The AIPLA's
2022–2023 Giles Sutherland Rich Memorial
Moot Court Competition

Three Fairies, Inc. v. Maleficent, Inc., Case No. 2022-GSR

Problem Materials:

This year's problem materials include:

(1) This problem prompt.

(2) The Joint Appendix. The Joint Appendix includes pages Appx001–Appx021.

Patent-in-Suit:

The Patent-in-Suit is United States Patent GSR,978,016 to Aurora Charming (the "'016 patent"). The '016 patent is directed to pharmaceutical compositions and methods for the treatment of chronic fatigue. Independent claim 1 of the '016 patent recites a composition for the treatment of chronic fatigue. Independent claim 10 of the '016 patent recites a method of alleviating the symptoms of chronic fatigue syndrome comprising administering awakenate.

Issues on Appeal:

Two issues are on appeal to the United States Court of Appeals for the Federal Circuit:

(1) Whether the doctrine of equivalents can be applied to the limitation "about 5% by weight of awakenate" in claim 1 of the '016 patent.

(2) Whether the limitation "at least 100 mg of awakenate" in claim 10 of the '016 patent is enabled.

Trial Counsel:

The appellant was represented in the district court by the law firm of Smith & Smith LLP. The appellee was represented in the district court by the law firm of Jones & Jones LLP. The competitors are engaged as counsel only for the purposes of this appeal.

Background:

In the summer of 2010, Aurora Charming graduated from Magic Kingdom University with a Ph.D. in molecular biology, cell biology, and biochemistry. That fall, she started working as a research scientist at Three Fairies, Inc. ("Three Fairies"). At the same time, Dr. Charming's husband, Phillip, was starting his 3L year at Magic Kingdom Law School. After years of spending too much time in the library, Phillip was experiencing chronic fatigue. Dr. Charming was assigned to the biologics group at Three Fairies, and was inspired by Phillip to work on the development of a novel biologic that could be used in the treatment of conditions including chronic fatigue.

By the end of 2016, Dr. Charming was leading her own team of research scientists and had completed clinical studies on her biologic, which she named AWAKE® (awakenate). Between 2010 and 2016, Three Fairies filed several patent applications related to awakenate. Of note is U.S. Patent App. No. GSR/121,959 (the "'959 application"), which claims compositions of awakenate and methods of treatment using awakenate. Other patent applications relate to, *inter alia*, methods of producing awakenate.

Three Fairies filed the '959 application on January 3, 2014. In September 2014, the USPTO Examiner rejected claims 10–12 for failure to comply with the written description requirement of 35 U.S.C. § 112. In response, Three Fairies amended claim 10 in February 2015. At the same time, Three Fairies also amended claim 1, and commented that such amendment was

not being made in light of any prior art. An Examiner Interview took place via teleconference in June 2016. Following the interview, the Examiner allowed the claims.[1]

On July 27, 2016, the '959 application issued as U.S. Patent No. GSR,978,016 (the "'016 patent"). Dr. Charming is the sole named inventor on the '016 patent, and the '016 patent is assigned to Three Fairies. Independent claims 1 and 10 are representative:

1. A composition for the treatment of chronic fatigue, comprising awakenate, wherein the composition comprises about 5% by weight of awakenate.

10. A method of alleviating the symptoms of chronic fatigue syndrome comprising administering at least 100 mg of awakenate to a patient suffering from chronic fatigue.

In January 2017, Three Fairies submitted a Biologics License Application (BLA) for AWAKE® (awakenate) to the U.S. Food and Drug Administration (FDA). In March 2017, FDA approved the BLA, and Three Fairies began marketing AWAKE®. Three Fairies provided a patent list for AWAKE® to FDA for publication in the Purple Book. The patent list includes the '016 patent and twenty other issued patents related to awakenate.

AWAKE® quickly became the most widely used biologic for treatment of chronic fatigue because of its excellent efficacy and safety. Like most other biologics, AWAKE® was very expensive. Several other companies worked to develop biosimilars of AWAKE® that would be more affordable for patients. In April 2021, Maleficent, Inc. ("Maleficent") submitted a Section 351(k) BLA[2] to FDA for a biosimilar of AWAKE® called REVIVATE™ (awakenate-mlfn).

