NOTE: This disposition is nonprecedential.

United States Court of Appeals for the Federal Circuit

SANOFI-AVENTIS DEUTSCHLAND GMBH,
Appellant

v.

MYLAN PHARMACEUTICALS INC.,
Appellee

ANDREW HIRSHFELD, PERFORMING THE FUNCTIONS AND DUTIES OF THE UNDER SECRETARY OF COMMERCE FOR INTELLECTUAL PROPERTY AND DIRECTOR OF THE UNITED STATES PATENT AND TRADEMARK OFFICE,
Intervenor

2020-2066, 2020-2068, 2020-2069

Appeals from the United States Patent and Trademark Office, Patent Trial and Appeal Board in Nos. IPR2018-01679, IPR2018-01680, IPR2018-01682.

Decided: December 29, 2021

ADAM BANKS, Weil, Gotshal & Manges LLP, New York, NY, argued for appellant. Also represented by ANISH R.

DESAI, SARAH M. STERNLIEB, ELIZABETH WEISWASSER; WILLIAM SUTTON ANSLEY, Washington, DC; LAUREN ANN DEGNAN, Fish & Richardson P.C., Washington, DC; SCOTT MICHAEL FLANZ, JOHN STEPHEN GOETZ, New York, NY.

DOUGLAS H. CARSTEN, McDermott Will & Emery, Irvine, CA, argued for appellee. Also represented by ADAM WILLIAM BURROWBRIDGE, Washington, DC; WESLEY EUGENE DERRYBERRY, STEFFEN NATHANAEL JOHNSON, TASHA THOMAS, RICHARD TORCZON, Wilson, Sonsini, Goodrich & Rosati, PC, Washington, DC; ELHAM FIROUZI STEINER, San Diego, CA.

BRIAN RACILLA, Office of the Solicitor, United States Patent and Trademark Office, Alexandria, VA, for intervenor. Also represented by KAKOLI CAPRIHAN, DANIEL KAZHDAN, THOMAS W. KRAUSE, FARHEENA YASMEEN RASHEED.

Before DYK, CLEVENGER, and TARANTO, *Circuit Judges*.

PER CURIAM.

Sanofi-Aventis Deutschland GmbH ("Sanofi") owns U.S. Patent Nos. 8,992,486 ("the '486 Patent") and 9,526,844 ("the '844 Patent"). The patents, which relate to pen-type injectors for administering medicinal products from a multidose cartridge where the user may set the injection dose, share a common specification and claim priority to GB Patent Application No. 0304822.0 ("GB Application"). '844 Patent col. 1 ll. 6–21, 25–29.[1]

These consolidated appeals arise from three *inter partes* reviews ("IPRs"). On appeal, Sanofi challenges the

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[1] Citations to the common specification are to the '844 Patent.

Board's determinations that (1) substitute claims 58–64 of the '486 Patent would have been obvious over Steenfeldt-Jensen[2] with Klitgaard,[3] Atterbury,[4] and/or Burroughs[5]; (2) original claims 21–30 of the '844 Patent would have been obvious over Steenfeldt-Jensen or Steenfeldt-Jensen with Klitgaard; and (3) because the GB Application does not provide written description support for an internally-threaded piston rod, original claims 21–30 of the '844 Patent are not entitled to claim priority to the GB Application and substitute claims 31–38 of the '844 Patent are unsupported amendments.[6] We *affirm*.

THE '486 PATENT

In IPR2018-01679, Sanofi proposed substitute claims directed at three features. The first is an arc-shaped body ("ASB") that tracks each set dose of medicament. *See Mylan Pharm. Inc. v. Sanofi-Aventis Deutschland Gmbh*, IPR2018-01679, at 54–55 (P.T.A.B. May 29, 2020) ("*1679 Final Written Decision*"). The second and third are different versions of a clicker ("Clicker A" and "Clicker B") that produce audible clicks corresponding to a unit dose of medicament. *Id.* at 55–57. In Clicker A, one element of the clicker produces clicks only during dialing down of a dose and a separate element produces clicks when rotating and moving in a specific manner. *Id.* at 55–56. In Clicker B, one element of the clicker produces clicks only during dialing

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2 U.S. Patent No. 6,235,004.

