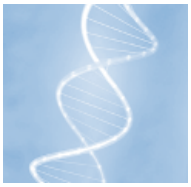

INTELLECTUAL PROPERTY

BIOTECH UPDATE

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Declaratory Judgment Jurisdiction: Orange Book Listings Alone Don't Make for Reasonable Apprehension

By: Mark A. Pals, P.C.*

The Federal Circuit clarified the scope of declaratory judgment jurisdiction in Abbreviated New Drug Application ("ANDA") cases in *Teva Pharmaceuticals USA, Inc. v. Pfizer, Inc*.[1] The court affirmed the dismissal of Teva's declaratory judgment action, ruling that the listing of a patent in the Orange Book, even combined with an earlier suit against a prior ANDA applicant, did not establish a reasonable apprehension of suit. The court also ruled that the Medicare Amendments[2] did not broaden the declaratory judgment jurisdiction of courts in ANDA cases. The court thus limited the ability of ANDA applicants to challenge patents listed in the Orange Book, but not asserted, by research pharmaceutical companies.

"We are not prepared to hold that listing a patent in the Orange Book evinces an intent to sue any ANDA filer who submits a paragraph IV certification with respect to the patent."

Background

Pfizer markets the antidepressant Zoloft®. It lists, among others, U.S. Patent Nos. 4,536,518 and 5,248,699 in the Orange Book as covering its product. Teva filed an ANDA, seeking approval to market a generic version of this product. Teva filed a paragraph III certification as to the '518 patent, stating that it would not market its product until the '518 patent expires. As to the '699 patent, it filed a Paragraph IV certification, asserting that its proposed product did not infringe the '699 patent or, alternatively, that the claims of the '699 patent are invalid.

Although Teva's filing was an act of infringement[3], Pfizer did not sue Teva within the 45-day standard period. Teva then filed suit, however, seeking a declaration of noninfringement or invalidity of the claims of the '699 patent. Pfizer moved to dismiss Teva's complaint for lack of subject matter jurisdiction, claiming that Teva failed to satisfy the first part of the Federal Circuit's two-part test,[4] which requires conduct by Pfizer that created a "reasonable apprehension of imminent suit." The trial court granted Pfizer's motion and dismissed Teva's suit.

On appeal, Teva argued that it had reasonable, objective grounds to fear an infringement suit by Pfizer. It also argued that the Medicare Amendments establish jurisdiction over such an action by an ANDA applicant whether or not a reasonable apprehension existed. The Federal Circuit rejected both arguments.

Teva lacked a reasonable apprehension of suit

Teva highlighted the following facts in arguing that Pfizer's actions created a reasonable apprehension of suit: (1) Pfizer

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listed the '699 patent in the Orange Book; (2) Teva submitted an ANDA with a paragraph IV certification as to the '699 patent; and (3) Pfizer did not sue Teva within 45 days of receiving notice of Teva's paragraph IV certification. The court noted that these facts do not distinguish this from other ANDA cases in which an infringement suit is not filed. The court refused to rule that declaratory judgment jurisdiction exists in all such cases: "We are not prepared to hold that listing a patent in the Orange Book evinces an intent to sue any ANDA filer who submits a paragraph IV certification with respect to the patent."[5]

Teva also argued that Pfizer had a history of enforcing the '699 patent. In fact, IVAX Pharmaceuticals USA was first to file an ANDA seeking approval of a generic version of Zoloft®. Like Teva, IVAX had filed a paragraph III certification as to the '518 patent and a paragraph IV certification as to the '699 patent. But Pfizer sued IVAX for infringement of the '699 patent, and the parties subsequently settled the action.

"Teva virtually concedes that Pfizer will not bring immediate suit for infringement of the '699 patent."

According to Teva, Pfizer's settlement with IVAX gave it reason to delay filing suit against Teva under the '699 patent.[6] As the first ANDA applicant, IVAX is entitled to a 180-day period of generic market exclusivity. Teva's ANDA cannot be approved until IVAX's period of exclusivity expires. Unless there is an earlier court ruling of noninfringement or invalidity of the '699 patent, this period will not begin to run until IVAX begins commercial marketing after expiration of the '518 patent.[7] Teva argued that Pfizer was delaying suit against Teva to avoid the risk of an earlier adverse ruling of noninfringement or invalidity of the '699 patent.

