in mind while developing and enforcing their patent portfolios.

In brief, the Medicare Act permits generic drug applicants to bring declaratory judgment actions against innovators, provided certain conditions are met. These actions are designed to provide certainty to generic drug applicants concerning the scope of innovators' patents, before approval of the generic drugs themselves. The Medicare Act also requires some generic drug applicants wishing to bring declaratory judgment actions to offer innovators access to their applications, to allow the innovators to evaluate whether to bring infringement suits. Finally, the law provides that if innovators do bring such suits, the generic drug applicants may bring counterclaims, seeking correction of any patent information submitted to the Food and Drug Administration (FDA) by the innovators. These provisions, coupled with the Medicare Act's other changes to the Drug Price Competition and Patent Term Restoration Act (the Hatch-Waxman Act)[2], could influence innovators' patent strategies.

[1] *See* Title XI, Access to Affordable Pharmaceuticals, Pub. L. No. 108-173, 117 Stat. 2066 (Dec. 8, 2003).

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Background

1. Patent Listing and Litigation

Under the Federal Food, Drug, and Cosmetic Act (FFDCA), any company that submits, or that has submitted, a new drug application (NDA) must list with FDA all patents that claim the drug or an approved method of using the drug, and "with respect to which a claim of patent infringement could reasonably be asserted . . . ."[3] FDA distributes this information in its

[2] Pub. L. No. 98-417, 98 Stat. 1585 (1984).
[3] 21 USC 355(b)(1), *see id.* at 355(c)(2); 21 CFR 314.53.

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publication, *Approved Drug Products With Therapeutic Equivalence Evaluations* (better known as the *Orange Book*).

Generic drug applicants may then seek to market copies of these approved drugs, based on reference to the safety and effectiveness data contained within the innovators' applications.[4] In order to protect innovators' patent rights, each generic drug applicant must include in its application a certification for each patent listed with a referenced drug.[5] One such certification—a so-called ''paragraph IV'' certification—asserts that the listed patent is invalid or will not be infringed by the manufacture, use, or sale of the generic drug. Any time a paragraph IV certification is filed with a generic drug application, the applicant must provide notice to the NDA holder and patent owners, together with a detailed statement of the factual and legal basis for the applicant's opinion that the patent is invalid or will not be infringed.[6] The notified parties may then sue to resolve any patent dispute.[7]

If such a suit is brought within 45 days of receipt of this notice, FDA is barred from approving the generic drug application for 30 months, or until the conclusion of the patent litigation.[8] If, on the other hand, the NDA holder or patent owners do not sue within 45 days, the generic drug applicant may receive approval once FDA completes its review of the application. The NDA holder and patent owners remain free, however, to sue the applicant for infringement when the product is approved and marketed.

2. Declaratory Judgment Actions

The generic drug industry asserts that innovators' ability to sue outside the 45-day period creates uncertainty about the marketability of generic drugs. Potentially, an innovator may wait to sue until the eve of a generic drug's marketing, creating an *in terrorem* effect intended to keep the product off the market. Under this theory—never tested in practice—the generic drug applicant's fear of losing the infringement suit, and of being liable for willful infringement and treble damages, keeps it off the market long after approval.[9] Therefore, several generic drug applicants have brought declaratory judgment actions against innovators, once the 45-day period has expired, seeking to obtain early clarity as to the scope—and enforceability—of the listed patents.

