United States Court of Appeals for the Federal Circuit

IBSA INSTITUT BIOCHIMIQUE, S.A., ALTERGON, S.A., IBSA PHARMA INC.,
Plaintiffs-Appellants

v.

TEVA PHARMACEUTICALS USA, INC.,
Defendant-Appellee

2019-2400

Appeal from the United States District Court for the District of Delaware in No. 1:18-cv-00555-RGA, Judge Richard G. Andrews.

Decided: July 31, 2020

RYAN JOHNSON, Fenwick & West LLP, New York, NY, argued for plaintiffs-appellants. Also represented by JEFFREY J. OELKE, LAURA MORAN; ERICA RUTH SUTTER, Mountain View, CA.

JOHN CHRISTOPHER ROZENDAAL, Sterne Kessler Goldstein & Fox, PLLC, Washington, DC, argued for defendant-appellee. Also represented by KRISTINA CAGGIANO KELLY, MICHAEL E. JOFFRE, DEIRDRE M. WELLS.

Before PROST, *Chief Judge*, REYNA and HUGHES, *Circuit Judges*.

PROST, *Chief Judge*.

IBSA Institut Biochimique, S.A., Altergon, S.A., and IBSA Pharma Inc. (collectively, "IBSA") appeal a decision by the United States District Court for the District of Delaware holding claims 1, 2, 4, and 7–9 of U.S. Patent No. 7,723,390 ("the '390 patent") invalid as indefinite under 35 U.S.C. § 112. *See IBSA Institut Biochimique, S.A. v. Teva Pharm. USA, Inc.*, No. 1:18-cv-00555-RGA, 2019 WL 3936656 (D. Del. Aug. 20, 2019) ("*Decision*"); Claim Construction Order and Final Judgment, *id.*, ECF No. 111. For the reasons below, we affirm.

I

IBSA is the assignee of the '390 patent. The '390 patent issued from U.S. Application No. 10/188,467 ("the '467 application"). In addition, the '390 patent claims priority from Italian Patent Application No. MI2001A1401 ("the Italian Application"), which is written in Italian and appears in the '390 patent's file history.

The '390 patent, entitled "Pharmaceutical Formulations for Thyroid Hormones," provides "pharmaceutical formulations based on thyroid hormones enabling a safe and stable oral administration in the framework of the strict therapeutic index prescribed in case of thyroid disorders." '390 patent Abstract. The '390 patent is listed in the U.S. Food and Drug Administration's *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book") for IBSA's Tirosint® product. Tirosint® is a soft gel capsule formulation containing the active ingredient levothyroxine sodium.

Teva Pharmaceuticals USA, Inc. ("Teva") sought to market a generic version of Tirosint® and filed Abbreviated New Drug Application ("ANDA") No. 211369. The ANDA included a certification pursuant to 21 U.S.C.

§ 355(j)(2)(A)(vii)(IV) ("Paragraph IV certification") that the '390 patent is invalid, unenforceable, or will not be infringed by Teva's generic product. IBSA, after receiving notice of Teva's Paragraph IV certification, filed suit ultimately alleging infringement of claims 1, 2, 4, and 7–9.

II

Central to this appeal is the parties' dispute over the construction of "half-liquid," which appears in independent claim 1. Claims 2, 4, and 7–9 each ultimately depend from claim 1. Claim 1 is shown below:

> 1. A pharmaceutical composition comprising thyroid hormones or their sodium salts in the form of either:
>
> a) a soft elastic capsule consisting of a shell of gelatin material containing a liquid or half-liquid inner phase comprising said thyroid hormones or their salts in a range between 0.001 and 1% by weight of said inner phase, dissolved in gelatin and/or glycerol, and optionally ethanol, said liquid or half-liquid inner phase being in direct contact with said shell without any interposed layers, or
>
> b) a swallowable uniform soft-gel matrix comprising glycerol and said thyroid hormones or their salts in a range between 0.001 and 1% by weight of said matrix.

'390 patent claim 1.