The court turned this argument back on Teva, reasoning that "Teva virtually concedes that Pfizer will not bring immediate suit for infringement of the '699 patent."[8] The court thus concluded that Teva did not demonstrate a reasonable apprehension of imminent suit.

The Medicare Amendments did not change the jurisdictional analysis

The Medicare Amendments amended 35 U.S.C. § 271(e)(5) to provide that, if a patentee does not bring suit within 45 days of notice of a paragraph IV certification, "the courts of the United States shall, to the extent consistent with the Constitution, have subject matter jurisdiction in any action brought by [an ANDA filer] … for a declaratory judgment that such patent is invalid or not infringed." Teva argued that this amendment, which applies retrospectively to any proceeding pending as of December 8, 2003, broadened its right to seek declaratory relief. The FTC argued in an *amicus* brief that the Federal Circuit's two-part test should not apply because a subsequent ANDA applicant may be injured not only by the threat of an infringement suit, but also by other actions taken by the patentee as to its patents.[9]

In rejecting these arguments, the Federal Circuit considered the statutory language and legislative history, and concluded that Congress did not "intend to cause courts to alter the present test for determining whether an actual controversy exists in the Hatch-Waxman setting."[10] Although the court acknowledged that at least one previous Federal Circuit case "suggests that the traditional two-part test is not the only way of determining in all cases that the constitutional requirement of an actual case or controversy has been met,"[11] it ruled that ANDA filing does not clear an alternate path to declaratory judgment jurisdiction. The Federal Circuit thus upheld the district court's determination under the two-part test that Teva failed to establish subject matter jurisdiction for a declaratory judgment action.

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No Copies? No Index? No Problem. Poster Presentations Can Be Printed Publications Anyway

By: Jeremy M. Grushcow*

Before the Federal Circuit's recent decision in *In re Klopfenstein*,[1] the law was unclear as to whether conference poster presentations constitute "printed publication[s]" that would bar patentability under 35 U.S.C. § 102(b). Cautious inventors nevertheless generally withheld data from conference presentations until they filed a patent application.[2] There was, of course, always a risk that a public presentation of research could either be a printed publication or otherwise make an invention "known by others." The Federal Circuit eliminated any uncertainty in *In re Klopfenstein* by finding posters, the most common form of conference presentation, to be "printed publications" that can be prior art.

"throughout our case law, public accessibility has been the criterion by which a prior art reference will be judged for the purposes of § 102(b)"

The Federal Circuit's Decision in *In re Klopfenstein*

The inventors in *In re Klopfenstein* presented a "poster"[3] for 2 ½ days at a meeting of the American Association of Cereal Chemists ("AACC") and again for "less than a day" at Kansas State University. As is typical for a poster, "no copies of the presentation were disseminated either at the AACC or at [the university], and the presentation was never catalogued or indexed in any library or database."[4] What was perhaps less typical about this poster presentation is that the inventors did not dispute that it "disclosed every limitation of the invention disclosed in the [subject] patent application."[5]

Two years after the AACC presentation, the inventors applied for a patent. The examiner rejected the patent application under 35 U.S.C. § 102(b) as fully anticipated by a printed publication — the poster presentation. The Board of Patent Appeals and Interferences affirmed the examiner's decision. The question for the Federal Circuit was whether the poster presentation constituted a "printed publication" under Section 102(b). The inventors argued that previous interpretations of the term "printed publication" required indexing or distribution of the prior art at issue, citing primarily: *In re Cronyn*, *In re Hall*;[6] *Massachusetts Institute of Technology v. AB Fortia*;[7] and *In re Wyer*.[8]