Under the Declaratory Judgment Act, an ''actual controversy'' must exist between the parties to vest jurisdiction in a court to hear the dispute.[10] In the context of patent litigation, courts typically require: (1) An explicit threat or other action by the patentee that creates on the part of the plaintiff a ''reasonable apprehension'' of an infringement suit; and (2) present activity by the plaintiff that could constitute infringement.[11] These are constitutional criteria, arising from Article III limitations on the authority of the federal courts.[12] And, even if the two-part test is met, the court may, in its ''sound discretion,'' decline to hear the case.[13]

Generic drug applicants' attempts to bring these cases have met with varying degrees of success, depending on the particular facts and circumstances of the situation. For example, in *Dr. Reddy's Laboratories v. Pfizer Inc.*, the applicant failed to demonstrate an actual controversy sufficient to confer subject matter jurisdiction on the court.[14]

The plaintiff failed to meet the first prong of the test because it could point to no specific threat or other action by Pfizer, sufficient to create a reasonable apprehension of suit. The court noted that this determination must be on ''the objective actions of the patentee, not the subjective impressions of the plaintiff.''[15]

Dr. Reddy's pointed the court to five factors that it believed created a reasonable apprehension. These included: (1) Pfizer's listing the patent in the *Orange Book*; (2) its refusal to provide Dr. Reddy's with a covenant not to sue and its public hostility toward the applicant; (3) its aggressive patent litigation in other situations; (4) its enforcement of this particular patent against other generic drug applicants; and (5) its incentive to delay, for as long as possible, the triggering of another generic drug applicant's ''180-day exclusivity.''[16]

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[4] For purposes of this discussion, the phrase ''generic drug applicants'' refers to applicants submitting either abbreviated new drug applications (ANDAs) or NDAs under section 505(b)(2) of the FDCA. *See* 21 USC 355(b)(2), 355(j).

[5] *See id.* at 355(b)(2), 355(j)(2)(A)(vii); 21 CFR 314.50(i), 314.94(a)(12).

[6] *See* 21 USC 355(b)(3), 355(j)(2)(B); 21 CFR 314.52, 314.95.

[7] *See* 35 USC 271(e)(2).

[8] *See* 21 USC 355(c)(3), 355(j)(5)(b); 21 CFR 314.107.

[9] *See* 35 USC 284.

[10] 28 USC 2201(a).

[11] *BP Chemicals Ltd. v. Union Carbide Corp.*, 4 F.3d 975, 978 (Fed. Cir. 1993).

[12] *See id.* at 981.

[13] *Fina Research, S.A. v. Baroid Ltd.*, 131 F.3d 147, 1481 (Fed. Cir. 1998).

[14] No. Civ. A. 03-CV-726 (JAP), 2003 WL 21638254 (D.N.J. July 8, 2003). Dr. Reddy's was able to meet the second prong of the two-part test easily, because the patent statute specifically deems the submission of a generic drug application to be an infringing act, when the applicant intends to market its product before the expiration of the patent. *See id.* at *3; *see also* 35 USC 271(e)(2); *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1569 (Fed. Cir. 1997).

[15] *Dr. Reddy's Labs.*, 2003 WL 21638254, at *5.

[16] *See id.* Under the Hatch-Waxman Act, the first applicant to submit an ANDA with a paragraph IV certification was entitled to 180 days of marketing exclusivity, beginning either on the date of a decision of a court that the patent is invalid or not infringed, or on the company's first commercial marketing of the drug. *See* 21 USC 355(j)(5)(B); 21 CFR 314.107(c). By bringing a declaratory judgment action, Dr. Reddy's was attempting to trigger an earlier applicant's 180-day exclusivity, so that it would run by the time Dr. Reddy's application was approved. *See Teva Pharms. USA v. FDA*, 182 F.3d 1003 (D.C. Cir. 1999). In contrast, by not suing Dr. Reddy's, Pfizer was attempting to delay triggering this exclusivity, in order to keep multiple generic drug applicants off the market. Recently, the District Court for the District of Columbia granted Pfizer's motion to dismiss in a declaratory judgment action brought by Mutual Pharmaceutical Co., where the generic drug applicant was explicit that its suit was intended to trigger a competitor's 180-day exclusivity. *See Mutual Pharm. Co. v. Pfizer Inc.*, No. 03-1116 (RMU) (D.D.C. Mar. 24, 2004) at *5 n.1 (''The court does not suggest that this is an impermissible motive for the plaintiff's suit.'').

