



Pharmaceutical Litigation

**Tasha Francis and
Tucker N. Terhufen**

Kyle Bass Wins at the PTAB

On October 21, 2016, the Patent and Trial Appeals Board (PTAB) issued two final written decisions invalidating claims of US Patent No. 7,056,886 ('886 patent), covering Shire's drug Gattex®, which were challenged by Dallas-based hedge fund manager Kyle Bass last year. Although Bass allegedly used the IPR process as part of a strategy to short the stock of targeted pharmaceutical companies, he has publicly stated that he was motivated by a desire to reduce drug prices. From the outset, Bass vowed to see his IPR petitions through to the end if instituted. Bass made good on that promise and succeeded in invalidating all instituted claims, overcoming arguments alleging abuse of the IPR process along the way.

Background

Gattex® is a prescription medicine that increases the intestinal uptake of nutrients, supports intestinal cell growth, and may allow some users to avoid the need for intravenous feeding (parenteral support). Gattex® received FDA approval in 2012, and had sales of \$67.9 million in 2014, and \$142 million in 2015. The '886 patent discloses stable formulations of GLP-2 peptides and analogs, which have been determined to have therapeutic applications in the treatment of diseases of the gastrointestinal tract. Most GLP-2 peptides are very unstable. The '886 patent discloses the use of a buffer to increase the pH to desired levels, the addition

of some amount of the amino acid L-histidine, and a bulking agent of either sucrose or mannitol to increase stability of certain GLP-2 peptides. The claims set forth several combinations of GLP-2 peptides and peptide concentrations, pH levels, L-histidine concentrations, and different bulking agents and concentrations.

The '886 patent claims were challenged in two IPR petitions filed by Bass and the Coalition for Affordable Drugs II LLC in April of 2015. The first IPR challenged claims 46-52 and 61-75, and the second followed a few weeks later challenging claims 1-45. On October 23, 2015 the PTAB instituted review of all of the claims challenged in the first IPR, and claims 1-27, 31-40, and 44-45 of the second IPR—all on obviousness grounds. All instituted claims were held unpatentable in the final written decisions.

The First Decision

The first set of challenged claims was considered in view of six prior art references that disclose the use of buffers, L-histidine, and sucrose and mannitol as GLP-2 peptide stabilizers. [IPR2015-00990, Paper 68 at 2, 9-12.] The PTAB found all of the challenged claims obvious in light of the cited prior art combinations. [*Id.* at 24-28.] The PTAB then considered secondary considerations of non-obviousness. Shire put on evidence of unexpected results over the prior art, substantial commercial success as evidenced by high sales, market share, and high price, as well as long-felt need in the industry because Gattex® was the first FDA approved drug of its kind. [*Id.* at 30-36.] The

PTAB was not persuaded that there was sufficient evidence of nexus between the claims in the patent and the secondary considerations of non-obviousness, finding that the benefits of the drug could be attributed to the active ingredient found in another patent listed in the Orange Book as covering Gattex®. [*Id.* at 35-36.] Having found the claims obvious in light of the prior art, and rejecting any objective indicia of nonobviousness, the PTAB held claims 46-52 and 61-75 unpatentable. [*Id.* at 37.]

The Second Decision

The second set of challenged claims was considered in view of five of the same references from the previous IPR, and one new reference. [IPR2015-01093, Paper 67 at 2-3.] The PTAB again held all of the challenged claims obvious in light of the combination of disclosures in the prior art. [*Id.* at 21-26.] The PTAB then considered secondary considerations of nonobviousness. Shire put on essentially the same evidence in support of unexpected results, commercial success, and long-felt need. [*Id.* at 26-34.] The PTAB again held that there was insufficient evidence of nexus between the challenged claims and the secondary indicia provided. [*Id.*] Based on these findings, the PTAB held claims 1-27, 31-40, and 44-45 unpatentable. [*Id.* at 34.]

The PTAB's decision regarding these IPRs left only claims 28-30, 41-43, and 53-60 as valid in the '886 patent. Three other patents are listed in the Orange Book as covering Gattex®. Shire can request a rehearing by panel within 30 days of the final written decision, and must articulate all grounds it feels the PTAB "misapprehended or overlooked." [37 C.F.R. § 42.71(d).] Alternatively, Shire may appeal directly to the Federal Circuit [35 U.S.C. § 319], and must file a notice of appeal within 63 days of the final written decision. [37 C.F.R. § 90.3.]

