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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

COALITION FOR AFFORDABLE DRUGS VI, LLC,
Petitioner,

v.

CELGENE CORPORATION,
Patent Owner.

Case IPR2015-01096 (Patent 6,315,720 B1)
Case IPR2015-01102 (Patent 6,315,720 B1)
Case IPR2015-01103 (Patent 6,315,720 B1)[1]

Before MICHAEL P. TIERNEY, *Vice Chief Administrative Patent Judge*, GRACE KARAFFA OBERMANN, and TINA E. HULSE, *Administrative Patent Judges*.

OBERMANN, *Administrative Patent Judge*.

DECISION
Granting Patent Owner's Request for Rehearing
37 C.F.R. § 42.71(d)

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[1] Patent Owner filed a substantially identical Request for Rehearing in each proceeding. IPR2015-01096, Paper 74; IPR2015-01102, Paper 76; IPR2015-01103, Paper 77. This Decision addresses issues common to all cases. Accordingly, we issue a single Decision to be entered in each case. For convenience, we refer to papers filed in IPR2015-01096.

I. INTRODUCTION

On November 25, 2016, Celgene Corporation ("Patent Owner") filed a Request for Rehearing of the Final Written Decision. Paper 74 ("Req."). In the Final Written Decision, we held that claims 1–32 of U.S. Patent No. 6,315,720 B1 ("the '720 patent") are unpatentable. Paper 73, ("Dec."). The Request for Rehearing is confined to our holding that claim 10 is unpatentable. Req. 1; *see* Dec. 27–28 (addressing claim 10).

For reasons that follow, we grant the Request for Rehearing. We are persuaded that the Final Written Decision should be modified as to claim 10. Specifically, we hold that Petitioner fails to establish by a preponderance of the evidence that claim 10 of the '720 patent is unpatentable. This Decision does not disturb our holding, stated in the Final Written Decision, that Petitioner establishes by a preponderance of the evidence that claims 1–9 and 11–32 are unpatentable. Dec. 34.

II. ANALYSIS

Patent Owner asserts that the Board overlooked or misapprehended evidence and arguments showing that the subject matter of claim 10 would not have been obvious under 35 U.S.C. § 103(b). Req. 1.

In pertinent part, 37 C.F.R. § 42.71(d) states:

> The burden of showing a decision should be modified lies with the party challenging the decision. The request must specifically identify all matters the party believes the Board misapprehended or overlooked, and the place where each matter was previously addressed in a motion, an opposition, or a reply.

Claim 10 depends from claim 7, which depends from claim 1. Claim 1 requires, *inter alia*, defining a set of information to be obtained from a patient. Ex. 1001, 18:30–31. Claim 7 further requires that the "information to be obtained" from the patient "includes the results of diagnostic testing." *Id*. at 18:59–60. Claim 10 requires that "said diagnostic testing comprises genetic testing." *Id*. at 18:66–67.

In the Final Written Decision, we found that the subject matter of claim 10 would have been obvious, even though "the references of record do not disclose or suggest genetic testing." Dec. 27–28. On that point, we credited Dr. Fudin's declaration testimony that genetic testing was a known diagnostic procedure as of the effective filing date of the '720 patent. *Id*. at 28. We reasoned that Dr. Fudin's testimony was consistent with FDA Meeting Minutes (Ex. 1013), which contained a statement from a Dr. Holmes, said to represent the American College of Medical Genetics and the Teratology Society. Ex. 1013, 137. Specifically, Mr. Holmes stated that:

> It may seem strange to you that a genetics society would be standing here, commenting on potential environmental exposures with awful fetal effects, but many clinical geneticists around the country are expected to provide counseling to pregnant women about exposures in pregnancies, so the geneticists, in fact, are often the clinical teratologists. And I am speaking myself as an active clinical teratologist in the Boston area.

Id.

Based on that objective support, we held "that the genetic testing of dependent claim 10 represents a combination of known elements for their known use to achieve a predictable result, genetic testing to obtain information for diagnosis and treatment." Dec. 28. Having reconsidered the

record on rehearing, however, we find that this finding is not supported by a preponderance of the evidence.

As an initial matter, Patent Owner argues that the Board improperly shifted the burden of proof by holding that Patent Owner "did not dispute that genetic testing was known in the art for obtaining diagnostic information."[2] Req. 3 (quoting Dec. 27). Patent Owner, in fact, timely disputed that genetic testing would have been understood as common in the art, and identified a gap in Petitioner's evidence on that point. Req. 3 (citing PO Resp. 45–56). Specifically, Patent Owner pointed to the absence of disclosure in the asserted prior art, which teaches various other tests but not genetic testing. PO Resp. 46. Patent Owner argued that the lack of disclosure in the record evidence "undermines Dr. Fudin's opinion that such testing was 'common.'" *Id*.

