Keywords: prior art references; publicly accessible

General: A reference is publicly accessible when it is broadly disseminated to interested persons of ordinary skill for a substantial time with no expectations of confidentiality.

Jazz Pharmaceuticals, Inc. v. Amneal Pharmaceuticals LLC (Fed. Cir. 2018)
Decided July 13, 2018

I. Facts

Jazz Pharmaceuticals, Inc. ("Jazz") owns seven patents, including U.S. Patent No. 7,668,730 ("the '730 patent"), related to a drug distribution system for tracking prescriptions of a sensitive drug. The '730 patent was filed on December 17, 2002. Jazz manufactures Xyrem® which is used to treat narcolepsy, but which may also be used as a "date-rape drug." As such, the subject of the patents owned by Jazz are directed to a system that tracks prescriptions of sensitive drugs such as Xyrem® to limit abusive use of the drug. Amneal Pharmaceuticals LLC ("Amneal") brought six *inter partes* review ("IPR") proceedings challenging the validity of Jazz's patents. Specifically, Amneal asserted that materials used during a regulatory meeting in front of the U.S. Food and Drug Administration ("FDA") were prior art references.

The proceedings in front of the FDA were announced on May 14, 2001, in the Federal Register. Specifically, the Federal Register noted that the meeting was open to the public and that the meeting would focus on risk management issues associated with Xyrem®. Moreover, the Federal Register included a hyperlink to the FDA's website where background material related to Xyrem® would be posted before the meeting and materials provided or used during the meeting would be posted after the meeting was conducted. The Federal Register also included brief instructions for accessing the materials. During the IPR proceedings, the Patent Trial and Appeal Board ("the Board") found that four references at issue were accessible on October 4, 2001, more than two months before the one-year grace period from the filing date of the '730 (December 17, 2001). Further, the Board held that the four specific references that were publicly accessible via the hyperlink and that the four references obviated all of the claims of Jazz's patents.

II. Issue

Did the Board err in finding that the references available from the hyperlink included in the Federal Register were publicly accessible?

III. Discussion

No. During the appeal, Jazz submitted 1) that constructive notice of the materials provided by the Federal Register was insufficient to establish public accessibility, 2) that a person of ordinary skill exercising reasonable diligence would not have been able to locate the references, and 3) that the references were not publicly accessible because searchability or indexing is required.

The court applied the rule for determining whether a reference is publicly accessible, which is whether the reference 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 the reference. Further, the court noted that there is no requirement to show

that any particular person actually received or viewed the reference to satisfy the publicly accessibility test. As such, the court broke down the rule into three factors to determine whether the four references from the FDA proceedings were publicly accessible.

The first factor for assessing public accessibility is the breadth of dissemination. In determining that the breadth of dissemination factor weighed in favor of public accessibility of the references at issue, the court appeared to rely on the amount of people who could have accessed the references and whether a person of ordinary skill would have been able to access the references. The court adopted the Board's interpretation of a person having ordinary skill in the art as being a pharmacist or computer scientist having familiarly with computerized drug distribution procedures. The court noted that the Board's decision that such a person of ordinary skill would have been familiar with reviewing the Federal Register to look for notices related to drug proceedings was not challenged on appeal, and thus, that the first factor weighed in favor of public accessibility.

The second factor is the amount of time that the references are available before the critical date of the patent at issue. In this case, the court noted that the references were accessible for more than two months prior to the critical date of the '730 patent, which was certainly sufficient to weigh in favor of public accessibility. The court referenced *Klopfenstein* where it was held that slides presented during a three day meeting were publicly accessible.

The third factor is the expectation of confidentiality and/or whether the references will be copied. The court stated that there could be no dispute that materials disclosed in the Federal Register and available online would have no expectation of confidentiality because of the Federal Register is in the public domain, and thus, is widely accessible by the public. Indeed, no academic norms or expectations were presented that would suggest otherwise.

The court also compared the facts of the present case to various other cases decided by the court. Specifically, the court referenced the *Medtronic* case and noted that the references of the present case were disseminated even more broadly and for a longer duration than those in the Medtronic case.

Further still, the court addressed Jazz's argument that searchability or indexing is required to establish public accessibility. The court noted that this is not a requirement of the public accessibility rule. However, the court then performed a brief analysis and determined that the Federal Register is indexed because it includes a clearly labeled table of contents.

IV. Conclusion

The court held that upon weighing the three factors, the references were publicly accessible, and thus, prior art. The court then affirmed the decision of the Board and found Jazz's patents invalid.