This motivation for a generic drug applicant to bring a declaratory judgment action has been lessened, because the Medicare Act retrospectively changes the definition of the word ''court'' in the 180-day exclusivity provision to mean an appellate court. Consequently, generic drug applicants like Dr.

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The court dismissed these factors as insufficient to give rise to a reasonable apprehension that Pfizer would enforce its patent through litigation because none constituted objective evidence of Pfizer's intent *as to Dr. Reddy's*. The listing of Pfizer's patent in the *Orange Book*, for example, merely indicated that Pfizer *could* assert a claim a patent infringement, not that it *would* assert such a claim, as required by the Declaratory Judgment Act.[17] Similarly, in *Teva Pharmaceuticals USA v. Pfizer Inc.*, a case decided on the very day the Medicare Act was signed into law, and which involved the same patent at issue in *Dr. Reddy's Laboratories*, a different court found the identical five factors insufficient to give rise to a reasonable apprehension of suit.[18]

On the other hand, in *Teva Pharmaceuticals USA v. Abbott Laboratories*, the declaratory judgment plaintiff was successful in demonstrating a reasonable apprehension.[19] In that case, however, Abbott had asserted the same patent against Novopharm—a Teva affiliate—in a regulatory proceeding in Canada. ''In combination with the Canadian proceedings,'' the court held, ''Abbott's recent history of enforcement of its patent rights against Teva and its affiliates is sufficient to create a reasonable apprehension that Abbott will initiate a patent infringement suit against Teva if Teva attempts to market a generic version of the drug.''[20]

The Medicare Act

1. The Declaratory Judgment Provision

The Medicare Act sought to facilitate these declaratory judgment actions, permitting them to be brought after the 45-day period, provided certain conditions are met.[21] It also amended the patent statute, to provide that ''the courts of the United States shall, to the extent consistent with the Constitution, have subject matter jurisdiction in any action . . . for a declaratory judgment that such patent is invalid or not infringed.''[22]

Arguably, however, these provisions do not change the law regarding declaratory judgment actions. Article III of the Constitution determines when a federal court has subject matter jurisdiction over a case, and the Medicare Act did not (indeed, could not) change this standard to ensure that applicants can establish jurisdiction. Consequently, a district court's jurisdiction will continue to depend on the particular facts and circumstances of the case. Declaratory judgment jurisdiction was difficult to maintain before enactment of the Medicare Act, and remains difficult today. The very fact that the NDA holder or patent owners have decided *not* to sue within the first 45 days cannot easily be characterized as *increasing* the likelihood of such a suit in the future.[23]

In an unusual move, the Federal Trade Commission (FTC) recently filed an *amicus curiae* brief, encouraging the Court of Appeals for the Federal Circuit to reverse the lower court in *Teva Pharmaceuticals USA v. Pfizer Inc.*[24] Rather than apply the familiar, two-prong ''reasonable apprehension'' test, FTC urges the Federal Circuit to take into account the ''specific regulatory context of the Hatch-Waxman regime'' and instead consider the ''totality of the circumstances.''[25] Specifically, FTC argues that the district court erred in ignoring Teva's injury, as the company will be kept off the market during a prior applicant's 180-day exclusivity.[26]

Ultimately, the Medicare Act's declaratory judgment provision may serve as a tiebreaker, in cases where the reasonable apprehension test may be met, or where it is met, but where the court would otherwise decline to hear the case. Another place the provision may have an effect is where an innovator lists several patents in the *Orange Book*, but sues only on one, to take advantage of the 30-month stay of approval. If the innovator holds off on suing on the other patents, hoping to capitalize

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Reddy's will no longer able to trigger a competitor's 180-day exclusivity in a district court. Prospectively, the Medicare Act eliminates the court decision trigger entirely. *See* Medicare Act section 1102 (codified as amended at 21 USC 355(j)(5)(B)(iv), 355(j)(5)(D)).