IBSA proposed that the term "half-liquid" should be construed to mean "semi-liquid, i.e., having a thick consistency between solid and liquid." J.A. 75. Teva argued that the term "half-liquid" is indefinite or should be construed as "a non-solid, non-paste, non-gel, non-slurry, non-gas substance." J.A. 79.

The district court held claims 1, 2, 4, and 7–9 invalid as indefinite. In support, the court found, first, that IBSA's proposed construction was unsupported by the record, and, second, that the meaning of "half-liquid" was not otherwise reasonably ascertainable from the record.

A

The district court began by acknowledging that the parties "agree that the intrinsic record does not define 'half-liquid.'" *Decision*, 2019 WL 3936656, at *4 (citing J.A. 78). It then turned to the intrinsic evidence IBSA presented.

IBSA pointed out that the Italian Application used the term "semiliquido" in the same places where the '390 patent used "half-liquid," and where a certified translation of the Italian Application prepared for IBSA in 2019 used "semi-liquid." IBSA contended that there is a link between these terms such that a person of ordinary skill in the art ("POSA") would understand "half-liquid" and "semi-liquid" to be synonyms. The district court disagreed.

The district court observed that there were a number of differences between the certified translation and the '390 patent's specification, besides the use of "half-liquid." These differences included the "Field of Invention" and "Prior Art" sections. Because of these differences, the court reasoned that the document that best reflected the applicant's intent was the document submitted for examination—the '467 application. Accordingly, the district court gave the Italian Application and the certified translation no weight in its analysis and determined that differences between the certified translation and the '390 patent's specification were intentional.

The district court also noted that, during prosecution, the applicant proposed a dependent claim using the term "semi-liquid." This claim depended on an independent claim that used the term "half-liquid." Although the

dependent claim using the term "semi-liquid" was removed by the applicant, the district court reasoned this portion of the prosecution history was "evidence that the applicant did not mean 'semi-liquid' when he used the term 'half-liquid.'" *Decision*, 2019 WL 3936656, at *5.

Similarly, in reviewing the '390 patent's specification, the district court determined that citation to pharmaceutical references, including *Remington's Pharmaceutical Sciences*, which used the term "semi-liquid," did not show that "half-liquid" meant "semi-liquid." Instead, the court reasoned that such citation showed that the applicant knew of the term "semi-liquid" yet intentionally chose not to use it. *Id.* at *4.

The district court then turned to the extrinsic evidence. The court found IBSA's extrinsic evidence "minimally probative" and "unpersuasive." *Id.* at *5. It first determined that IBSA's reliance on dictionary definitions did not support IBSA's position because they were not in the context of the claimed invention. Likewise, the court found that IBSA's reliance on a handful of patents from other companies did not support IBSA's position. The court concluded that, because IBSA failed to present evidence regarding the use of the term "half-liquid" in the art besides these patents, which used the term "half-liquid" only in the context of "half-liquid bases," it is "exceedingly unlikely that ['half-liquid'] was a term of art at the relevant date." *Id.* at *6. Finally, because the court determined that the opinion of IBSA's expert, Dr. Chyall, was exclusively based on evidence that the court already found unpersuasive, the court afforded Dr. Chyall's opinion no weight on this matter. *Id.*

B

After determining that IBSA's proposed construction was not supported by the record, the district court turned to the second part of its analysis and sought to determine whether a skilled artisan could nevertheless ascertain a reasonably certain meaning for "half-liquid."

The court first noted that the language of claim 1 does not provide "what manner of substance qualifies as a half-liquid." *Id.* Instead, the court determined that claim 1's language only supports that a "half-liquid" is neither a liquid nor a solid.

The district court next determined that a POSA reading the specification would understand that a "half-liquid" is not, or at least is not necessarily, a gel or a paste. The court reached this conclusion based on a passage of the '390 patent stating: "In particular, said soft capsule contains an inner phase consisting of a liquid, a half-liquid, a paste, a gel, an emulsion or a suspension comprising the liquid (or half-liquid) vehicle and the thyroid hormones together with possible excipients in suspension or solution." *See id.* (quoting '390 patent col. 7 l. 65–col. 8 l. 2).

