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Federal Circuit: Prior Art Disclosure with Same Specificity as Patent Inherently Anticipates Claims

May 16, 2023

Reading Time : **3 min**

By: Vincent P. Jones, Rachel J. Elsby

In a recent appeal from the PTAB, the Federal Circuit held that claims of a patent were inherently anticipated where the patent and prior art incorporated the same reference to describe a process for making the claimed composition of particles, and that process was responsible for determining the morphology of the claimed particles.

Claim 1 of the challenged patent is directed to a composition of acid-lipid particles of a specific composition and with a specific non-lamellar morphology. The primary question before the PTAB was whether the prior art inherently disclosed the morphology limitation. According to the disclosures in the patent, two factors determine the morphology of the particles—their formulation and the process used to make them. It was undisputed that the prior art expressly disclosed the formulations of the particles. The prior art reference did not expressly disclose the process for making them, but did incorporate a second reference for that purpose. Because the challenged patent incorporated the exact same reference for the same purpose (i.e., as a disclosure of methods of making the particles), the PTAB found the limitation inherently anticipated.

Appellant-Patent Owner Arbutus argued on appeal that the method of making the particles did not meet the requirements for inherent anticipation because it would not necessarily result in the claimed morphology. By way of background, the prior art patent and the challenged patent are related, commonly owned by Arbutus, and share overlapping inventors.

On review, the Federal Circuit first confirmed that the prior art patent disclosed the formulations of the claimed particles. In particular, the written description in both patents are

substantially similar—they describe two of the five relevant formulation with almost identical wording and the specificity provided in the disclosures is the same.

The Federal Circuit next compared the methods disclosed in the prior art and the challenged patent. In this regard, the challenged patent explained that the non-lamellar morphology could be determined using techniques *known to and used by those of skill in the art*. The challenged patent referred to a specific method, the Direct Dilution Method, as carrying out the process necessary to produce the non-lamellar morphology, and incorporated by reference a patent publication that provided the details of the Direct Dilution Method. Although the challenged patent provided some details about the Direct Dilution Method not found in the asserted prior art, the Federal Circuit found it was sufficient that the prior art incorporated the same patent publication.

Because the formulation and method of making the particles was disclosed in the prior art, the Federal Circuit affirmed the PTAB's decision that the prior art inherently anticipated the morphology limitation. The court reasoned that to anticipate, the prior art need only meet the inherently disclosed limitation to the same extent as the patented invention. It was not persuaded by Arbutus's argument that the morphology limitation would not necessarily result from the combination of the formulation and method of making. Here, there were a limited number of tools—five formulations and two processes—in the claims that a POSA would have to follow. As a result, the Court held that it was reasonable for the PTAB to have found that a POSA would follow the particular formulation and process disclosures that would inherently lead to the Morphology Limitation.

Practice Tip: When prosecuting claims that have the same or substantially the same written descriptions as patents and applications that could be prior art, it is important to include limitations that can be relied on to distinguish over those patents. This is particularly important where the claims include compositions with properties that result from specific methods of making those compositions.

Arbutus Biopharma Corp. v. ModernaTX, Inc., No. 2020-1183 (Fed. Cir. Apr. 11, 2023).

Categories

Federal Circuit | Patent Trial & Appeal Board | Patent Litigation | Prior Art