[17] *Dr. Reddy's Labs.*, 2003 WL 21638254, at *5. Dr. Reddy's had cited to *Minnesota Manufacturing and Mining Co. v. Barr Laboratories*, in which Judge Gajarsa issued a concurring opinion that the statutory standard for listing a patent – that a claim for infringement could reasonably be asserted—coincided with the standard for a declaratory judgment—a reasonable apprehension of suit – and that the former should support the latter. 289 F.3d 775, 791 (Fed. Cir. 2002) (Gajarsa, C.J., concurring); *see also Mova Pharm. Corp. v. Shalala*, 140 F.3d 1060, 1073 n.18 (D.C. Cir. 1998). The court in *Mutual Pharmaceutical Co*. acknowledged these opinions, but ''[deferred] to the general rule[.]'' *Mutual Pharm. Co*., No. 03-1116, at *8. The court declined to find a reasonable apprehension where the innovator refused provide a covenant not to sue, and had previously engaged in litigation against generic drug applicants, including the plaintiff. *See id.* at *9.

[18] No. Civ. A. 03CV10167RGS, 2003 WL 22888848 (D. Mass. Dec. 8, 2003).

[19] No. 03 C 5455, 2004 WL 226093 (N. D. Ill. Jan. 12, 2004).

[20] *Id.* at *6.

[21] *See* Medicare Act sections 1101(a)(2)(C), 1101(b)(2)(D) (codified as amended at 21 USC 355(c)(3)(D), 355(j)(5)(C)).

[22] *See id.* at 1101(d) (codified as amended at 35 USC 271(e)(5)).

[23] Before its enactment, the Senate version of the Medicare Act went much further, and attempted to confer subject matter jurisdiction on the courts whenever declaratory judgment actions are brought. Concerns about the constitutionality of such a provision, including skepticism from the Patent and Trademark Office and the Department of Justice, brought about the enacted compromise. Now, in the ''Explanatory Statement'' accompanying the Medicare Act, the congressional conferees encourage courts to provide generic drug applicants with ''appropriate access'' to declaratory judgment relief, and to examine the ''particular policies'' of the Hatch-Waxman Act, but acknowledge that courts may or may not find a reasonable apprehension of suit in any given case.

[24] No. Civ. A. 03CV10167RGS, 2003 WL 22888848.

[25] Brief of *Amicus Curiae* at 16-17, *Teva Pharms. USA v. Pfizer Inc.* (Fed. Cir. Mar. 31, 2004) (No. 04-1186).

[26] *See id.* at 12. By focusing on the alleged injury to Teva in being kept off the market, FTC ignores the competing policy interest at stake: The prior applicant's 180-day exclusivity is its reward for being the first to challenge Pfizer's patent with a paragraph IV certification.

AARP also has filed an *amicus curiae* brief in support of Teva. In it, AARP focuses on Congress's intent behind the Medicare Act, and on the realities of the pharmaceutical market: ''[W]here generic competition is likely to result in the brand name drug losing half its market share within one year, the economics of the situation compels the conclusion that Teva not only has a reasonable apprehension of suit, but that it has every basis to believe that Pfizer will bring a patent infringement action at a time designed to protect its lucrative product as long as possible.'' Brief of *Amicus Curiae* at 11, *Teva Pharms. USA v. Pfizer Inc.* (Fed. Cir. Mar. 26, 2004) (No. 04-1186).

on the generic drug applicant's uncertainty, that applicant may be able to bring a declaratory judgment action.

