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Paul Hastings Wins Federal Circuit Affirmance Upholding Key Patent Covering Once-Daily Formulation for ORACEA®

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On August 7, 2013, the U.S. Court of Appeals for the Federal Circuit (Judges Newman, Reyna and Taranto) issued a unanimous *per curiam* decision affirming the judgment of the U.S. District Court for the District of Delaware (Judge Leonard P. Stark) that U.S. Patent No. 7,749,532 ("the '532 patent") covering the formulation for Oracea® is infringed by the proposed generic versions of Oracea® of Mylan Pharmaceuticals Inc., Lupin Ltd. and Impax Pharmaceuticals Inc., and is not invalid as anticipated or obvious. *See Research Found. of State Univ. of N.Y., et al. v. Mylan Pharms. Inc., et al.*, No. 2012-1523 *et seq.* (Fed. Cir. Aug. 7, 2013) (Slip. Op.). Oracea® is a specially formulated once-daily, 30 mg immediate-release, 10 mg delayed-release doxycycline composition indicated for the treatment of the inflammatory lesions (papules and pustules) of rosacea, and the '532 patent claims this novel once-daily, low dose formulation and its use to treat rosacea. Oracea® is marketed in the United States by Galderma Laboratories, L.P., and the '532 patent is assigned to Supernus Laboratories Inc. and exclusively licensed to Galderma.

Paul Hastings represented Galderma and Supernus in the appeal (argued by Gerald J. Flattmann, Jr. on July 9, 2013), as well as in the July 2011 bench trial before Judge Stark in the District of Delaware. Read the Federal Circuit's decision here.

As a result of the Federal Circuit's decision, Mylan, Lupin and Impax[1] ("the generic challengers") continue to be enjoined from marketing a generic version of Oracea® until the expiration of the '532 patent in December 2027.

The Oracea® appeal was instituted by the generic challengers to dispute the ruling below by Judge Stark that the '532 patent was not invalid on the alleged grounds of anticipation, obviousness or improper inventorship under 35 U.S.C. § 102(f). Specifically, on appeal, the generic challengers argued that the '532 patent was anticipated or obvious over certain other patents and applications allegedly directed to once-daily formulations of doxycycline or other drugs. The generic challengers also argued that the '532 patent was allegedly invented by another, unnamed individual, instead of by the named inventors.

Despite this multiplicity of challenges, the Federal Circuit affirmed the district court's rulings on the '532 patent "in every respect," accepting Galderma and Supernus's position that the district court's findings regarding the novelty and nonobviousness of the 30 mg immediate-release, 10 mg delayed-

release formulations claimed in the '532 patent were soundly reasoned and based on "extensive analysis." *See* Op. at 6. The Court was not moved by the generic challengers' arguments that the district court made any errors of law (including allegations that the district court misapplied *KSR v. Teleflex*). The Federal Circuit also accepted the district court's factual findings – based on evidence presented by Paul Hastings at trial through witnesses on behalf of Galderma and Supernus and cross-examination of Mylan's witnesses – that the '532 patent was not an obvious formulation using alleged "off-the-shelf" or "platform" technologies previously applied by the inventors in formulating other unrelated once-daily drug products, but rather represented an innovative, unpredictable solution to a challenging once-daily drug formulation problem.

In addition, the Federal Circuit let stand the district court's ruling that Mylan's submission of an ANDA infringing the '532 patent mandates the remedy of withdrawal of ANDA approval under 35 U.S.C. § 271(e)(4)(A), despite the fact that Mylan had not filed a Paragraph IV certification with respect to the '532 patent. Our prior client alert on this legal issue can be viewed here. The Federal Circuit also declined to overturn the district court's rulings that Mylan may not recover a $26 million preliminary injunction bond posted by Galderma, or that Lupin may not vacate a stipulation to be bound to the district court's judgment against Mylan.

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[1] The Oracea® appeal arose from judgment following a bench trial in which Mylan was the only generic challenger, and from judgments entered in related actions against generic challengers Lupin and Impax, who agreed to be bound to judgment in the Mylan action, with the right to appeal any judgment on the record of the Mylan action.