3 U.S. Patent No. 6,582,404.

4 W.O. Patent Publication No. 2002/092153.

5 U.S. Patent No. 6,221,046.

6 Under the governing statutory and regulatory requirements, a substitute claim must have support in the original disclosure, as well as in any earlier-filed disclosure to which there is a priority claim, and may not enlarge the scope of the claims or introduce new matter. 35 U.S.C. § 316(d); 37 C.F.R. § 42.121.

up of a dose and a separate element provides clicks only during dialing down of a dose. *Id*. at 56–57. The Board concluded that the ASB claims would have been obvious over Steenfeldt-Jensen and Klitgaard, where Klitgaard's nut member (modified into a half-nut) would serve as the ASB in Steenfeldt-Jensen's device, *id*. at 61–75; the Clicker A claims would have been obvious over Steenfeldt-Jensen and Atterbury, where Atterbury's clickers would be incorporated into Steenfeldt-Jensen's device, *id*. at 77–90; and the Clicker B claims would have been obvious over Steenfeldt-Jensen, Burroughs, and Atterbury, where Atterbury's clickers and Burroughs's cartridge would be combined with Steenfeldt-Jensen's device, *id*. at 93–99.

Sanofi presents numerous arguments on appeal, chief among these being that the Board inappropriately relied on common knowledge to supply limitations missing in the prior art and on its Clicker A analysis, which the Board also used for the Clicker B claims. Based on the record before us, we find that substantial evidence supports the Board's obviousness determination. For the ASB claims, the Board found, based on the arguments and evidence presented, that partial nuts and half-nuts were known, the proposed modifications would have been within the skill of a person of ordinary skill in the art ("POSA"), and a POSA would have been motivated to make those modifications. *See 1679 Final Written Decision* at 64–73. The Board credited the testimony of Mylan Pharmaceuticals Inc.'s ("Mylan") expert, Mr. Karl Leinsing, on what was known in the art, a POSA's motivations for modifying the prior art, and the operation of the modified device. *See id*. at 65–69, 71, 73. Sanofi provides no basis for disturbing the Board's credibility determinations. For the Clicker A claims, the Board noted that Sanofi did not dispute the alleged benefit of the modified device, nor that a POSA would have had a reasonable expectation of success in arriving at the first element. *Id*. at 85–86, 89. Although Sanofi disputed that the modification for the second element could be readily

accomplished, the Board found Mylan's arguments and evidence to be "more persuasive" in light of evidence demonstrating a POSA's knowledge. *Id*. at 88–90. The numerous exhibits on which the Board relied provide substantial evidence for its findings. For the Clicker B claims, the Board noted that Sanofi used the same arguments for both Clickers A and B. *Id*. at 97. The Board therefore appropriately relied on its analysis for the Clicker A claims in its analysis for the Clicker B claims.

THE '844 PATENT

Independent claim 21 of the '844 Patent discloses "[a] drug delivery device comprising" a number of components, including "a driving member comprising a third thread" and "a piston rod comprising either an internal or an external fourth thread that is engaged with the third thread." '844 Patent col. 8 ll. 16–49.

In IPR2018-01680, Mylan's grounds for unpatentability all included Giambattista,[7] which issued from a patent application filed one month after the GB Application. *Mylan Pharm. Inc. v. Sanofi-Aventis Deutschland Gmbh*, IPR2018-01680, at 13 (P.T.A.B. May 29, 2020) ("*1680 Final Written Decision*"). The Board held that claims 21–30 are not entitled to claim priority to the GB Application because the GB Application does not provide written description support for an internally-threaded piston rod. *Id*. at 29. The Board determined that (1) the GB Application as a whole disclosed only a piston rod with *external* threads, *id*. at 16–22, and (2) a POSA reading the GB Application would not understand the inventors to be in possession of an *internally*-threaded piston rod, *id*. at 22–29. After determining that Giambattista constituted prior art, the Board found that claims 21–30 would have been unpatentable. *Id*. at 40–90, 128. In IPR2018-01682, the Board separately

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[7] U.S. Patent No. 6,932,794.

found that claims 21–29 would have been obvious over Steenfeldt-Jensen and claim 30 would have been obvious over Steenfeldt-Jensen and Klitgaard. *Mylan Pharm. Inc. v. Sanofi-Aventis Deutschland Gmbh*, IPR2018-01682, at 132 (P.T.A.B. May 29, 2020) ("*1682 Final Written Decision*").

