2019-2400

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.

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

PETITION FOR REHEARING AND REHEARING *EN BANC* ON BEHALF OF PLAINTIFFS-APPELLANTS

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August 31, 2020

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

CERTIFICATE OF INTEREST

Case Number 2019-2400

Short Case Caption IBSA Institut Biochimique, S.A. v. Teva Pharmaceuticals USA, Inc.

Filing Party/Entity IBSA Institut Biochimique, S.A., Altergon, S.A., IBSA Pharma Inc.

Instructions: Complete each section of the form. In answering items 2 and 3, be specific as to which represented entities the answers apply; lack of specificity may result in non-compliance. **Please enter only one item per box; attach additional pages as needed and check the relevant box**. Counsel must immediately file an amended Certificate of Interest if information changes. Fed. Cir. R. 47.4(b).

I certify the following information and any attached sheets are accurate and complete to the best of my knowledge.

Date: 08/31/2020

Signature: /s/ Jeffrey J. Oelke

Name: Jeffrey J. Oelke

1. Represented Entities. Fed. Cir. R. 47.4(a)(1).	**2. Real Party in Interest.** Fed. Cir. R. 47.4(a)(2).	**3. Parent Corporations and Stockholders.** Fed. Cir. R. 47.4(a)(3).
Provide the full names of all entities represented by undersigned counsel in this case.	Provide the full names of all real parties in interest for the entities. Do not list the real parties if they are the same as the entities.	Provide the full names of all parent corporations for the entities and all publicly held companies that own 10% or more stock in the entities.
☐ None/Not Applicable	☑ None/Not Applicable	☐ None/Not Applicable
IBSA Institut Biochimique, S.A.		Wholly owned subsidiary of IBSA Holding SA; no publicly held company owns 10% or more stock.
Altergon, S.A.		N/A
IBSA Pharma Inc.		Wholly owned subsidiary of IBSA Institut Biochimique, S.A.; no publicly held company owns 10% or more stock.

☐ Additional pages attached

4. Legal Representatives. List all law firms, partners, and associates that (a) appeared for the entities in the originating court or agency or (b) are expected to appear in this court for the entities. Do not include those who have already entered an appearance in this court. Fed. Cir. R. 47.4(a)(4).

☐ None/Not Applicable ☐ Additional pages attached

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5. Related Cases. Provide the case titles and numbers of any case known to be pending in this court or any other court or agency that will directly affect or be directly affected by this court's decision in the pending appeal. Do not include the originating case number(s) for this case. Fed. Cir. R. 47.4(a)(5). See also Fed. Cir. R. 47.5(b).

☑ None/Not Applicable ☐ Additional pages attached

6. Organizational Victims and Bankruptcy Cases. Provide any information required under Fed. R. App. P. 26.1(b) (organizational victims in criminal cases) and 26.1(c) (bankruptcy case debtors and trustees). Fed. Cir. R. 47.4(a)(6).

☑ None/Not Applicable ☐ Additional pages attached

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FEDERAL CIRCUIT RULE 35(b) STATEMENT

A. Based on my professional judgment, I believe the panel decision is contrary to the following precedent of this Court:

Guangdong Alison Hi-Tech Co. v. ITC, 936 F.3d 1353 (Fed. Cir. 2019) and *Sonix Tech. Co. v. Publications Int'l, Ltd.*, 844 F.3d 1370 (Fed. Cir. 2017).

B. Based on my professional judgment, I believe this appeal requires an answer to one or more precedent-setting questions of exceptional importance:

Where a non-English language foreign priority application is the best intrinsic evidence of the inventors' understanding of claim scope, can the foreign priority application be discounted during claim construction due to minor, irrelevant differences from the United States application?

/s/ Jeffrey J. Oelke

Jeffrey J. Oelke, Counsel of Record

FEDERAL RULE OF APPELLATE PROCEDURE 40(a)(2) STATEMENT OF POINTS OF LAW OR FACT OVERLOOKED OR MISAPPREHENDED

Pursuant to Federal Circuit Rule 40, counsel for Plaintiffs-Appellants IBSA Institut Biochimique, S.A., Altergon, S.A., and IBSA Pharma Inc. state that:

1. The Panel erred during claim construction by discounting intrinsic evidence in the form of a non-English language foreign priority application due to minor, irrelevant differences from the United States application.

