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CLAIM CONSTRUCTION: A MATTER OF LAW OR A MATTER OF FACT? THE U.S. SUPREME COURT CASE OF TEVA PHARMACEUTICALS USA, INC. v. SANDOZ, INC.

By: Ariel L. Atkinson

n January 20, 2015, the U.S. Supreme Court handed down the decision in *Teva Pharmaceuticals USA*, *Inc. v. Sandoz*, *Inc.*, ruling on the U.S. Court of Appeals for the Federal Circuit's standard for resolving factual matters, which relate to claim construction.

Prior to the *Teva* case, claim construction was considered to be a matter of law, and not a matter of fact. Because matters of law are reviewed *de novo* on appeal, the Federal Circuit could construe the claims in a manner completely different than the district court. Now with this new ruling, factual conclusions which are used as "extrinsic evidence" for claim construction must be reviewed for "clear error." The standard of clear error gives substantial deference to the district court's findings, and thus changes the landscape of patent litigation in several ways.

To begin, the U.S. Supreme Court distinguishes between "extrinsic" and "intrinsic" evidence for claim construction. The intrinsic evidence includes the patent document itself, and the prosecution history of the patent. Determinations regarding this evidence will continue to be reviewed *de novo* before the Federal Circuit. Extrinsic evidence includes other facts which are presented during litigation, which relate to and assist in determining claim construction. It is in the determinations of this extrinsic evidence which will be subject to the clear error standard.

In addition, as stated above, factual findings which are presented to the U.S. Patent and Trademark Office (U.S. PTO) during prosecution to persuade an Examiner are <u>not</u> covered by this new rule. That evidence, as it is used in prosecution, would be considered intrinsic evidence. Thus, findings by the U.S. PTO with regard to facts presented during prosecution will be given no deference on appeal, as intrinsic evidence places it in the realm of *de novo* review. Thus, patent practitioners may wish to tailor the evidence presented to the U.S. PTO, if possible, in case they foresee litigation in the future.

The decision in the *Teva* case was a 7-2 majority opinion written by Justice Breyer, with Justice Thomas writing in dissent, joined by Justice Alito. In his dissenting opinion, Justice Thomas argued that claim construction is similar to statutory construction, and therefore should likewise be subject to de novo review on appeal.

DESIGN PATENTS IN U.S. PRACTICE AND WIPO PRACTICE (GENEVA ACT AND HAGUE AGREEMENT) By: Ariel L. Atkinson

Applications for a design patent in U.S. applications and international applications under the Geneva Act have slightly different requirements with respect to the drawings. Because applicants may want to avail themselves of submitting an application to WIPO under the Geneva Act as well as to the U.S. PTO, we provide a short guide to navigating the interactions between the two practices.

Volume IX, No. 1 | 2015

In 2012, the U.S. enacted the Patent Law Treaties Implementation Act of 2012 (PLTIA) to amend the U.S. patent laws to implement the provisions of the Geneva Act. The PLTIA allows U.S. applicants to request protection for a design patent in the other contracting parties of the Geneva Act, and it also allows international applicants to file a Hague Agreement design application designating the U.S. PTO as the examining Office.

Article 12 of the Geneva Act states that a contracting country to the Act may reject a design application if the application does not meet the conditions necessary for a grant in that country. Thus, the examination in the U.S. PTO of an international (Geneva) application will be subject to the laws and regulations governing grants of design applications in the U.S.

Of note is that the Geneva Act allows applications to include multiple designs (up to 100) for a single application. However, in the U.S., an application must be directed to a single invention. Thus, the U.S. PTO may issue a restriction requirement for applications which include multiple patentably distinct designs. This means that international applicants may have to file one or more divisional applications in the U.S. PTO to receive the same protection afforded by other jurisdictions.

In other cases, because different countries have their own formality requirements, a particular element in a drawing in an international application may be required in one country, but cause for rejection in another. In U.S. practice, replacement drawings can be submitted as long as they do not add any new matter. Thus, even if there is a problem only in formalities, it can usually be easily corrected by submitting a replacement sheet of drawing(s).

Because the laws in different jurisdictions may vary, an applicant looking to receive protection in multiple countries must carefully look at the requirements in each country. The requirements of the Geneva Act themselves provide a baseline, but just as with a utility patent, a design patentee must also be familiar with the laws and requirements of individual countries.

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