We agree that the proper focus is not whether Patent Owner disputed that fact, but whether Petitioner came forward with evidence sufficient to demonstrate that genetic testing was known and would have been used in the combination required by claim 10. We also agree that the lack of disclosure in the prior art of record—coupled with the record's disclosure of other types of tests—cuts against a finding "that genetic testing would be used, let alone that it would have been common." Req. 3. Dr. Fudin states that "[i]t was common in the art at the time of" the invention "to conduct genetic

[2] Patent Owner asserts that in its Patent Owner Response it did dispute that genetic testing was known in the art or common. Req. 3. Other than citing its entire argument regarding claim 10, which we already address throughout this Decision, Patent Owner does not identify any specific argument or evidence that we overlooked or misapprehended in connection with this assertion. *Id.*

testing at the same time as the pregnancy testing taught in" the prior art, but directs us to no disclosure in the asserted prior art, or any other objective evidence, on point. Pet. 27–31 (citing Ex. 1021 ¶¶ 141–143).

On that point, Dr. Fudin does not cite, or otherwise explain the significance of, the disclosure in the FDA Meeting Minutes that we relied upon in the Final Written Decision. Ex. 1021 ¶¶ 140–143. PO Resp. 45–46; Pet. 58 (citing Ex. 1021 ¶¶ 229–231); Dec. 28. That disclosure, cited for the first time in Petitioner's Reply[3], does not refer to genetic testing, much less suggest using genetic testing in the combination required by claim 10. Reply 25–26 (citing Ex. 1076[4], 137); *see* Req. 3 (arguing on rehearing that the Petitioner "relied solely on a single passage" in the FDA Meeting Minutes "that focuses on the geneticist acting as a clinical teratologist that might counsel patients on the risks of exposure") (citing Reply 25–26; Ex. 1013, 137). Patent Owner correctly points out that "the cited passage says nothing about genetic testing, nor does it suggest such testing." Req. 3 (emphasis omitted); Ex. 1013, 137; Ex. 1076, 137.

We find that the FDA Meeting Minutes fail to support adequately Dr. Fudin's opinion testimony that genetic testing would have been common at the time of the invention. Contrary to "Dr. Fudin's opinion that [genetic] testing was 'common,'" the asserted prior art references do not disclose, teach, or suggest genetic testing, "despite disclosing various other types of

[3] The Petition cites other disclosures in the FDA Meeting Minutes to support arguments unrelated to the genetic testing limitation of claim 10. Pet. 13–14 (citing Ex. 1013).

[4] The same material appears on page 137 of Exhibit 1013, which is cited in the Final Written Decision. Dec. 28.

tests." Req. 2; PO Resp. 46. Given that Dr. Fudin's opinion on that point is unsupported by objective evidence, we assign his testimony little weight in the analysis of claim 10. Req. 2–3; PO Resp. 46 (citing 37 C.F.R. § 42.65(a) and *Ashland Oil, Inc. v. Delta Resins & Refractories, Inc.*, 776 F.2d 281, 294 (Fed. Cir. 1985)). The gap in the disclosures of the prior art, occurring at or near the time of the invention, carries more weight than the much later, unsupported opinion of Dr. Fudin.

Petitioner fails to demonstrate that it would have been obvious at the time of the invention to use genetic testing in the method of claim 10. Req. 3. The objective evidence on point consists of a single paragraph from the FDA Meeting Minutes, raised in Petitioner's Reply, which is not relied upon in the relevant witness testimony, and does not disclose genetic testing. Accordingly, we hold that Petitioner fails to establish by a preponderance of the evidence that claim 10 is unpatentable.

II. CONCLUSION

For the foregoing reasons, Patent Owner establishes that the Final Written Decisions in each proceeding should be modified to hold that, based on the record developed in this proceeding, a preponderance of the evidence demonstrates that claim 10 is not proven unpatentable.

III. ORDER

It is

ORDERED that the Request for Rehearing is *granted*;

FURTHER ORDERED that the Final Written Decision is modified to hold that, based on the record developed in this proceeding, a preponderance of the evidence demonstrates that claim 10 is not proven unpatentable;

FURTHER ORDERED that this Decision does not disturb the holding in the Final Written Decision that Petitioner establishes by a preponderance of the evidence that claims 1–9 and 11–32 are unpatentable.

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