[1] The issue of loss of resort to the doctrine of equivalents due to the presence of an amendment is not an issue on appeal.
[2] *See* 42 U.S.C. § 262(k).

FDA accepted Maleficent's Section 351(k) BLA for review, and Maleficent decided to initiate the "patent dance"[3] under the Biologics Price Competition and Innovation Act (BPCIA) rather than launch REVIVATE™ at risk. Maleficent sent a copy of its Section 351(k) BLA to Three Fairies. In response, Three Fairies provided a list of ten patents it wanted to assert against Maleficent—including the '016 patent—and identified three patents on the list that it would be prepared to license Maleficent. The '016 patent was not one of the patents that Three Fairies was prepared to license. In response, Maleficent did not identify any other patents it believed should be included in litigation, and it accepted Three Fairies' license offer for the three patents. Maleficent also provided detailed statements with factual and legal bases for invalidity, unenforceability, and non-infringement of the '016 patent and the other six remaining patents. Three Fairies responded with its own detailed statements on validity, enforceability, and infringement of the '016 patent and the other six patents. Three Fairies and Maleficent negotiated, and agreed to litigate only the '016 patent in the first wave of litigation under the BPCIA.[4]

The Case Below:

On January 10, 2022, Three Fairies sued Maleficent in the United States District Court for the District of Gilesead, which is part of the First Circuit. This was the first BPCIA litigation filed in the District of Gilesead. The complaint accused Maleficent of infringing independent claims 1 and 10 of the '016 patent. Three Fairies alleged that Maleficent infringes claim 1 under the doctrine of equivalents (DOE) and literally infringes claim 10.

Three Fairies and Maleficent had already exchanged detailed statements addressing infringement, validity, and enforceability during the patent dance, and the parties maintained those

[3] *See* 42 U.S.C. § 262(*l*).
[4] For purposes of this appeal, assume that the parties complied with 42 U.S.C. § 262(*l*) and did not skip any parts of the patent dance.

positions in the litigation. Maleficent argued that it does not infringe claim 1 because DOE is unavailable as a matter of law and that claim 10 is invalid for lack of enablement. Three Fairies argued that DOE is available for claim 1 and that claim 10 is enabled.

The parties requested that the district court construe the terms "about 5% by weight of awakenate" (claim 1) and "at least 100 mg of awakenate" (claim 10). A magistrate judge held a *Markman* hearing and issued a report and recommendation, which recommended that the district judge apply the plain and ordinary meaning for each term. The district judge adopted the report and recommendation in its entirety.[5]

Fact discovery focused on the percent by weight of awakenate in REVIVATE™ and the administration of REVIVATE™ to patients suffering from chronic fatigue, including the instructions that Maleficent provides to doctors prescribing REVIVATE™.

On January 6, 2023, Maleficent moved for summary judgment of non-infringement of claim 1 and invalidity of claim 10 under Federal Rule of Civil Procedure 56. Regarding claim 1, Maleficent argued that DOE is unavailable as a matter of law for claim limitations that recite the term "about." In response, Three Fairies argued that the "about" limitation in claim 1 is not critical to the invention, so DOE is available. Regarding claim 10, Maleficent argued that the claim is invalid for lack of enablement because the limitation "at least 100 mg of awakenate" recites an unbounded upper range. In response, Three Fairies argued that a person of ordinary skill in the art (POSITA) would understand that there is an inherent upper limit on the maximum therapeutically effective amount of awakenate.

[5] The magistrate judge's report and recommendation and the district judge's order adopting the report and recommendation are not at issue in this appeal, but an excerpt of the magistrate judge's report and recommendation that summarizes the '016 patent's prosecution history is included in the Joint Appendix.

The district court granted Maleficent's motions for summary judgment of non-infringement of claim 1 and invalidity of claim 10.

The Appeal:

Three Fairies timely appeals the district court's grant of Maleficent's motions for summary judgment of non-infringement of claim 1 and invalidity of claim 10 to the United States Court of Appeals for the Federal Circuit.