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FDA Xyrem Meeting Materials Qualify As Printed Publication

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In *Jazz Pharmaceuticals, Inc. v. Amneal Pharmaceuticals, LLC,* the Federal Circuit affirmed decisions of the Patent Trial and Appeal Board (PTAB) that invalidated seven Orange Book-listed patents for Xyrem®. The main issue on appeal was whether FDA meeting materials available on a web page published in a Federal Register Notice qualified as a "printed publication" under 35 USC § 102. The Federal Circuit agreed with the PTAB that they did.

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The Xyrem® Patents At Issue

Xyrem® is approved for the treatment of symptoms associated with narcolepsy, but its active ingredient (gamma-hydroxybutyrate) also is known as the "date-rape drug." As noted in the Federal Circuit decision, "[b]ecause of its potential for abuse, the FDA approved Xyrem® under 'restricted distribution regulations … to assure safe use of the product." The seven Jazz' patents at issue (U.S. Patent Nos. 7,668,730; 7,765,106; 7,765,107; 7,895,059; 8,589,182; 8,457,988; and 8,731,963) relate to methods of distributing a prescription drug that is under the exclusive control of an exclusive central pharmacy that involves verifying the credentials of the prescribing doctor and screening for potential abuse.

The Advisory Committee Art

The prior art at issue was four documents associated with a public meeting of the FDA advisory committee for Xyrem®: "(1) the FDA advisory committee meeting transcript and slides; (2) an FDA preliminary clinical safety review of Xyrem®; (3) a Xyrem® briefing booklet; and (4) a video and transcript regarding a proposed distribution system for Xyrem®." The PTAB determined that the ACA materials were publicly accessible on an FDA website no later than October 4, 2001, which was prior to the critical date of December 17, 2001. The FDA website was publicized in a May 14, 2001 Federal Register Notice that announced the meeting.

The Federal Circuit Decision

The Federal Circuit decision was authored by Judge Lourie and joined by Judges Newman and Reyna.

In its summary of the applicable law, the Federal Circuit emphasized "public accessibility" as the "touchstone in determining whether a reference constitutes a 'printed publication.'" As to "public accessibility," the court noted:

A reference is considered publicly accessible upon a satisfactory showing that such document has been disseminated or otherwise made available to the extent that persons interested and ordinarily skilled in the subject matter or art, exercising reasonable diligence, can locate it.

The court noted further:

If accessibility is proved, there is no requirement to show that particular members of the public actually received the information.

In finding the meeting materials qualified as printed publications the court noted:

- the breadth of the dissemination:
  "[T]he Notice in the Federal Register widely disseminated the ACA materials through a hyperlink to a public FDA website where the ACA materials could be accessed. The Notice explained what materials were located on the FDA website, approximately when they would be available, and how to navigate to them."
- the disseminated material was addressed to or of interest to persons of ordinary skill in the art:
  "The Board found, unchallenged on appeal, that a person of ordinary skill 'would have been familiar with the Federal Register and motivated to look for notices related to drug distribution, safety, or abuse prevention.'"
- the materials "were available online for a substantial time before the critical date"
- the materials "were distributed via public domain sources with no possible expectation that the materials would remain confidential or not be copied"

The Federal Circuit rejected Jazz's argument that "indexing or searchability" were legally required "for a reference to be a printed publication under § 102(b)," but also found that the Federal Register was adequately indexed.

> As we have explained, the ACA materials were publicly accessible because they were broadly disseminated to interested persons of ordinary skill for a substantial time with no expectations of confidentiality. The Board did not need to find that specific persons actually received or examined the materials.

Scientific Meetings Versus Agency Meetings

In reaching its decision, the Federal Circuit noted that "[t]his is not the first time we have considered whether materials disclosed in association with meetings or conferences were 'printed publications." However, the court's previous decisions related to scientific meetings, not meetings of a Federal agency. That said, perhaps the "person of ordinary skill in the art" for these patents would have been particularly interested in FDA meetings and motivated to keep up with FDA activity by monitoring the Federal Register. Or perhaps interest in the Federal Register is another *fictitious* characteristic of the "person of ordinary skill" in this particular art.