NOTE: This disposition is nonprecedential.

United States Court of Appeals for the Federal Circuit

IN RE: MATTHEW MCLEAY,
Appellant

2023-2338

Appeal from the United States Patent and Trademark Office, Patent Trial and Appeal Board in No. 17/231,735.

Decided: February 18, 2025

BARTHOLOMEW L. MCLEAY, Kutak Rock LLP, Omaha, NE, argued for appellant. Also represented by RYAN STEVEN HINDERLITER, Kansas City, MO.

SARAH E. CRAVEN, Office of the Solicitor, United States Patent and Trademark Office, Alexandria, VA, argued for appellee Coke Morgan Stewart. Also represented by MICHAEL S. FORMAN, AMY J. NELSON, FARHEENA YASMEEN RASHEED.

Before MOORE, *Chief Judge*, STOLL, *Circuit Judge*, and GILSTRAP, *Chief District Judge*.[1]

GILSTRAP, *Chief District Judge*.

Matthew McLeay appeals from a decision of the United States Patent Trial and Appeal Board (the "Board"). The Board affirmed an Examiner's rejection of claims 20–24 of U.S. Patent Application No. 17/231,735 (the "Application") as unpatentable for lack of enablement under 35 U.S.C. § 112(a). For the reasons provided below, we affirm.

BACKGROUND

On April 15, 2021, McLeay filed the Application. The Application discloses using ribavirin, amongst other medications, for the treatment of certain respiratory conditions. The Application included 20 method of treatment claims, including three independent claims. Appx83–85. McLeay amended claim 20, which as amended recites the following:

> 20. A method of treating a SARS-CoV-2 lung infection in a patient in need thereof comprising administering to a lung of said patient by inhalation a liquid aerosol composition comprising >50% (w/w) water and <50% (w/w) ribavirin, wherein said liquid aerosol is delivered to the lung with a nebulizer.

Appx3 (alteration removed).[2] Claims 21–24 each depend from claim 20.

During prosecution, the Examiner issued a Final Office Action that rejected claims 20–24 for lack of enablement.

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[1] Honorable Rodney Gilstrap, Chief Judge, United States District Court for the Eastern District of Texas, sitting by designation.

[2] All limitations of claim 20 were disclosed in the Application as-filed. *See* Appx84–85.

Particularly relevant here, the Examiner found that the breadth of the claims was not fully enabled by the Application because there is insufficient disclosure of the claimed composition. Appx988. Further, the Examiner found that the Application admits "that the use of ribavirin in treating COVID-19 is not expected to be successful by skilled pulmonologists and infectious disease specialists." Appx989. In view of this finding, the Examiner found that "[o]ne skilled in the art cannot readily anticipate the effect of administering to the lung infected with SARS-CoV-2 an aerosolized liquid comprising >50% water and <50% ribavirin, and thus there is lack of predictability in the art." Appx990. The Examiner also found that the Application fails to disclose whether the claimed compound is effective in treating a SARS-CoV-2 lung infection in a patient. Appx990–91. Finally, the Examiner found that the quantity of experimentation needed to make or use the claimed invention "would be significant." Appx991.

In the Final Office Action, the Examiner also rejected McLeay's argument that the prior art reference Gilbert and McLeay[3] discloses how to make, use, and administer the claimed composition. The Examiner found that Gilbert and McLeay "teaches treatment of influenza A virus infections using MegaRibavirin aerosol, and the treatment of influenza A is not indicative of its effectiveness against SARS-CoV-2 lung infection." Appx993. McLeay also argued that Messina,[4] a post-filing date reference, established that the administration "of aerosolized ribavirin according to the

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[3] Brian E. Gilbert and Matthew T. McLeay, *MegaRibavirin Aerosol for the Treatment of Influenza A Virus Infections in Mice*, 78 Antiviral Res. 223–29 (2008) (Appx955–61).

[4] Messina et al., *Ribavirin Aerosol in the Treatment of SARS-CoV-2: A Case Series*, 10 Infect. Dis. Ther. 2791-804 (2021) (Appx962–75).

subject patent application as disclosed in the written description has been demonstrated to be efficacious in the treatment of [five] patients with COVID-19." Appx945. The Examiner found this argument unpersuasive since Messina does not enable the full scope of the claims (*i.e.*, a composition comprising less than 50% ribavirin). Appx56–57.

McLeay appealed the Examiner's decision to the Board. The Board found "that a preponderance of the evidence supports Examiner's analysis of the *Wands* factors and adopt[ed] them as" their own. Appx27. The Board further denied McLeay's rehearing request and did not modify its decision. Appx2.

McLeay timely appeals to this court. We have jurisdiction under 28 U.S.C. § 1295(a)(4)(A).