Indexing appeared to play an important role in *In re Cronyn*, *In re Hall*, and *In re Wyer*. In *In re Cronyn* and *In re Hall*, the Federal Circuit held that "a single cataloged thesis in one university library … constitute[s] sufficient accessibility to those interested in the art exercising reasonable diligence."[9] The court distinguished *In re Bayer*,[10] in which a thesis had not been indexed by the critical date. Instead, the thesis was "in a private library office accessible only to library employees."[11] *In re Wyer* involved an Australian patent application that was available on microfilm at the Australian Patent Office and its five satellite offices. The court held that "there is … no genuine issue as to whether the application was properly classified, indexed, or abstracted" and that therefore "the contents of the application were sufficiently accessible to the public and to persons skilled in the pertinent art as to qualify as a 'printed publication'."[12]

Distribution appears to have played an important role in *MIT v. Fortia*. In that case the Federal Circuit held that the oral presentation of a paper to 50–500 people at a conference along with distribution of the full paper "without restriction" to at least six individuals did constitute a printed publication.[13] There was no evidence that the presentation or the paper were indexed in any way.

Defining and Avoiding Public Accessibility

The Federal Circuit clarified in *In re Klopfenstein*, that "public accessibility"— not distribution or indexing — is required. The court set out the following factors as relevant to determining public accessibility: "the length of time the display was exhibited, the expertise of the target audience, the existence (or lack thereof) of reasonable expectations that the material displayed would not be copied, and the simplicity or ease with which the material displayed could have been copied."[14]

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However, the court's analysis suggests that firm lower limits cannot be placed on any of these factors. For example, the court references *Regents of the Univ. of Cal. v. Howmedica, Inc.*,[15] which held that "the mere presentation of slides accompanying an oral presentation at a professional conference" was not a printed publication, but admits only that there is no "per se rule" that such presentations *are* printed publications.[16] This suggests that even a transient slide presentation could constitute a printed publication if the audience was sufficiently expert and the material could be copied freely and easily.

"… protective measures could include license agreements, non-disclosure agreements, anti-copying software or even a simple disclaimer … that no copying … will be allowed …"

The court does suggest, however, that future presenters could take "protective measures" including "license agreements, non-disclosure agreements, anti-copying software or even a simple disclaimer informing members of the viewing public that no copying of the information will be allowed or countenanced."[17] It remains to be seen whether by disabusing viewers of an expectation of free use via a disclaimer or other means suggested above, presenters may be able to avoid having their posters considered prior art under Section 102(b). Now more than ever, conference presentations may undermine a researcher's ability to patent an invention.

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1 395 F.3d 1324 (Fed. Cir. 2005).
2 Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066.
3 35 U.S.C. § 271(e)(2).
4 *See* M. Wang, "Patent Challenges by a Licensee in Good Standing: *Gen-Probe v. Vysis.*"
5 395 F.3d at 1333.
6 *Id.* at 1333-34.
7 The provisions of the Medicare Amendments relating to the 180-day generic market exclusivity period apply as to ANDA's filed after December 8, 2003. *See* 21 U.S.C. § 355(j)(5)(D). The amendments, therefore, did not apply to IVAX's period of exclusivity.
8 395 F.3d at 1333.
9 *Id.* at 1338.
10 *Id.* at 1336.
11 *Id*. at 1335.

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1 380 F.3d 1345 (Fed. Cir. 2004).
2 Grushcow, Jeremy M. 2004. Measuring Secrecy: A Cost of the Patent System Revealed. Journal of Legal Studies 33:59–84.
3 It was described by the court as a "fourteen-slide presentation … printed and pasted onto poster boards." 380 F.3d at 1347.
4 380 F.3d at 1347.
5 *Id.* at 1347.
6 781 F.2d 897, 900 (Fed. Cir. 1986).
7 774 F.2d 1104 (Fed. Cir. 1985).
8 655 F.2d 221 (CCPA 1981).
9 781 F.2d 897, 900 (Fed. Cir. 1986).
10 568 F.2d 1357 (CCPA 1978).
11 781 F.2d at 899.
12 665 F.2d at 226.
13 774 F.2d at 1109.
14 380 F.3d at 1350. Presumably, distribution and indexing (identified by the court as "factors to be considered") are related to the expectation and ease of copying, although the court does not clarify whether they are to be considered separately.
15 530 F. Supp. 846 (D.N.J. 1981).
16 380 F.3d at 1349 (note 4).
17 *Id.* at 1351.