

**United States Court of Appeals
for the Federal Circuit**

REGENERON PHARMACEUTICALS, INC.,
Plaintiff-Appellant

v.

MERUS N.V.,
Defendant-Appellee

2016-1346

Appeal from the United States District Court for the Southern District of New York in No. 1:14-cv-01650-KBF, Judge Katherine B. Forrest.

ON PETITION FOR REHEARING EN BANC

NEAL KUMAR KATYAL, Hogan Lovells US LLP, Washington, DC, filed a petition for rehearing en banc for plaintiff-appellant. Also represented by WILLIAM DAVID MAXWELL; THOMAS SCHMIDT, New York, NY; CHRISTOPHER P. BORELLO, MICHAEL ENZO FURROW, BRENDAN M. O'MALLEY, ROBERT SETH SCHWARTZ, Fitzpatrick, Cella, Harper & Scinto, New York, NY.

PATRICIA A. CARSON, Kirkland & Ellis LLP, New York, NY, filed a response to the petition for defendant-appellee. Also represented by SAUNAK DESAI, AARON D.

RESETARITS, DAVID N. DRAPER; JOHN C. O'QUINN, Washington, DC; PETER B. SILVERMAN, Merus US, Inc., Cambridge, MA.

KEVIN EDWARD NOONAN, McDonnell, Boehnen, Hulbert & Berghoff, LLP, Chicago, IL, for amicus curiae Seven Chicago Patent Lawyers. Also represented by JEFFREY PALMER ARMSTRONG, AARON VINCENT GIN, JAMES LEE LOVSIN, JEREMY E. NOE, ANDREW W. WILLIAMS, DONALD LOUIS ZUHN, JR.

RICHARD ABBOTT SAMP, Washington Legal Foundation, Washington, DC, for amicus curiae Washington Legal Foundation.

EDWARD DAVID MANZO, Husch Blackwell LLP, Chicago, IL, for amicus curiae Intellectual Property Law Association of Chicago. Also represented by ROBERT H. RESIS, Banner & Witcoff, Ltd., Chicago, IL.

MELISSA A. BRAND, Biotechnology Innovation Organization, Washington, DC, for amicus curiae Biotechnology Innovation Organization. Also represented by HANSJORG SAUER; BRIAN PAUL BARRETT, Eli Lilly and Company, Indianapolis, IN.

AARON RUSSELL FISCHER, Patterson Belknap Webb & Tyler LLP, New York, NY, for amicus curiae New York Intellectual Property Law Association. Also represented by ANNEMARIE HASSETT, NYU School of Law, New York, NY; ROBERT JOSEPH RANDO, The Rando Law Firm, P.C., Syosset, NY.

MICHAEL EDWARD MCCABE, JR., McCabe Law LLC, Potomac, MD, for amici curiae David Hricik, Michael Edward McCabe, Jr.

Before PROST, *Chief Judge*, NEWMAN, LOURIE, DYK, MOORE, O'MALLEY, REYNA, WALLACH, TARANTO, CHEN, HUGHES, and STOLL, *Circuit Judges*.

NEWMAN, *Circuit Judge*, with whom REYNA, *Circuit Judge*, joins, dissents from the denial of the petition for rehearing en banc.

PER CURIAM.

ORDER

A combined petition for panel rehearing and rehearing en banc was filed by appellant Regeneron Pharmaceuticals, Inc., and a response thereto was invited by the court and filed by appellee Merus N.V. Several motions for leave to file amici curiae briefs were also filed and granted by the court. The petition for rehearing and amici curiae briefs were first referred to the panel that heard the appeal, and thereafter, the petition for rehearing, response, and amici curiae briefs were referred to the circuit judges who are in regular active service. A poll was requested, taken, and failed.

Upon consideration thereof,

IT IS ORDERED THAT:

The petition for panel rehearing is denied.

The petition for rehearing en banc is denied.

The mandate of the court will issue on January 2, 2018.

FOR THE COURT

December 26, 2017

Date

/s/ Peter R. Marksteiner
Peter R. Marksteiner
Clerk of Court

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NEWMAN, *Circuit Judge*, with whom REYNA, *Circuit Judge*, joins, dissenting from the denial of the petition for rehearing en banc.

I respectfully dissent from the denial of the requested rehearing en banc, for this decision creates conflicts in important areas of law and practice.