2. The Panel erred by applying an overly demanding legal standard for definiteness.

ARGUMENT

I. PRELIMINARY STATEMENT

The deck was stacked against the Italian inventors of the '390 patent when they sought patent protection in the United States. They could not have known that by entering the United States through their Italian Application's English language counterpart they had relinquished reliance on any expression of their invention in their native language. The panel opinion turns on an untenable reading of the intrinsic evidence (beginning with the Italian Application) and application of an overly demanding legal standard, resulting in invalidity for indefiniteness. Rehearing is required to correct these errors.

The panel misinterpreted, and then discounted, the Italian Application, leading it to incorrectly conclude that the claim term "half-liquid" is not a synonym for "semi-liquid." As explained below, *none* of the reasons the panel gave for discounting the Italian Application are sound. When properly considered, the Italian Application (in the inventors' native language) establishes that half-liquid is simply a translation of semiliquido (i.e., semi-liquid). No person of ordinary skill in the art could conclude otherwise, and Appellee Teva's feigned confusion as to the connection between the two terms is, while convenient, implausible. The panel's unreasonable conclusion that the '390 patent's Italian inventors—who used half-liquid in their United

States patent application the same number of times they used semiliquido, in the exact same places, in their Italian Application—intended to coin a new term without ever indicating its meaning, warrants rehearing.

The panel also applied an overly demanding test for definiteness that is at odds with this Court's precedent. Per the panel, even if the intrinsic evidence did show that half-liquid means semi-liquid, the boundaries of that term would still be too nebulous. But it is undisputed that semi-liquid is a well-known and commonly understood term of art. There is no precedent for finding a claim indefinite where its scope matches that of a term well-known in the field, as is the case here. As a matter of law, a patentee need not employ mathematical precision in claim-drafting. Accordingly, IBSA's expert Dr. Chyall's reticence to provide a numerical range corresponding to half-liquid or a specific test method to evaluate it, are of no moment, particularly since there is no evidence persons of skill need such information to understand the claims. The panel was wrong to hold IBSA and Dr. Chyall to such a standard. In fact, Dr. Chyall explained how persons of ordinary skill would easily understand the claims' scope and gave clear examples of materials falling within the term's scope, and others falling outside it. On the whole, his testimony, rather than supporting the panel's decision, supports a definite construction.

II. THE PANEL ERRED BY NOT CONSTRUING HALF-LIQUID TO MEAN SEMI-LIQUID

A. The Panel's Reasons for Discounting the Italian Application Are Not Sound

In concluding that the Italian Application's use of semiliquido did not inform the '390 patent's use of half-liquid, the panel focused on minor, immaterial differences between the two documents and incorrectly concluded that those differences severed any link between the two terms. Op. at 10. First, the panel pointed to the "Field of the Invention" and "Prior Art" sections of the documents, as did the district court. Op. at 10. But a comparison of these sections reveals nothing more than minor changes to phrasing and syntax resulting from a translator's judgment, not a difference in meaning.

The translation's "Field of the Invention" section states, in toto: "The present invention relates to pharmaceutical formulations for thyroid hormones." Appx0323. The corresponding section in the '390 patent states: "The present invention relates to pharmaceutical compositions for thyroid hormones." Appx0040. This change to a single word does not suggest any substantive change and does not support the panel's conclusion that the inventors intended the adjective half-liquid to mean something different than semi-liquid.