In both IPR2018-01680 and IPR2018-01682, Sanofi filed a contingent motion to amend proposing substitute claims 31–38. Substitute claim 31 is identical to claim 21 except for the removal of the phrase "either an internal or an external" such that claim 31 recites "a piston rod comprising a fourth thread that is engaged with the third thread." *1680 Final Written Decision* at 93, 101–102; *1682 Final Written Decision* at 95–96, 105. The Board observed that Sanofi, in making this amendment, sought to maintain the same claim scope while receiving the benefit of the GB Application priority date. *1680 Final Written Decision* at 102–103; *1682 Final Written Decision* at 106. As in its analysis of the original claims, the Board found that the GB Application did not provide written description support for an internally-threaded piston rod and denied Sanofi's motion to amend. *1680 Final Written Decision* at 103–115; *1682 Final Written Decision* at 107–19.

Sanofi appeals the Board's determination that claims 21–30 are not entitled to the priority date of the GB Application; claims 21–30 separately would have been obvious over Steenfeldt-Jensen or Steenfeldt-Jensen with Klitgaard; and substitute claims 31–38 are unsupported amendments. Sanofi does not contest the Board's ultimate determination in IPR2018-01680 that claims 21–30 would have been anticipated by Giambattista and/or obvious in view of Giambattista with Steenfeldt-Jensen or Klitgaard.

On appeal, Sanofi repeats its argument from below that the GB Application provides sufficient written description for an internally-threaded piston rod because (1) it broadly discloses a piston rod with "a first threaded

portion at a first end and a second threaded portion at a second end" without specifying whether the threading is internal or external, J.A. 3935 (2:2–3), and (2) original claim 1 of the GB Application broadly claims "a piston rod" without reference to any threading, J.A. 3945 (12:3–4). Sanofi also repeats its argument that the GB Application's disclosure of an *externally*-threaded piston rod is sufficient to describe the genus of threaded piston rods because a POSA would understand that externally-threaded and internally-threaded piston rods are the only two species in that genus.

The Board, in its final written decision, correctly responded to these arguments in detail and its analysis shows it considered the GB Application in its entirety, as well as Sanofi's additional references that allegedly disclose internally-threaded piston rods and testimony from both parties' experts on this issue. *See 1680 Final Written Decision* at 16–29, 101–15; *1682 Final Written Decision* at 105–19. Based on the record before us, substantial evidence supports the Board's written description analysis for claims 21–30 and substitute claims 31–38. In particular, the Board cited the GB Application's claimed limitations and the arrangement of the features in the disclosed injector as evidence that the threading on the piston rod is limited to *external* threading. *See 1680 Final Written Decision* at 16–29, 102–107, 109–12; *1682 Final Written Decision* at 105–10. The Board found Sanofi's references to be unconvincing, crediting Mr. Leinsing's testimony regarding what a POSA would understand from the GB Application and Sanofi's references. *See 1680 Final Written Decision* at 20–22, 25–26, 107, 110–14; *1682 Final Written Decision* at 111, 113–14, 116–18. Finally, the Board rejected the testimony from Sanofi's expert, Dr. Alexander Slocum, that a POSA would have known to implement an alternative mechanism with an internally-threaded piston rod in the disclosed injector, finding Dr. Slocum's testimony to be not credible, conclusory, and inconsistent with the GB Application's

disclosures and crediting Mr. Leinsing's testimony instead. *See 1680 Final Written Decision* at 17, 19–29, 106–14; *1682 Final Written Decision* at 110, 111–18. Sanofi provides no basis for overturning these findings.

Because we affirm the Board's determination in IPR2018-01680 that claims 21–30 would have been unpatentable as obvious and/or anticipated and the Board's decision to deny Sanofi's motion to amend with substitute claims 31–38, the appeal from the final written decision in IPR2018-01682 is moot and we accordingly dismiss as moot Appeal No. 2020-2069.

AFFIRMED IN PART, DISMISSED IN PART

COSTS

Costs to Appellee.