I previously stated my concern with this ruling that inequitable conduct in patent prosecution can be retrospectively imposed by “adverse inference” arising from later misconduct in litigation, without a showing of decep-

tive intent before the Patent Office.¹ This departure from precedent is a disservice to the patent practitioner, the patentee, and the public.

The district court imposed this adverse inference as a sanction for later litigation misconduct in an infringement suit.² Precedent does not permit such inference, for it was established in *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276, 1290–91 (Fed. Cir. 2011) (en banc), that both materiality and deceptive intent must be proved. Of particular concern are the district court’s cancellation of its scheduled evidentiary hearing on the question of intent, and its subsequent nullification of the patent as a litigation sanction, based not on evidence of specific intent, but on inference. *Therasense* instructs:

Intent and materiality are separate requirements. *Hoffmann–La Roche, Inc. v. Promega Corp.*, 323 F.3d 1354, 1359 (Fed. Cir. 2003). A district court should not use a “sliding scale,” where a weak showing of intent may be found sufficient based on a strong showing of materiality, and vice versa. Moreover, a district court may not infer intent solely from materiality. Instead, a court must weigh the evidence of intent to deceive independent of its analysis of materiality.

649 F.3d at 1290.

Therasense also requires that, when both materiality and intent are established by clear and convincing evidence, “the district court must weigh the equities to determine whether the applicant’s conduct before the PTO warrants rendering the entire patent unenforceable.”

¹ *Regeneron Pharms., Inc. v. Merus N.V.*, 864 F.3d 1343 (Fed. Cir. 2017) (“Maj. Op.”).

² *Regeneron Pharms. Inc. v. Merus B.V.*, 144 F. Supp. 3d 530 (S.D.N.Y. 2015).

Id. at 1287. None of this happened here. Nonetheless, the court departs from precedent, and sustains the “adverse inference of specific intent to deceive,” with no hearing and no evidence. Maj. Op. at 1364. En banc review is warranted.

This court further departs from precedent concerning sanctions for litigation misconduct. In *Aptix Corp. v. Quickturn Design Systems, Inc.*, this court held:

The doctrine of unclean hands does not reach out to extinguish a property right based on misconduct during litigation to enforce the right. Indeed neither the Supreme Court nor this court has ever declared a patent unenforceable due to litigation misbehavior. . . . [T]he remedies for litigation misconduct bar the malfeasant who committed the misconduct. The property right itself remains independent of the conduct of a litigant. Litigation misconduct, while serving as a basis to dismiss the wrongful litigant, does not infect, or even affect, the original grant of the property right.

269 F.3d 1369, 1375 (Fed. Cir. 2001). The court also stated that, “[t]he Supreme Court’s decision in *Keystone [Driller Co. v. General Excavator Co., 290 U.S. 240 (1933)]*, upon which the district court primarily relied, illustrates that litigation misconduct does not affect the viability of the property right itself.” *Id.* (also discussing *Hazel-Atlas Glass Co. v. Hartford-Empire Co., 322 U.S. 238 (1944)*, *overruled on other grounds by Standard Oil Co. v. United States, 429 U.S. 17, 18 (1976)*).

These newly created conflicts have received the attention of amici curiae, reflecting the importance of the issues. For example, the New York Intellectual Property Law Association states concern that the decision is “open to the interpretation that ‘widespread’ litigation misconduct may warrant an adverse inference of specific intent whenever it is ‘directly related’ to patent prosecution,

even if the evidence does *not* otherwise support an inference of specific intent to deceive the Examiner during prosecution.” The Intellectual Property Law Association of Chicago observes that this ruling “stigmatizes a prosecuting attorney for the sake of punishing his employer for the actions of litigation counsel.” The Biotechnology Innovation Organization writes that “it is hard to understand how conduct having no direct nexus to evidence relating to intent to deceive the PTO could be relevant, nor how it could ‘*require* a finding of deceitful intent in light of all the circumstances.’”

The Washington Legal Foundation observes that “the district court never conducted any sort of evidentiary hearing on the issue.” Professor David Hricik and Michael McCabe, Jr., point to inconsistencies with precedent. Seven Chicago Patent Lawyers state that “this case raises an important Constitutional issue: whether a district court’s imposition of an adverse inference sanction, which bypassed proceedings on specific intent to deceive the USPTO for inequitable conduct, violated the procedural due process protections of the Constitution.” The amici are unanimous in their apprehension of the implications of the decision.

The court’s contrary holding has produced an irreconcilable split in our jurisprudence, to the detriment of stability of law and practice. Our en banc attention is required. I respectfully dissent.