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Federal Circuit Affirms District Court's Obviousness Judgment on ImmunoGen Patent Application

1. Background: ImmunoGen's Patent Application & Dispute

In 2014, ImmunoGen, Inc. (Immunogen) filed U.S. Patent Application No. 14/509,809 (the '809 application).[1] The '809 application has three independent claims, all of which are directed to methods of treating ovarian and peritoneal cancers by administering an antibody drug conjugate (ADC) known as IMGN853 (i.e., mirvetuximab soravtansine) according to certain dosing regimens. Specifically, the '809 application claims administering the ADC "at a dose of 6 milligrams (mg) per kilogram (kg) of adjusted ideal body weight (AIBW) of the patient."[2]

According to the specification, IMGN853 was found to cause ocular toxicity (i.e., blurred vision, keratitis, etc.) at certain doses.[3] The inventors of the '809 application discovered that "the high Cmax and initial AUC values are not required for efficacy" and developed "a therapeutically effective dosing regimen that results in minimal adverse effects."[4]

The patent examiner, however, rejected the claims of the '809 application on various grounds, including obviousness and obviousness-type double patenting. The Patent Trial and Appeal Board affirmed the examiner's rejections and ImmunoGen filed suit in the Eastern District of Virginia seeking a judgment that it was entitled to a patent under 35 U.S.C. § 145.

After a three-day bench trial,[5] the district court agreed with the Patent Office and determined that the claims of the '809 application were obvious and were not patentably distinct from subject matter claimed in other patents owned by ImmunoGen (and thus were not patentable under the doctrine of obviousness-type double patenting).[6,7] ImmunoGen appealed, and on March 6, 2025, the Federal Circuit affirmed the district court's judgment on obviousness in a precedential opinion.

2. The Federal Circuit's Decision

The Federal Circuit began its obviousness analysis by explaining that "Immunogen first argues that the district court erred in its motivation-to-combine analysis because it was undisputed that at the time of the invention, a person of ordinary skill in the art would not

Related People

- Corey M. Casey, Pharm.D.
- Christopher Jones

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have known that IMGN853 caused ocular toxicity in humans."[8] According to ImmunoGen, because the problem that the inventors aimed to solve was not known (i.e., that IMGN853 can cause ocular toxicity), the dosing regimen recited in the claims of the '809 application could not have been obvious.

The Federal Circuit disagreed, explaining that "it does not follow that a claimed solution to an unknown problem is *necessarily* non-obvious."[9] And the Federal Circuit explained "that the specific problem the inventors of the '809 application purported to solve via the claimed dosing regimen was unknown does not necessarily mean that the dosing regimen itself was not obvious."[10] In other words, the motivation provided by the prior art does not need to match the alleged motivation of the inventors—what matters is that a POSA would have been motivated by the prior art to arrive at the claimed dose, regardless of the reason, and would have had a reasonable expectation of success.

Regardless, the district court found that ocular toxicity was a known problem in the context of immunoconjugates like IMGN853 and thus a POSA would have known to monitor patients for those side effects when administering IMGN853. The district court also explained that pre-clinical studies were conducted in rabbits in which they were given IMGN853, but that ocular toxicity was *not* found to be a side effect in those studies. But experts on both sides agreed that pre-clinical animal studies do not *always* translate to humans, thus those rabbit studies would not have deterred a POSA from monitoring for those side effects in humans. The Federal Circuit found no clear error in the district court's reasoning on these points.[11]

The district court also found that a POSA would have been motivated to reduce the toxicity of IMGN853 by experimenting with the dosing regimen and that AIBW was a known dosing methodology for that purpose.[12] ImmunoGen took issue with the fact that the district court did not explain why a POSA would have been motivated to use AIBW specifically, as opposed to other known dosing methodologies.

