On July 27, 2017, a Federal Circuit panel affirmed 2-1 a district court’s determination that Regeneron Pharmaceuticals, Inc.’s patent on genetically modified mice is unenforceable due to inequitable conduct during prosecution of the patent. In *Regeneron Pharmaceuticals, Inc. v. Merus N.V.*, the Federal Circuit upheld the district court’s unconventional approach to finding inequitable conduct, holding that the district court did not clearly err in finding the prior art Regeneron withheld from the Patent Office to be “but-for material” to patentability and did not abuse its discretion by drawing an adverse inference of specific intent to deceive the Patent Office as a sanction for Regeneron’s misconduct during litigation, and therefore, the district court did not abuse its discretion in holding the patent unenforceable due to inequitable conduct. No. 2016-1346 (Fed. Cir. July 27, 2017) (precedential).

During prosecution of Regeneron’s patent-in-suit, and only days before its allowance, a third-party submitted three relevant prior art references to the Patent Office during prosecution of another application related to the patent-in-suit. Regeneron’s in-house counsel admitted knowing of these references, as well as a fourth reference authored by a member of Regeneron’s scientific advisory board. Regeneron disclosed the references in other related Regeneron patent applications after the patent-in-suit was allowed but never disclosed them during prosecution of the patent-in-suit.

In the district court, the judge planned to hold two separate bench trials, one for each of the two elements of inequitable conduct: materiality and specific intent to deceive the Patent Office. Following the first bench trial on materiality, the district court issued an opinion detailing the materiality of each of the prior art references withheld from the Patent Office, but never scheduled a second trial on intent. Instead, the district court invoked Regeneron’s egregious discovery misconduct throughout the litigation and imposed sanctions for that misconduct by drawing an adverse inference that Regeneron failed to disclose the withheld prior art references with specific intent to deceive the Patent Office, ultimately holding Regeneron’s patent unenforceable for inequitable conduct.

On appeal to the Federal Circuit, Regeneron argued that the district court improperly reached its conclusions on both elements of inequitable conduct. The Federal Circuit disagreed and concluded that under the broadest reasonable interpretation of the claims, the district court did not clearly err in finding each of the withheld references but-for material and not cumulative of the prior art considered by the examiner. The Federal Circuit also adopted the district court’s factual findings regarding Regeneron’s litigation misconduct, which the district court described as “gamesmanship” and “tactical choice[s]”—including Regeneron’s failure to produce documents related to its in-house counsel’s and other witnesses’ mental impressions of the prior art withheld from the Patent Office, as well as Regeneron’s repeated failures to comply with discovery orders. Regeneron argued that the district court improperly applied an adverse inference because, under regional circuit law, such an adverse inference can only be applied to a particular piece of evidence that was missing, destroyed, or untimely produced. The Federal Circuit rejected Regeneron’s argument, explaining that district courts have broad discretion to sanction parties for violating discovery obligations and are not limited to applying sanctions against specific pieces of evidence. Acknowledging that the district court considered various alternative sanctions and weighed fairness to the parties and the court, the majority ultimately determined that the district court did not abuse its broad discretion by imposing sanctions on Regeneron in the form of an adverse inference of specific...
intent to deceive the Patent Office.

In a dissenting opinion, Judge Newman criticized the majority for “apply[ing] incorrect law and adding confusion to precedent,” explaining that the withheld prior art references were not but-for material to patentability and that “the purported ‘litigation misconduct’ . . . has no relation to whether there was inequitable conduct in the prosecution before the patent examiner.”

While Regeneron takes an unusual path to finding inequitable conduct, it nonetheless provides a cautionary tale for patent owners, patent prosecutors, and litigants alike that particularly egregious misconduct during litigation can infect prosecution, at least when the misconduct seemingly relates to the information withheld from the Patent Office.

Other Notable Decisions – Week Ending July 28, 2017

Soft Gel Technologies, Inc. v. Jarrow Formulas, Inc., Nos. 2016-1814, 2016-1815, 2017-1051 (Fed. Cir. July 26, 2017) (precedential): In Soft Gel Technologies, the Federal Circuit affirmed the Patent Trial and Appeal Board’s decisions in three inter partes reexaminations invalidating as obvious claims of three Soft Gel patents for a soft gelatin capsule composition and related method involving solutions of the coenzyme CoQ10 dissolved in limonene. Following rejection of the claims during reexamination, the Board found that the combination of the prior art references at issue suggests the claimed invention and that a person of skill in the art would have been motivated to combine the references with a reasonable expectation of success in doing so. The Federal Circuit agreed with the Board’s obviousness determination and found either no error or harmless error in each of the Board’s challenged findings. In doing so, the Federal Circuit underscored that obviousness requires only “a reasonable expectation of success,” not “absolute predictability,” as Soft Gel’s arguments implied. The Federal Circuit further noted that supplemental or confirmatory studies related to the prior art at issue do not negate obviousness, as suggested by Soft Gel, but instead could be indicative of such a reasonable expectation of success.

Teresa H. Earnhardt v. Kerry Earnhardt, Inc., No. 2016-1939 (Fed. Cir. July 27, 2017) (precedential): In Earnhardt, the Federal Circuit vacated and remanded for reconsideration the Trademark Trial and Appeal Board’s dismissal of Teresa Earnhardt’s opposition to Kerry Earnhardt, Inc.’s (“KEI’s”) registration of the mark EARNHARDT COLLECTION for furniture and custom construction of homes. In dismissing the opposition, the Board concluded that EARNHARDT COLLECTION is not primarily a surname as Ms. Earnhardt had argued. On appeal, the Federal Circuit rejected the Board’s conclusion, holding that the Board’s analysis of the mark as a whole was deficient.

While the Board’s decision stated that “collection” is “not the common descriptive or generic name” for KEI’s goods and services, it was unclear to the Federal Circuit whether the Board properly engaged in a merely descriptive inquiry for the term “collection” or improperly limited its analysis to only a genericness inquiry. The Federal Circuit directed the Board on remand to determine “(1) whether the term ‘collection’ is merely descriptive of KEI’s furniture and custom home construction services, and (2) the primary significance of the mark as a whole to the purchasing public.”

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