The same is true for the "Prior Art" section. For example, the translation of the Italian Application states that "[s]erum thyroid hormone concentrations are precisely regulated by thyrotropin hormone with a classic negative feedback system." Appx0323. In the corresponding location, the '390 patent states that "[t]he concentrations of thyroid hormones in serum are strictly regulated by the hormone thyrotropin through a typical negative feedback system." Appx0040. These minor differences are representative of all of those within the "Prior Art" section, which the '390 patent refers to as the "State of the Art" section.[1] Teva's argument is grounded on the false supposition that a term in Italian can only have one proper translation in English. But this ignores the realities of a translator's job, which necessarily allows for more than one "correct" translation of a term, often reflective of a translator's judgment, rather than a decision by the translator to coin a new meaning. No person of ordinary skill in the art would reach that conclusion upon reviewing the two documents. Accordingly, any differences between

[1] As another example, the translation of the Italian Application states: "Among the specific symptoms of hypothyroidism were severe depression, fatigue, weight gain, constipation, cold intolerance, edema and difficulty in concentrating." Appx0326-0327. The '390 patent states: "Among the specific symptoms of hypothyroidism the following were reported: severe depression, tiredness, weight increase, constipation, intolerance to cold, edema and difficulty to concentrate." Appx0040. Again, these minor differences do not suggest a different meaning. Overall, these sections of the two documents are all but identical in content.

these sections should not detract from the documents' parallel use of semiliquido and half-liquid. Indeed, the "Field of the Invention" and "Prior Art" sections of the documents do not even use either of those terms, underscoring their irrelevance to the claim construction issue here.

Next, the panel credited Teva's argument that claim 1 of the '390 patent encompasses the Fourth Embodiment, while claim 1 of the Italian Application does not. Op. at 10. Neither the panel nor Teva explained why this fact should bear on the relationship between half-liquid and semiliquido. And it does not. The Fourth Embodiment is a distinct type of formulation consisting of a single uniform matrix, set off within a separate subpart of claim 1. It is *not* a capsule filled with a liquid or half-liquid (i.e., the Third Embodiment). The addition to the claims of a new and different type of formulation—one that does not relate to half-liquids in any way—does not suggest that the patent's use of half-liquid should differ from the Italian Application's use of semiliquido. Yet that is what the panel concluded. *Id.*

Finally, the panel concluded that the '390 patent's use of "gel" in one location, which does not appear in the corresponding location in the Italian Application, reinforced the Application's irrelevance. Op. at 10. But the panel's reasoning on this issue was inconsistent with the rest of its opinion. Elsewhere, the panel relied on the very same section of the specification to

conclude that gels are *not* half-liquids. Op. at 8-9. If that were true, the presence of gels in the '390 patent should not change the meaning of half-liquid or its relationship to the semi-liquids of the Italian Application. Yet the panel concluded it did.

Had the panel's analysis of this issue focused on what truly matters—the two documents' parallel use of the two terms—the connection between half-liquid and semiliquido would have been undeniable. This connection is critical because semi-liquid is a well-understood and commonly used term of art. As explained further below, half-liquid cannot be indefinite when its connection to semi-liquid is appreciated. *See infra* Section III. The panel's misinterpretation of this intrinsic evidence led it to an incorrect indefiniteness ruling.

B. The Panel Improperly Dismissed Other Links Between Half-Liquid and Semi-Liquid

The panel focused on a list in the specification that it found indicated what half-liquids are *not*. Op. at 8-9. But the specification also reinforces the Italian Application's teaching that half-liquids are semi-liquids.

First, the specification cites *Remington's* as a primer on making half-liquids, but the reference discusses making semi-liquids, a further indication (beyond the Italian Application) that the terms are synonyms. The panel acknowledged this connection. Op. at 9.

Second, the specification contains a list of well-known chemicals that can serve as "liquid or half-liquid vehicles," providing guidance as to the properties of half-liquids. Dr. Chyall explained that many of these examples were substances persons of ordinary skill would know to be semi-liquids. Appx0729, 111:11-112:4; Appx0737, 142:4-144:3; Appx0737, 143:14-144:3.

The panel opinion focused instead on the existence of a dependent claim proposed-then-cancelled during prosecution that used the term semi-liquid, which indicated to the panel that semi-liquid and half-liquid must have different meanings. Op. at 11. Since the claim term semi-liquid had no verbatim appearance in the United States application, it necessarily relied on half-liquid for support in the specification. To find otherwise is to assume that the proposed claim was drafted without any support in the specification. In any event, the Applicants did not pursue the claim.

In sum, the panel was wrong to conclude that half-liquid is not a synonym for semi-liquid; the Italian Application clearly shows that it is, and the other intrinsic evidence supports it. As explained below, this well-known and commonly understood term of art is easily understood by persons of ordinary skill. It should not have been found indefinite.