DISCUSSION

"Whether a claim satisfies the enablement requirement is a question of law that may be based on underlying factual findings." *Medytox, Inc. v. Galderma S.A.*, 71 F.4th 990, 996 (Fed. Cir. 2023) (citing *Alcon Rsch. Ltd. v. Barr Lab'ys, Inc.*, 745 F.3d 1180, 1188, 1190 (Fed. Cir. 2014)). We review the Board's legal conclusions de novo and its factual findings for substantial evidence. *In re Kotzab*, 217 F.3d 1365, 1369 (Fed. Cir. 2000). "If the evidence in record will support several reasonable but contradictory conclusions, we will not find the Board's decision unsupported by substantial evidence simply because the Board chose one conclusion over another plausible alternative." *In re Jolley*, 308 F.3d 1317, 1320 (Fed. Cir. 2002).

Section 112(a) provides in relevant part that

> [t]he specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same.

35 U.S.C. § 112(a). "The specification must enable the full scope of the invention as defined by its claims, allowing for a reasonable amount of experimentation." *Baxalta Inc. v. Genentech, Inc.*, 81 F.4th 1362, 1364–65 (Fed. Cir. 2023) (quoting *Amgen Inc. v. Sanofi*, 598 U.S. 594, 610–12 (2023)) (cleaned up).

I

McLeay argues the Board erred in concluding that undue experimentation is required to practice the claimed invention. To start, the Board found that a person of ordinary skill in the art would not have expected that ribavirin would be effective in treating a SARS-CoV-2 lung infection, and therefore, the quantity of experimentation needed to practice the claimed method, absent some disclosure to the contrary, would be considerable. Appx45. The Board's fact findings are supported by substantial evidence, including that the Application itself recognized that Ribavirin's "use in treating COVID-19 is not expected by skilled pulmonologists and infectious disease specialists to be successful in treating COVID-19." Appx447–49 (collecting articles that concluded that ribavirin would not be effective for treating patients infected with COVID-19).

Nor do the portions of the Application cited by McLeay provide guidance to a person of ordinary skill in the art as to how to arrive at the claimed invention without undue experimentation. Notably, McLeay relies upon "Example 7" of the Application, which is titled "Coronavirus infection" and describes treating a single patient exhibiting "symptoms of fever" with dry powder ribavirin. Appx478–79. The Board found that the Application's Example 7 does not describe treating a SARS-CoV-2 lung infection with the composition recited in claim 20, as it fails to describe treatment "with a liquid aerosol comprising >50% (w/w) water and < 50% of said ribavirin and excipient." Appx31. This finding is supported by substantial evidence. Appx478–79.

Additionally, McLeay advances arguments substantially similar to those rejected by the Board that references outside the Application enable claim 20. This court is similarly unpersuaded by these arguments. With respect to the Gilbert and McLeay prior art reference and the post-filing Messina reference, neither discloses the up-to-50% range of ribavirin recited by claim 20. At best, these references disclose 2%, 6%, and 10% ribavirin. Gilbert and McLeay discloses treating patients infected with influenza A—not a SARS-CoV-2 lung infection—with compositions comprising 2%, 6%, and 10% doses of ribavirin. Appx958. Messina discloses treating patients infected with a SARS-CoV-2 lung infection, but only with a composition comprising 10% ribavirin. Appx964. There is no disclosure of record, pre- or post-Application filing, that administration of a liquid aerosol composition comprising over 10% ribavirin—let alone one as high as 49.99% ribavirin—may effectively treat a SARS-CoV-2 lung infection. Accordingly, substantial evidence supports the Board's conclusion that the Application does not disclose that the full range recited in claim 20 is effective for treating a SARS-CoV-2 lung infection.[5]

II

This court has held that "[e]nablement is closely related to the requirement for utility." *In re '318 Pat. Infringement Litig.*, 583 F.3d 1317, 1323 (Fed. Cir. 2009). Moreover, this Court has held that "[i]f a patent claim fails to meet the utility requirement because it is not useful or operative, then it also fails to meet the how-to-use aspect of the enablement requirement." *Process Control Corp. v. HydReclaim Corp.*, 190 F.3d 1350, 1358 (Fed.Cir.1999). Here, the Board correctly found that McLeay has failed to show that claim 20 meets the how-to-use aspect of the enablement requirement because, as explained above, the full

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[5] McLeay does not separately argue that the Board erred with respect to dependent claims 21–24.

scope of the claim is not "useful or operative." This requirement prevents McLeay from "patenting [] a mere research proposal" for possibly effective amounts of ribavirin for treating a SARS-CoV-2 lung infection. *'318 Pat. Litig.*, 583 F.3d at 1324.

However, we reject the Board's overbroad contention that the claim is not enabled because the Application "lacked any evidence of ribavirin's efficacy against COVID-19." Appellee's Br. at 24. While utility informs a court in making an enablement determination, a claim's utility alone should not end the enablement inquiry. In this case, claim 20's fatal flaw is that there is substantial evidence for the Board's fact findings underlying its conclusion that practicing the full scope of the claimed range would require undue experimentation.

CONCLUSION

We have considered McLeay's remaining arguments but find them unpersuasive. For the reasons stated above, we affirm the Board's finding that claims 20–24 are not enabled.

AFFIRMED