No. 20-

IN THE
Supreme Court of the United States

IBSA INSTITUT BIOCHIMIQUE, S.A., ALTERGON, S.A., IBSA PHARMA INC.,
Petitioners,

v.

TEVA PHARMACEUTICALS USA, INC.,
Respondent.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

PETITION FOR WRIT OF CERTIORARI

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QUESTION PRESENTED

Patents are unique: the rights they confer are strictly territorial in nature, yet there exists an agreed-upon framework among the vast majority of countries for efficiently securing patent rights. This mutual arrangement permits both U.S. and foreign inventors to seek patent protection first in their home country and then, if they choose, to seek similar rights abroad. In both cases, the inventor can claim "priority" to their domestic application, a critical step for warding off the potentially preclusive effects of "prior art" that can bar patenting.

This efficient system would suffer, if not disappear, without international agreements like the Agreement on Trade-Related Aspects of Intellectual Property Rights (the "TRIPS Agreement"), which establishes a baseline for intellectual property protections among its 140 signatory countries. Amongst other protections, the TRIPS Agreement demands that foreign inventors, and foreign priority applications, be treated like their domestic counterparts. This "national treatment" is a critical protection for U.S. inventors abroad, and for the many foreign inventors who seek to pursue their patent rights in the United States. But the courts below rejected these treaty obligations by choosing to give no weight to a foreign patent application, resulting in a finding of indefiniteness.

The question presented is:

Whether, pursuant to the United States' obligations under the TRIPS Agreement, codified at 19 U.S.C. § 3511, a court construing the claims of a U.S. patent may give no weight to a foreign priority

patent application, despite its submission to the U.S. Patent & Trademark Office during prosecution of the patent-in-question, because it is written in a foreign language and exhibits minor differences from the U.S. patent resulting from a translator's judgment.

PARTIES TO THE PROCEEDING AND RULE 29.6 STATEMENT

IBSA Institut Biochimique, S.A., petitioner on review, was a plaintiff-appellant below and states that it has no parent corporation, and that no publicly held corporation owns, directly or indirectly, 10% or more of its stock.

Altergon, S.A., petitioner on review, was a plaintiff-appellant below and states that it has no parent corporation, and that no publicly held corporation owns, directly or indirectly, 10% or more of its stock.

IBSA Pharma Inc. petitioner on review, was a plaintiff-appellant below and states that it is a wholly owned subsidiary of IBSA Institut Biochimique, S.A., and that no publicly held corporation owns, directly or indirectly, 10% or more of its stock.

Teva Pharmaceuticals USA Inc., respondent on review, was defendant-appellee below.

STATEMENT OF RELATED CASES

IBSA Institut Biochimique, S.A., et al. v. Teva Pharms. USA, Inc., No. 2019-2400 (United States Court of Appeals for the Federal Circuit) (opinion and judgment entered July 31, 2020; petition for rehearing denied October 2, 2020; mandate issued October 7, 2020).

IBSA Institut Biochimique, S.A., et al. v. Teva Pharms. USA, Inc., No. 18-cv-555-RGA (United States District Court for the District of Delaware) (judgment entered September 10, 2019).

There are no additional proceedings in any court that are directly related to this case.

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Petitioners IBSA Institut Biochimique, S.A., Altergon, S.A., and IBSA Pharma Inc. respectfully petition for a writ of certiorari to review the judgment of the United States Court of Appeals for the Federal Circuit.

OPINIONS BELOW

The opinion of the Federal Circuit (App. 1a) is reported at 966 F.3d 1374. The Federal Circuit's order denying rehearing and rehearing *en banc* (App. 41a) is unreported. The opinion of the district court (App. 17a) is reported at 2019 WL 3936656.

JURISDICTION

The Federal Circuit entered judgment on July 31, 2020. Petition for rehearing of that appeal was denied on October 2, 2020. On March 19, 2020, this Court extended the deadline to file any petition for a writ of certiorari due on or after that date from 90 days to 150 days. This petition is filed within 150 days of the Federal Circuit's denial of the petition for rehearing. This Court has jurisdiction under 28 U.S.C. § 1254(1).