III. THE PANEL ERRED BY APPLYING AN OVERLY DEMANDING LEGAL STANDARD FOR DEFINITENESS

The '390 patent explains that the pharmaceutical capsules the inventors discovered can be filled with (1) solid material (powders, granules, or non-compacted microgranules), (2) liquid material, or (3) half-liquid material. Appx0043-0044. There is nothing in the patent to suggest that half-liquid means anything other than substances with properties falling between solids and liquids—in other words, half-liquid means semi-liquid, a connection that the Italian Application (among other evidence) makes clear, as explained above. *See supra* Section II.

Semi-liquids are well-known in the pharmaceutical field, a category of substance that persons of ordinary skill readily understand and regularly use. Appx0473-0477; Appx0707, 23:22-24:4; Appx0751, 18:4-19:9; Appx0753, 26:16-19; Appx0760, 56:9-17; Appx0762, 64:5-18. Thus, the '390 patent relies on a well-known concept, reinforced by the information in the patent and readily understood by persons of ordinary skill, to define its claims' scope.

Yet the panel demanded more. It began its analysis from the premise that the claims' scope was uncertain and searched repeatedly for some details on the "boundaries" of the term half-liquid. Op. at 6, 9, 12, 13. This search required more from IBSA than this Court's precedents demand. "[A] patentee need not define his invention with mathematical precision in order to comply

with the definiteness requirement." *Exmark Mfg. Co. v. Briggs & Stratton Power Prods. Grp, LLC*, 879 F.3d 1332, 1346 (Fed. Cir. 2018) (internal quotation omitted); *BASF Corp. v. Johnson Matthey Inc.*, 875 F.3d 1360, 1365 (Fed. Cir. 2017) ("'Reasonable certainty' does not require 'absolute or mathematical precision.'") (quoting *Biosig Instruments, Inc. v. Nautilus, Inc.*, 783 F.3d 1374, 1381 (Fed. Cir. 2015)). This is because "[p]atentable inventions cannot always be described in terms of exact measurements, symbols and formulae…." *In re Packard*, 751 F.3d 1307, 1313 (Fed. Cir. 2014) (quoting *Georgia-Pacific Corp. v. U.S. Plywood Corp.*, 258 F.2d 124, 136 (2d Cir. 1958)). IBSA brought this precedent to the panel's attention, but the panel did not address it.

Indeed, this Court has "rejected the proposition that claims involving terms of degree are inherently indefinite." *Sonix Tech. Co. v. Publications Int'l, Ltd.*, 844 F.3d 1370, 1377 (Fed. Cir. 2017) *see also Guangdong Alison Hi-Tech Co. v. ITC*, 936 F.3d 1353, 1359-63 (Fed. Cir. 2019) (rejecting an attempt to "seek[] a level of 'mathematical precision' beyond what the law requires"). For example, in *Sonix* this Court reversed the district court's finding that the claim term "visually negligible" was indefinite for having no objective measure. *Id.* at 1371. The Court considered the specification's description of variables such as differentiability, brightness, and homogeneity,

as well as examples of "visually-negligible indicators." *Id.* at 1373, 1378-79. Additionally, in finding the claim term definite, the Court discredited unsupported expert opinion that there "was no objective test to define" the claim term, instead holding that "'visually negligible' is not a purely subjective term." *Id.* at 1380-81.

"Half-liquid" is no different, and by holding the term to be indefinite the panel opinion is in direct conflict with this Court's decisions in *Sonix* and *Guangdong*. This is because, as with "visually negligible," half-liquid is not purely subjective, given the guidance in the intrinsic evidence. *See Sonix*, 844 F.3d at 1377-1381; *see also Guangdong,* 936 F.3d at 1360 (finding "the written description [ ] provides objective boundaries for the claim term"). Half-liquid's connection to semi-liquid is clear from the intrinsic evidence, and that term is well-known and well-understood by persons of ordinary skill in the art. No more is required under this Court's precedent. The panel was wrong to hold otherwise.