The district court then analyzed the prosecution history. The court noted that the prosecution history contained two instances in which the applicant distinguished the claimed invention from alleged prior art. In one instance, in overcoming an obviousness rejection, the applicant stated that the claimed invention "is not a ***macromolecular*** gel-**lattice** matrix." *Id.* (quoting J.A. 232 (emphases in original)). In the second instance, the applicant stated that the claimed invention is not a "high concentration slurry." *Id.* (citing J.A. 258). While the court noted that the full scope of these disclaimers was not clear, the court determined that the "applicant disclaimed some portion of the claim's scope that might otherwise qualify as a half-liquid." *Id.*

Finally, the district court reviewed the extrinsic evidence. Noting Dr. Chyall's "difficulty articulating the boundaries of 'half-liquid'" during his deposition, the district court determined that the opinion of Teva's expert, Dr. Khan, that "half-liquid is not a well-known term in the art" must be correct. *Id.* at *7.

Accordingly, the district court concluded that the "ambiguity renders it impossible for a POSA to know, with reasonable certainty, whether they are dealing with a half-liquid within the meaning of the claim." *Id.* The court held claims 1, 2, 4, and 7–9 invalid under 35 U.S.C. § 112.

IBSA timely appealed. We have jurisdiction under 28 U.S.C. § 1295(a)(1).

III

A

The definiteness requirement of 35 U.S.C. § 112 "must take into account the inherent limitations of language." *Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 U.S. 898, 909 (2014). At the same time, "a patent must be precise enough to afford clear notice of what is claimed, thereby 'appris[ing] the public of what is still open to them.'" *Id.* (quoting *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 373 (1996) (alteration in original)). Accordingly, a "claim is invalid for indefiniteness if its language, read in light of the specification and prosecution history, 'fail[s] to inform, with reasonable certainty, those skilled in the art about the scope of the invention.'" *HZNP Meds. LLC v. Actavis Labs. UT, Inc.*, 940 F.3d 680, 688 (Fed. Cir. 2019) (quoting *Nautilus*, 572 U.S. at 901 (alteration in original)).

We review the ultimate question of indefiniteness de novo. *Id* at 698. "Determinations about governing legal standards and about intrinsic evidence are reviewed de novo, and any factual findings about extrinsic evidence relevant to the question, such as evidence about knowledge of those skilled in the art, are reviewed for clear error." *BASF Corp. v. Johnson Matthey Inc.*, 875 F.3d 1360, 1365 (Fed. Cir. 2017).

B

1

"We look first to the language of the claim to determine whether the meaning of ['half-liquid'] is reasonably clear." *Berkheimer v. HP Inc.*, 881 F.3d 1360, 1363 (Fed. Cir. 2018). As neither party meaningfully disputes, the claim language of the '390 patent does not make the meaning of "half-liquid" reasonably clear. The term "half-liquid" is merely used alongside "liquid" to describe the inner phase of a soft elastic capsule. *See* '390 patent claim 1 ("a soft elastic capsule consisting of a shell of gelatin material containing a liquid or half-liquid inner phase"). Therefore, the claim language clarifies only that a "half-liquid" differs from a liquid.

2

We next look to the specification. The district court relied on a passage of the specification stating that "[i]n particular, said soft capsule contains an inner phase consisting of a liquid, a half-liquid, a paste, a gel, an emulsion or a suspension comprising the liquid (or half-liquid) vehicle and the thyroid hormones together with possible excipients in suspension or solution," to determine that a "half-liquid is not, or at least is not necessarily, a gel or a paste." *Decision*, 2019 WL 3936656, at *6 (quoting '390 patent col. 7 l. 65–col. 8 l. 2). Not only do we agree with the district court's interpretation of this passage, but a second passage reinforces this interpretation. *See* '390 patent col. 10 ll. 38–39 ("Soft capsules (SEC) with liquid, half-liquid, paste-like or gel-like inner phase"). These disjunctive lists designate that a "half-liquid" is an alternative to the other members of the list, including pastes and gels. *See, e.g.*, *SkinMedica, Inc. v. Histogen Inc.*, 727 F.3d 1187, 1199–1200 (Fed. Cir. 2013) ("The disjunctive 'or' plainly designates that a series describes alternatives."). Pastes and gels, however, have a thick consistency between a liquid and a solid and would be included in IBSA's proposed

construction. Such inclusion is at odds with the above passages and creates uncertainty as to the boundaries of a "half-liquid."