Also, the district court opined in dicta in *Dr. Reddy's Laboratories* that jurisdiction might be warranted in a case where an innovator refuses to provide a generic drug applicant with a covenant not to sue, nearer to the time of approval: ''Pfizer's continued silence on the issue may create an objectively reasonable fear on [Dr. Reddy's] part that Pfizer is deliberately delaying infringement litigation in order to 'sandbag' [Dr. Reddy's] at the last possible moment.''[27]

2. The Confidential Access Provision

Several other provisions of the Medicare Act also will impact declaratory judgment and patent infringement actions. For example, if the generic drug applicant's paragraph IV certification asserts noninfringement of the listed patent (as opposed to invalidity), and the applicant wishes to bring a declaratory judgment action, it must provide the NDA holder and patent owners a right of confidential access to its application. The access shall be for the ''sole and limited purpose'' of allowing the notified parties to evaluate whether to bring an infringement action, and may contain restrictions on access to and use of the information.[28]

Of course, it has always been in the interest of generic drug applicants to provide innovators with sufficient information about their products to prompt any lawsuits (and begin any 30-month stays of approval). However, without any requirement of confidentiality or limits on use of the information, applicants were wary of providing sensitive information on their products and manufacturing processes. The parties were free to negotiate confidentiality agreements, but such negotiations might consume the entire 45-day period.

By providing for such confidentiality, the Medicare Act should speed these negotiations and improve the quality of applicants' notifications to innovators. Importantly, however, all the statute requires is that generic drug applicants *offer* such access, and applicants can be expected to limit severely innovators' access to the generic drug applications. For example, they may seek to limit access to innovators' outside counsel. Innovator companies may, in the future, seek dismissal of the declaratory judgment actions, if generic drug applicants place so many restrictions on this offer as to make it meaningless.

3. The Patent Listing Provision

Finally, the Medicare Act provides that if an NDA holder or patent owner brings an infringement action, the generic drug applicant may bring a counterclaim, ''seeking an order requiring the holder to correct or delete the patent information submitted by the holder. . . .''[29] Money damages are not available for such a counterclaim, nor may it be brought as an independent cause of action.

This provision is intended to address a perceived problem under the current regime, where FDA publishes in the *Orange Book* patent information it receives from innovators, without independently reviewing it, and where generic drug applicants have no private right of action to challenge the listings themselves.[30] It is important to note, however, that these patent listing challenges may only be brought as counterclaims. So, for instance, if a generic drug applicant were forced to bring a declaratory judgment action to determine the scope of a questionably listed patent, it would have no way to challenge the listing of the patent itself.

Conclusion

The declaratory judgment provision was a priority for the generic drug industry throughout negotiation of the Medicare Act, and debate over its constitutionality was heated. The generic drug industry's fear is that, under a system that allows for only a single 30-month stay, innovators will increasingly seek to delay litigation until the last possible moment. Although this fear remains largely hypothetical, a patent strategy that aims to enforce patents after approval of the generic drug could be a rewarding one for innovators. It may create large disincentives for generic drug applicants to go to market, long after the traditional 30-month stay expires.

In order to attempt such an approach, innovators will have to fight off the inevitable declaratory judgment actions, but the decisions discussed above provide fairly detailed guidance on how to avoid creating declaratory judgment jurisdiction. The upcoming Federal Circuit decision in *Teva Pharmaceuticals USA v. Pfizer Inc*. exemplifies, however, how the law in this area will continue to change. It remains to be seen whether the Medicare Act provides generic drug applicants with new tools to thwart this approach, or whether innovators will remain largely free to enforce patents in jurisdictions—and at times—of their choosing.

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[27] *Dr. Reddy's Laboratories,* 2003 WL 21638254, at *7 n.12.

[28] *See* Medicare Act sections 1101(a)(2)(C), 1101(b)(2)(D) (codified as amended at 21 USC 355(c)(3)(D)(i)(III), 355(j)(5)(C)(i)(III)).

[29] *See id.* at 1101(a)(2)(C)(ii), 1101(b)(2)(D)(ii) (codified as amended at 21 USC 355(c)(3)(D)(ii), 355(j)(5)(C)(ii)).

[30] *See Mylan Pharms. Inc. v. Thompson*, 268 F.3d 1323 (Fed. Cir. 2001); *see also* 21 CFR 314.53(f).

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