STATUTORY PROVISIONS INVOLVED

The statutes and provisions involved are the Paris Convention for the Protection of Industrial Property, Article 2, as last revised at the Stockholm Revision Conference, July 14, 1967 reproduced at App. 43a, the Agreement on Trade-Related Aspects of Intellectual Property Rights: Marrakesh Agreement Establishing the World Trade Organization, Article 3 (Apr. 15, 1994) reproduced at App. 44a, 19 U.S.C. § 3511, reproduced at App. 46a, Exec. Order No. 13042, 62

F.R. 18017 (Apr. 9, 1997) reproduced at App. 49a, Proclamation No. 6763, 60 F.R. 1007 (Dec. 23, 1994) reproduced at App. 52a, Proclamation No. 6780, 60 F.R. 15845 (Mar. 23, 1995) reproduced at App/ 63a, Memoranda on the Uruguay Round Agreements, 60 F.R. 1003 (Dec. 23, 1994) reproduced at App. 71a, 35 U.S.C. § 112, reproduced at App. 73a, and 35 U.S.C. § 282(a), reproduced at App. 75a.

STATEMENT OF THE CASE

This Petition seeks to remedy the lower courts' improper refusal to give weight to a U.S. patent's foreign priority application. The patent-in-question, U.S. Patent No. 7,723,390 (the "'390 patent"), protected four Italian-speaking inventors' discovery of a novel pharmaceutical approach to delivering a hormone needed by a substantial patient population. The '390 patent covers Petitioners' Tirosint® levothyroxine sodium capsule product. The inventors first filed for patent protection in Italy in their native language in Italian Application M12001A1401 (the "Italian Application"), and then, within the prescribed 12-month period, filed a parallel application in the United States claiming priority to the Italian Application.

The inventors' U.S. Application (in English, of course) included an overly literal translation of a key technical term: from the Italian "semiliquido" to the English "half-liquid." It is undisputed that "semiliquido" may be translated as "semi-liquid," which is a commonly used and well-understood term of art. But instead, presumably because the Italian prefix "semi" may be translated into English as "half," the comparatively obscure term "half-liquid" was used

in the specification and the claims of the issued U.S. patent.

Years later, Respondent Teva Pharmaceuticals USA Inc. ("Teva") challenged the patent through the patent certification process of the Hatch Waxman Act in filing its Abbreviated New Drug Application ("ANDA") seeking to market a generic copy of Tirosint®. Petitioners filed suit for patent infringement. Teva argued that the claim term "half-liquid" was indefinite under 35 U.S.C. § 112, asserting that no person in the field could possibly parse its meaning or scope. Petitioners explained that the term's meaning was perfectly clear based on the intrinsic evidence, which is the paramount source of information for ascertaining claim scope. Chief among this evidence was the original Italian Application, which is included in the patent's prosecution history, and establishes a clear and undeniable link between "half-liquid" and the Italian "semiliquido," i.e., semiliquid, an entirely unmysterious term.

The Italian Application uses "semiliquido" in the exact same places, the exact same number of times, to describe the exact same things, as the U.S. patent uses "half-liquid." Yet the district court refused to even consider this helpful guidance, instead electing to give the Italian Application no weight in its analysis. The court first expressed skepticism that any priority application written in a language other than English could be relevant. Then the court focused on minor differences between the Italian Application and the U.S. patent, concluding that those differences meant that the inventors must have made a conscious decision to describe a different invention,

making the Italian Application irrelevant. Turning a blind eye to the evidence, and unable to identify any other clear meaning for "half-liquid," the district court found the term indefinite.

The court of appeals affirmed. It found no fault in the district court's unjustified mistrust of foreign-language priority applications. It doubled down on the district court's choice to treat minor differences in syntax and phrasing, obviously a product of translation from Italian to English, as the inventors' intentional choice to claim a different invention with a largely unknown and inscrutable term—an illogical result. And it further justified excising the Italian Application from the analysis based on the addition of new subject matter in the United States, despite the undeniable irrelevance of this newly added subject matter to the meaning of the terms "semiliquido" and "half-liquid."

The lower courts' analysis flatly contradicts the TRIPS Agreement's mandate. TRIPS Article 3 specifically states: "Each Member shall accord to the nationals of other Members treatment no less favourable than that it accords to its own nationals with regard to the protection of intellectual property. . .."

As a signatory, the United States is required to treat foreign priority applications the same as domestic applications, and treat foreign inventors the same as domestic inventors. The courts here declined the inventors those rights. Their original patent application, written in the foreign inventors' native language, must be the best evidence of their own understanding of the invention. But the lower courts ignored it, in part because it was not written in

English, and in part because of the most minor of differences between the two documents. Those differences are the unsurprising consequence of translating a foreign language document to a different language[1]—here, the translation of a foreign language priority application, which is a requirement for any foreign inventor who seeks U.S. patent rights. They are not, as the lower court held, evidence of a conscious choice to claim a different invention in the United States.