IBSA argues that other portions of the specification are "at odds" with the above passages. Appellant Br. 63. As support, IBSA points to a passage of the specification describing a preferred formulation of the so-called Third Embodiment. This preferred formulation refers to "an SEC capsule containing an inner phase consisting of a paste or gel comprising gelatin and thyroid hormones or pharmaceutically acceptable salts thereof . . . in a liquid or half liquid vehicle." '390 patent col. 9 ll. 14–19. As Teva points out, however, IBSA conflates the vehicle within the inner phase with the inner phase itself, without "explain[ing] whether and why it contends the two are the same." Appellee Br. 46; *see also* J.A. 90. Accordingly, we disagree with IBSA that this passage, which discusses both the inner phase and the vehicle, is at odds with the specification's listing of "half-liquids" as alternatives to pastes and gels.

In light of the specification's guidance discussed above, we are not persuaded by IBSA's reliance on other portions of the specification that it contends support its proposed construction. For example, IBSA contends that the specification's citation to the *Remington's* primer on making "semi-liquids" using a rotary-die machine highlights that the applicant intended for "half-liquid" and "semi-liquid" to be synonyms. Even if this were the case, the discussion in *Remington's* of using a rotary-die machine does not help establish boundaries of a "half-liquid," given the lack of clarity in the specification described above. In addition, IBSA's reliance on the '390 patent's listing of a handful of "liquid or half-liquid vehicles," '390 patent col. 8 ll. 43–54, provides little guidance regarding the boundaries of a "half-liquid," as described by the specification. Similarly, the specification's suggestion to modify the viscosity of the capsule content does not help clarify the boundaries of a "half-liquid."

3

Next we turn to the prosecution history. IBSA contends that the Italian Application is the best source to understand the inventors' understanding of their invention and that the district court erred in how it considered the Italian Application. IBSA argues that because the term "semiliquido" appears in the Italian Application "the same number of times, in the same places, to describe the same things" as "half-liquid" does in the '390 patent, a POSA would equate "semiliquido" with "half-liquid." Appellant Br. 44. IBSA then contends, based on its certified translation, that "semiliquido" means "semi-liquid." Together IBSA contends that a POSA would find that "half-liquid" and "semi-liquid" are synonyms. We disagree.

Besides the differences the district court discussed between the Italian Application and the '390 patent, Teva also points out that the language of claim 1 of the '390 patent differs from that of claim 1 of the Italian application. As Teva notes, claim 1 of the '390 patent incorporates the Fourth Embodiment of the '390 patent, which was not found in the Italian Application. Further, unlike the '390 patent, the Italian Application does not use the term "gel." For example, the '390 patent includes the passage "an inner phase consisting of a liquid, a half-liquid, a paste, a gel, an emulsion or a suspension," while the certified translation of the Italian Application translates the Italian Application as "an internal phase consisting of a liquid, a semiliquid, a paste, an emulsion or a suspension." Appellant Br. 67 (Table 1). Accordingly, we agree with Teva that a POSA would likely consider the discrepant usage of "half-liquid" and "semiliquido" between the '390 patent and the Italian Application to be intentional, implying that the different word choice has a different scope.