The panel relied on the testimony of IBSA's expert Dr. Chyall to conclude that one of ordinary skill would have trouble "ascertaining" the boundaries of half-liquid as indeterminate and unidentifiable. Op. at 13. In fact, Dr. Chyall's testimony shows how one of ordinary skill would readily understand the term. For example, Dr Chyall:

- Testified that "half-liquids that are called out [in the specification] are clearly those materials that would be viewed as materials having a thick consistency" (Appx0729, 111:11-112:4);
- Identified examples of "half-liquids" described in the patent, including its examples, explaining that persons of skill know that those substances are "materials with thick consistencies" that are "clearly half-liquids," even if the patent does not "come out and say [it] explicitly" (Appx0737, 142:4-144:3);
- Explained that liquids are "free flowing," do "not have a thick consistency," and are "things that you buy in jugs and can pour out . . . readily that flow like water" (Appx0718, 66:5-7; Appx0722, 84:11-18);
- Detailed that "[i]f you place the material in a container and it takes the shape of the container, then that material would be a non-solid because it's responding to gravity and it's responding to the barriers of the container. Solids can maintain their own shape" (Appx0708, 27:14-20; see also Appx0713, 47:6-18); and
- Explained that "half-liquids" are different because they "have thick consistencies between a liquid and a solid;" they flow less freely than water-like liquids, but unlike solids, they will "eventually respond to gravity and will flow" (Appx0707, 23:22-25:19).

Instead of acknowledging and considering the above testimony, the panel focused on two excerpts of Dr. Chyall's testimony as allegedly supporting indefiniteness. Op. at 13. First was his reluctance to identify test methods to use in identifying whether one had made a half-liquid. Op. at 13. But because persons of ordinary skill readily recognize "semi-liquids," and because the law does not require the kind of mathematical precision that would make a test method mandatory, Dr. Chyall's testimony on this issue was not indicative of indefiniteness. Second, the panel relied on Dr. Chyall's refusal to confirm whether his construction of half-liquid would exclude certain prior art allegedly distinguished during prosecution. Op. at 13. But the panel's reliance on that testimony was misplaced for several reasons. First, Dr. Chyall was not given the relevant prosecution excerpts during his deposition, and so his reluctance to answer questions about what was disavowed (if anything) was prudent, not indicative of uncertainty. Appx0702; Appx0738, 147:4-21. Furthermore, gels and slurries were distinguished during prosecution based on their hormone concentration, not based on whether they were half-liquids. Appx0231-0232; Appx0258; Appx0268-0269.

Beyond Dr. Chyall, the panel focused on the paucity of dictionaries and scientific literature defining or discussing half-liquids in concluding that the

term's boundaries are indeterminate. Op. at 12-13. But when properly construed as semi-liquid, the absence of extrinsic information on half-liquid becomes irrelevant. In the end, the panel struck down as indefinite a term that is synonymous with a well-known and commonly used term, regularly used by those of ordinary skill in the art. It did so by holding the '390 patent and its Italian inventors to a heightened definiteness standard that far exceeds this Court's precedents.

IV. CONCLUSION

For the forgoing reasons, rehearing should be granted.

Dated: August 31, 2020

Respectfully submitted,

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FORM 19. Certificate of Compliance with Type-Volume Limitations **Form 19**
July 2020

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

CERTIFICATE OF COMPLIANCE WITH TYPE-VOLUME LIMITATIONS

Case Number: 2019-2400

Short Case Caption: IBSA Institut Biochimique, S.A. v. Teva Pharmaceuticals USA, Inc.

Instructions: When computing a word, line, or page count, you may exclude any items listed as exempted under Fed. R. App. P. 5(c), Fed. R. App. P. 21(d), Fed. R. App. P. 27(d)(2), Fed. R. App. P. 32(f), or Fed. Cir. R. 32(b)(2).

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Date: 08/31/2020

Signature: /s/ Jeffrey J. Oelke

Name: Jeffrey J. Oelke

ADDENDUM

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

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.

JUDGMENT

THIS CAUSE having been considered, it is

ORDERED AND ADJUDGED:

AFFIRMED

ENTERED BY ORDER OF THE COURT

July 31, 2020

/s/ Peter R. Marksteiner
Peter R. Marksteiner
Clerk of Court