If the lower courts' view holds, precedent will be set to give foreign applications no weight in claim construction proceedings, as the types of differences the courts found dispositive here are common with translations, no matter the foreign language. That rule would flatly contravene the requirement that a foreign application be treated equally as a domestic one. And the rule would have profound implications for foreign applicants' right to claim priority to their domestic applications.

This Court should grant certiorari to remedy the errors below and announce a rule that complies with the international obligations of the United States under the TRIPS Agreement: foreign language

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[1] "Translating from one language to another, unless it is from Greek and Latin, the queens of all languages, is like looking at Flemish tapestries from the wrong side, for although the figures are visible, they are covered by threads that obscure them, and cannot be seen with the smoothness and color of the right side." de Cervantes Saavedra, Miguel, *Don Quixote.* ch. xviii, pp. 873–74 (Edith Grossman trans., Harper Perennial ed. 2005).

priority applications *must* be considered in the claim construction analysis, and minor differences flowing from translation from a foreign language into English do *not* sever ties with the foreign priority document or establish that the inventors sought to claim something different in the United States.

BACKGROUND AND PROCEEDINGS BELOW

I. Invention of U.S. Patent No. 7,723,390

The invention of the '390 patent is a novel approach to delivering precise doses of the thyroid hormone levothyroxine (also known as T4). Thyroid hormones like T4 are critical for proper development and for a variety of important bodily functions. '390 patent at col.1, ll.18-29. Accordingly, an imbalance in thyroid hormones can have serious medical consequences. *See id*.

At the time of the invention, hypothyroidism (i.e., too little thyroid hormone) was known to affect 1 out of every 4,000-5,000 babies born in the United States, 2.7% of men over the age of sixty, and 7.1% of women over the age of sixty. *Id*. at col.1, ll.28-38. Most of these patients treated their hypothyroidism by taking pharmaceutical tablets containing thyroid hormones like T4. *See id*. at col.1, ll.18-29. But these tablets had serious drawbacks. The amount of T4 varied from tablet to tablet; the T4 within the tablets was unstable (i.e., degraded over time); and the absorption of T4 from the tablets into the body varied widely from patient-to-patient, and even from day-to-day. *See, e.g.*, '390 patent at col.2, ll.44-51.

This variability would be troubling for any drug, but was especially so for T4 because of the extreme

precision in dosing that it requires. Unlike many other drugs, physicians must take care to start patients suffering from hypothyroidism at an artificially low dose calculated based on traits such as age and physical condition, and then escalate the dose in small steps over time, until the patient reaches a precise amount tailored to their needs. Too low a dose of T4 will fail to treat patients' symptoms and potentially lead to complications like osteoporosis, while too high a dose can cause toxic effects like cardiac arrhythmia. '390 patent at col.2, ll.1-5. The high level of variability seen in T4 tablets frustrated efforts to keep patients at the precise amount required for effective treatment without causing side effects.

These issues became so severe that, at one point, the FDA recalled many thyroid hormone products from the market for issues related to dosing. '390 patent at col.3, ll.34-46. Yet a solution evaded the medical community for many years—until the invention of the '390 patent. *Id.* at col.2, l.27 - col.3, l.46, col.4, ll.33-48.

II. The '390 Patent

The invention of the '390 patent was discovered by four pharmaceutical scientists. At the time, they worked for the Swiss pharmaceutical company IBSA Institut Biochimique S.A. ("IBSA"). IBSA is based in Lugano, a city located in an Italian-speaking canton

of Switzerland. All four inventors are native Italian speakers. JA 888-89.[2]

On July 2, 2001, the inventors filed the Italian Application for their discovery. Under 35 U.S.C. § 119, they had one year to file a parallel application in the United States, claiming the benefit of the Italian Application. They did so on July 2, 2002. They submitted a certified copy of the Italian Application to the U.S. Patent Office a few months later. Years later, on May 25, 2010, the inventors' U.S. application (the "U.S. Application") issued as the '390 patent.

The '390 patent explains that the inventors had discovered that creating soft-gel capsules containing T4 had several significant advantages over the pre-existing tablet forms, including improved bioavailability and less degradation than the prior tablet forms. '390 patent at col.4, l.64 - col.6, l.12.