Furthermore, and contrary to IBSA's suggestion, such weighing of the evidence does not unfairly subordinate a foreign priority application and does not amount to a

refusal to consider a foreign priority document. Rather, when discrepancies between a foreign priority document and the U.S. filing exist, it may be proper to view the discrepancies as intentional. *See Abbott Labs. v. Sandoz, Inc.*, 566 F.3d 1282, 1290 (Fed. Cir. 2009) (determining that although a Japanese priority application mentioned Crystal A and B, the fact that the patent-at-issue excluded Crystal B "strongly suggest[ed] that the [patent-at-issue] intentionally excluded Crystal B compounds").[1]

In addition to the Italian Application, another portion of the prosecution history reinforces our conclusion that the applicant intentionally used "half-liquid" instead of "semi-liquid." During the prosecution of the '390 patent the applicant had a pending claim using "half-liquid" and another claim, depending from that claim, using the term "semi-liquid." *See Decision*, 2019 WL 3936656, at *5. Although the claim using "semi-liquid" was ultimately removed, this is additional evidence that the applicant knew the term "semi-liquid" yet elected to use "half-liquid" to mean something different.

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[1] We also disagree with IBSA's suggestion that the district court refused to consider the Italian Application solely because it was in a foreign language. While the court noted in a footnote that it was "dubious that Italian-language materials, even if part of the intrinsic record, inform a POSA's understanding of what the patent claims," it nevertheless considered the Italian Application and reasonably decided that the language of the U.S. filing was "significantly more probative of what the applicant meant than a litigation-inspired translation [of the Italian Application] done in 2019." *Decision*, 2019 WL 3936656, at *4 & n.3.

Accordingly, the intrinsic evidence fails to establish the boundaries of a "half-liquid." We next turn to the extrinsic evidence.

4

IBSA contends that extrinsic evidence, including dictionary definitions, other patents, and expert testimony, supports its proposed construction. The district court disagreed. It concluded that the dictionary definitions and four patents that predated the '390 patent are not related to the '390 patent and therefore do not provide context for what "half-liquid" means. In addition, the court found that Dr. Chyall was unable to articulate a boundary for what constitutes a "half-liquid" and could not tell how a skilled artisan would know when matter is not a "half-liquid" inner phase. Based on our review of the extrinsic evidence, we determine that the district court did not clearly err in its analysis.

Despite arguing that "half-liquid" would be a recognizable term of art, IBSA identified no scientific dictionaries containing the term. Instead, of the dictionaries that IBSA relies on, only one—a non-scientific dictionary—included the term "half-liquid" and only did so in defining the term "semi-liquid" as a "Half liquid; semifluid." Appellant Br. 61 (citing J.A. 605). But even Dr. Chyall, during his deposition injected uncertainty into this definition when he stated that "semifluid" and "half-liquid" are not necessarily synonymous. J.A. 724 at 91:10–92:8.

Second, the four cited patents that use "half-liquid" only use the term in the context of "half-liquid bases" and "half-liquid polyols." Because these patents use the term "half-liquid" in different contexts than the '390 patent, these patents do not help define "half-liquid" in the context of the '390 patent. IBSA did not provide any other scientific literature to support its position. Rather, its expert testified that he was unaware of any textbook or peer-reviewed

scientific journal that uses the term "half-liquid." J.A. 742 at 164:11–165:12.

Third, Dr. Chyall's testimony demonstrates the difficulty a POSA would face in ascertaining the boundaries of a "half-liquid." For example, when asked how someone could determine whether he or she made a soft-capsule inner phase that was not a "half-liquid," Dr. Chyall stated he was not sure. J.A. 714 at 50:7–14. Dr. Chyall was also unsure whether his construction of "half-liquid" would exclude the types of gel and slurry distinguished during prosecution. J.A. 738 at 147:4–148:18. As the district court found, Dr. Chyall's testimony corroborates Dr. Khan's opinion that "half-liquid" is not a well-known term in the art.

After reviewing the extrinsic evidence, we see no clear error in the court's determination that the extrinsic evidence does not supply "half-liquid" with a definite meaning under § 112, where the intrinsic evidence has failed to do so.

IV

We have considered IBSA's remaining arguments and find them unpersuasive. Taken together, the intrinsic and extrinsic evidence fail to inform, with reasonable certainty, those skilled in the art about the scope of the invention. We therefore affirm the judgment of the district court.

AFFIRMED