Tasha Francis, PhD, is an associate at Fish & Richardson in Minneapolis, MN, where she practices intellectual property litigation with an emphasis on patent litigation. Dr. Francis has represented plaintiffs and defendants in cases involving medical devices, biotechnology, and pharmaceuticals. In addition, she writes extensively on topics related to the Biologics Price Competition and Innovation Act and life sciences post-grant proceedings. Dr. Francis earned her PhD in Chemical Biology from the University of Michigan in 2010

and her JD from the University of Michigan Law School, where she was a contributing editor for the Michigan Telecommunications and Technology Law Review. Dr. Francis is licensed to practice law in the state of Minnesota and before the United State Patent and Trademark Office.

Tucker Terhufen is a litigation associate at Fish & Richardson in San Diego, CA. His practice focuses on patent litigation in federal district courts as well as before the International Trade Commission

for clients in the medical devices, life sciences, and chemical industries. Prior to joining Fish, he served as judicial extern to the Honorable David G. Campbell of the US District Court for the District of Arizona and to the Honorable Mary H. Murguia of the US Court of Appeals for the Ninth Circuit. Mr. Terhufen earned his JD from Arizona State University, Sandra Day O'Connor College of Law, where he was Note and Comment Editor of the Arizona State Law Journal. He is licensed to practice law in the state of California.



Trade Secret Litigation

Alexander Ip and
Patrick E. Premo

Ninth Circuit Leaves Open Whether Trade Secret Liability May Be Predicated on an Implied Theory of Confidentiality

In a recent decision, *Direct Technologies, LLC v. Electronic Arts, Inc.* [14-56266, 14-56745, (Sept. 6, 2016)], the US Court of Appeals for the Ninth Circuit called into question, but did not definitively resolve, whether trade secret liability could be predicated solely on an implied obligation of confidentiality under California law. The litigation arose in the context of a vendor dispute involving the design and manufacture of promotional USB flash drives. Defendant Electronic Arts (EA) was releasing one of its new video games, *The Sims 3*, and decided to order USB flash drives as a promotional trinket to be sold

with the game. Plaintiff Direct Technologies (DT) was contracted to design and produce a prototype of the flash drive. Without DT's knowledge, DT's prototype was sent to a Chinese company that offered to manufacture the USB drives at a discounted rate. After learning that it had lost the project, DT sued in the US District Court for the Central District of California for copyright infringement and trade secret misappropriation. EA moved for summary judgment on both claims and won.

Upon review, as to the copyright infringement claim, the Ninth Circuit reversed, holding that there was a genuine issue of material fact as to whether DT's cutaway design for removing the flash device merits copyright protection. With respect to the trade secrets claim, the Ninth Circuit affirmed summary judgment, but on alternative grounds. Originally, the district court held that no reasonable jury could find that Plaintiff took reasonable efforts to maintain the secrecy of its prototype. It was undisputed that there

was no written nondisclosure agreement (NDA) in place or any express obligation of confidentiality in the vendor agreement entered into by the parties. In addition, Plaintiff had placed no limitations on what could be done with the prototype flash drive and did not mark or label the prototype as confidential.

Despite expressly acknowledging that the manufacturer "did not do much, if anything, to explicitly protect its prototype design," the Ninth Circuit in *Direct Technologies* refused to affirm on that basis. As the Court in *Direct Technologies* explained, "a confidential relationship may reasonably be implied," citing an older Ninth Circuit decision, *Pachmayr Gun Works, Inc. v. Olin Mathieson Chemical Corp.*, issued before the California Uniform Trade Secrets Act (CUTSA) had been enacted.

In the end, the Ninth Circuit in *Direct Technologies* affirmed summary judgment in favor of the defense, but on alternative grounds, namely, that the USB prototype design did not qualify as a trade secret because it did not "[d]erive[] independent economic value from not being generally known to the public or to other persons who can obtain economic value from its disclosure or use." [See Cal. Civ. Code § 3426.1(d)(1); see *Altavion, Inc. v. Konica Minolta Sys. Lab. Inc.*]