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Paper No. 76
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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 IPR2015-01092
Patent 6,045,501

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

OBERMANN, *Administrative Patent Judge*.

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

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 1–10 of U.S. Patent No. 6,045,501 ("the '501 patent") are unpatentable. Paper 73, ("Dec."). The Request for Rehearing is confined to our holding that claim 10 is unpatentable. Req. 1; Dec. 25–26 (addressing claim 10).

For reasons that follow, we deny the Request for Rehearing.

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 1, which specifies a method for delivering a teratogenic drug to patients in need of the drug while avoiding the delivery of said drug to a foetus. Ex. 1001, 10:43–45. Claim 1 defines a method comprising six steps that include "identifying a subpopulation of . . . female patients who are capable of becoming pregnant." *Id*. at 10:55–57. Claim 10 requires an additional step of "providing to said patients who are capable of becoming pregnant a contraceptive device or formulation." *Id*. at 12:11–12.

We held in the Final Written Decision that "it would have been obvious from the prior art to 'provide contraception.'" Dec. 27. Patent Owner argues that this finding is not supported by a preponderance of the evidence. Req. 2. We disagree. That finding is supported by the declaration testimony of Dr. Fudin, which, in turn, is supported by objective evidence consisting of disclosures in the asserted prior art references. For example, Dr. Fudin testified that it would have been obvious from the asserted prior art to "provide contraception," where the Mitchell[1] reference, asserted in the Petition, discloses providing patients with "the necessary forms for a contraception referral program." Dec. 27 (quoting Dr. Fudin's testimony, Ex. 1002 ¶¶ 168–169).

Patent Owner argues that Mitchell discloses a "contraception referral program" that is "for 'contraception counseling' only." Req. 2–3 (emphasis omitted). On that basis, Patent Owner contends that "Dr. Fudin misunderstood the disclosure of Mitchell as disclosing the actual provision of contraception, instead of just contraception counseling." *Id*. at 3. In Patent Owner's view, that misunderstanding led Dr. Fudin "to erroneously allege that a [person of ordinary skill in the art] 'would have understood . . . that the physician would, after ensuring that it is medically appropriate, provide contraception—either in device or drug form.'" *Id*. (quoting Ex. 1002 ¶ 169). Patent Owner contends that Dr. Fudin never stated that such provision would have been obvious, but rather, argued that Mitchell provides "an actual disclosure of the additional element of 'providing'

[1] Allen A. Mitchell et al., *A Pregnancy-Prevention Program in Women of Childbearing Age Receiving Isotretinoin*, 333:2 NEW ENG. J. MED. 101, 101–06 (Jul. 13, 1995) (Ex. 1006, "Mitchell").

contraception recited in claim 10." *Id*. Patent Owner also contends that "all of the experts in this case, including [Petitioner's] expert, agree that 'counseling' is not the same thing as 'providing'" contraception. *Id*. at 4. Patent Owner further argues that Petitioner fails to carry its burden of proving that claim 10 would have been obvious, given the lack of express disclosure in the prior art of "providing contraception." *Id*.

In our Final Written Decision, citing the detailed claim charts and arguments in the Petition, we held that the subject matter of claim 10 would have been obvious at the time of the invention. Dec. 25 (citing Pet. 30–36 (for textual arguments, including citations to Dr. Fudin's testimony); Pet. 42–45 (claim charts)). The Petition, while not directing us to an express disclosure of "providing contraception" in the asserted prior art, identifies persuasive objective evidence, grounded in the disclosures in the prior art, establishing a suggestion to provide contraception according to the method specified in claim 10. *See, e.g*., Pet. 35–36 (and citations therein).

For example, the Powell[2] reference, asserted in the Petition, mandates exclusion from treatment those patients "who refuse to or cannot use a form of contraception." Pet. 35 (quoting Ex. 1002 ¶¶ 166–167 (citing Ex. 1005, 901)). Dr. Fudin acknowledges that, although Powell "does not explicitly state that patients should be provided with a contraceptive device, its discussion on counseling and encouraging contraception is extensive." *Id*. Based on that disclosure in Powell, Dr. Fudin reasonably concludes that providing contraception "would have been obvious to" an ordinary artisan.

[2] R.J. Powell & J.M.M Gardner-Medwin, *Guideline for the clinical use and dispensing of thalidomide*, 70 POSTGRAD MED. J. 901, 901–904 (1994) (Ex. 1005, "Powell").

Id. (quoting Ex. 1002 ¶ 166); *see id*. at 44–45 (claim chart for claim 10, directing us to Dr. Fudin's testimony as well as specific supporting disclosures in the asserted prior art references).

The Petition further directed us to a sample information sheet for patients, disclosed in Powell, warning patients that, "[i]f you wish to consider thalidomide you must be prepared to use adequate contraception through the duration of thalidomide therapy and for 3 months after." Pet. 35–36 (quoting Ex. 1005, Fig. 1); Pet. 44 (claim chart). The information sheet cited in the Petition explains that "[y]our doctor can advise you about adequate contraception." *Id*. at 36 (quoting Ex. 1005, Fig.1). The Petition also directs us to Mitchell's disclosure that "patients are provided with 'the necessary forms for a contraception referral program (in which the manufacturer would reimburse patients for a visit to another physician for contraception counseling)." *Id*. (quoting Ex. 1006, 101); Pet. 45 (claim chart).

On this record, we did not err in crediting Dr. Fudin's testimony that providing contraception would have been an obvious suggestion of those disclosures in the asserted prior art. Pet. 36 (quoting Ex. 1002 ¶ 170). We hold that substantial evidence supported our conclusion that it would have been obvious at the time of the invention to provide contraception as required by the method of claim 10. Ex. 1002 ¶¶ 166–170 (Dr. Fudin, concluding based on specific teachings in Powell and Mitchell, one "would have recognized the value of providing contraception to patients directly.").

II. CONCLUSION

For the foregoing reasons, we deny Patent Owner's Request for Rehearing.

III. ORDER

It is

ORDERED that the Request for Rehearing is *denied*.

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