The Federal Circuit again disagreed with ImmunoGen and found no clear error in the district court's reasoning. Specifically, the Federal Circuit agreed with the district court that a POSA would have been motivated to select a 6 mg/kg AIBW dose with a reasonable expectation of success in view of a prior art reference that taught a dose of IMGN853 based on total body weight (TBW) dosing.[13] The Federal Circuit acknowledged that TBW and AIBW are different types of weight-based dosing methodologies, but explained that the prior art reference's 6 mg/kg TBW dose of IMGN853 would have also led to a 6 mg/kg AIBW dose of IMGN853 in certain situations. And the Federal Circuit explained that "[a] doctor dosing a patient at his or her IBW with IMGN853 at a dose of 6 mg/kg TBW would necessarily be dosing that patient at 6 mg/kg AIBW, as claimed. This would be true regardless of whether a doctor *knew* of AIBW dosing"[14]

Finally, ImmunoGen argued that the district court erred because a POSA would not have had a reasonable expectation of success with respect to using a 6 mg/kg AIBW dose to ameliorate ocular toxicity. The problem with ImmunoGen's argument was that "the claims are silent as to any ocular toxicity problem," and thus "ImmunoGen's framing of the reasonable-expectation-of-success analysis is inapt."[15] Here, "[t]he inquiry merely required the district court to determine whether the evidence established that a person of ordinary skill in the art would have had a reasonable expectation that dosing a human at 6 mg/kg AIBW would have been effective in treating ovarian and peritoneal cancers, as claimed."[16] Because the prior art taught that dosing regimen, as claimed, the claims of the '809 application were found to be unpatentable as obvious.[17]

Conclusion and Takeaways

The Federal Circuit's opinion offers important guidance on obviousness issues in the context of "method of treatment" and dose-regimen patents. Namely, the fact that a dosing-related "problem" is not expressly known in the prior art may not save an otherwise obvious patent, particularly when the claims are "silent" on the dosing issues. In that case, a POSA can be motivated (and have a reasonable expectation of success) by the prior art for reasons distinct from what motivated the inventors to develop the claimed dosing-regimen.

Indeed, the Federal Circuit made clear that "the obviousness inquiry is generally agnostic to the particular motivation of the inventors,"[18] and that "*any* need or problem known in the field of endeavor at the time of invention and addressed by the patent can provide a reason for combining the elements in the manner claimed."[19] Also, a dosing patent may be obvious even if the prior art does not expressly teach the specific nuances of how to arrive at the claimed dose or dosing methodology (e.g., where the TBW dose necessarily meant the same thing as the AIBW dose in at least some patients). Ultimately, the Federal Circuit's opinion underscores the fact intensive nature of the motivation and reasonable expectation of success elements in the context of obviousness.

[1] The '809 application claims priority to a provisional application filed on October 8, 2013.

[2] *See, e.g.*, '809 application, claim 1.

[3] *See, e.g.*, *id*. at ¶ [0009].

[4] *Id*. at Abstract, ¶ [0009].

[5] Before this bench trial, the district court previously ruled in the patent office's favor after a motion for summary judgment was filed. But the Federal Circuit vacated and remanded the district court's summary judgment decision because "the district court resolved numerous factual disputes against" ImmunoGen.

[6] *ImmunoGen, Inc. v. Vidal*, 653 F. Supp. 3d 258, 307 (E.D. Va. 2023).

[7] The district court also found the claim term "adjusted ideal body weight (AIBW)" indefinite after trial, but the Federal Circuit did not address indefiniteness issues on appeal.

[8] *ImmunoGen, Inc. v. Stewart*, No. 2023-1762, 2025 WL 715996, at *3 (Fed. Cir. Mar. 6, 2025).

[9] *Id*.

[10] *Id*.

[11] *Id*.

[12] *Id*. at *4.

[13] *Id*. at *5.

[14] *Id*.

[15] *Id*.

[16] *Id*.

[17] The Federal Circuit also noted that “the government further challenged the patentability of the claims under the doctrine of obviousness-type double patenting,” but “[o]n appeal, the parties agree[d] that that issue rises and falls with the issue of obviousness,” and therefore double patenting was not addressed further by the Federal Circuit. *Id*., n. 3.

[18] *Id*. at *12, citing *KSR Int’l Co. v. Teleflex Inc*., 550 U.S. 398, 419 (2007)

[19] *Id*. at *7, citing *KSR Int’l*, 550 U.S. 420.