The '390 patent identifies four preferred approaches to carrying out the invention, each described as a "preferred embodiment:" (1) *hard* gelatin capsules filled with T4 and certain inactive ingredients in *solid* form ('390 patent at col.7, ll.9-17 (emphasis added)); (2) *soft* gelatin capsules filled with T4 and certain inactive ingredients in *solid* form (*id.* at col.7, ll.30-36 (emphasis added)); (3) *soft* gelatin capsules filled with T4 and certain inactive ingredients in *liquid or "half-liquid"* form (*id*. at col.7, l.59 – col.8, l.2 (emphasis added)); and (4) a "swallowable uniform soft-gel matrix," made of a

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[2] JA refers to the Joint Appendix filed with the Federal Circuit in Appeal No. 2019-2400.

"single phase" containing the T4 and certain inactive ingredients (*id.* at col.9, ll.21-27).

The first three preferred embodiments appear in the Italian Application, while the fourth was added when the inventors entered the United States. JA 318. Aside from this addition, the U.S. Application is essentially a translation of the Italian Application. One term in particular, used to describe the third preferred embodiment, received an overly literal translation: from the Italian "semiliquido" to the English "half-liquid," instead of "semi-liquid." "Semi-liquid" is regularly used in pharmaceuticals and understood by those in the field. *See, e.g.*, JA 362-374; JA 466-0485; JA 605. "Half-liquid" is much less common. The translation to the little-used "half-liquid" apparently resulted from the fact that "semi" in Italian may be translated as "half" in English.

The '390 patent's use of "half-liquid" perfectly mirrors the Italian Application's use of "semiliquido," reinforcing that this is a translation issue, not a substantive change. For example:

- In every place where the Italian Application describes the third embodiment with the phrase "liquido o semi-liquido," the '390 patent uses "liquid or half-liquid."

- The Italian Application provides a list of chemicals that can serve as "liquidi or semi-liquidi" vehicles. *See, e.g.*, JA 287 at 310; *see also* JA 318 at 340. The list is specific and references trade names of several commercially available chemicals. *Id.* (identifying "Sigma T3396," "Tweens®," and "Sigma P1754"). The same list appears in the '390

patent as examples of "liquid or half-liquid" vehicles. '390 patent at col.8, ll.43-53.

- The Italian Application suggests using specific manufacturing equipment, as described in a particular pharmaceutics treatise, to make soft capsules filled with "liquido o semi-liquido" contents. JA 287 at 307-08; *see also* JA 318 at 338-39. The '390 patent cites the same equipment and the same treatise as guidance on making capsules filled with "liquid or half-liquid" contents. '390 patent at col.8, ll.8-19. The treatise itself discusses the manufacture of "semiliquids."

Overall, the '390 patent's passages on the third embodiment—capsules with a "liquid or half-liquid" fill—are essentially identical to the Italian Application's passage on the third embodiment, aside from minor differences in syntax and word choice. And this extends to the rest of the '390 patent as well. Aside from the fourth embodiment, which was newly added in the U.S. application and does *not* concern "liquid or half-liquid" fillings, the patent's discussion of the prior art, its description of the invention, and its description of the first three embodiments are all but identical to that in the Italian Application. *Compare* JA 287 to JA 318 and JA 39.

The '390 patent's use of "half-liquid" extends to its claims. Claim 1, the patent's only independent claim, covers the patent's third and fourth preferred embodiments:

> 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 at claim 1 (emphasis added).

III. The District Court Finds the '390 Patent Invalid for Indefiniteness Because of Its Use of the Term "Half-Liquid"

IBSA Pharma Inc. ("IBSA Inc."), the U.S. subsidiary of IBSA, sells the invention of the '390 patent in the United States under the trade name Tirosint®. App. 2a. Per statutory and regulatory requirements, IBSA Inc. listed the '390 patent for Tirosint® in the U.S. Food and Drug Administration's *Approved Drug Products with Therapeutic*

Equivalence Evaluations (the "Orange Book"). *Id.* Tirosint® was the first levothyroxine product available in capsule form in the United States. *See* App. 3a; *see also See IBSA Institut Biochimique, S.A., et al. v. Teva Pharms. USA, Inc.*, 2019-2400 (Fed. Cir.) Opening Brief for Plaintiffs-Appellants ("Op. Br.") at 6.

Teva prompted the underlying litigation by filing an ANDA with the FDA seeking to market a generic version of Tirosint®. *See* App. 3a. An ANDA is an application to make a generic version of a branded drug that does *not* contain the requisite clinical investigations of safety and efficacy, but instead relies on the branded company's clinical studies to infer that the generic product will likewise be safe and effective. *See* 21 U.S.C. § 355(j)(2)(A).

Teva included with its ANDA a certification that, in Teva's opinion, the '390 patent is invalid or would not be infringed by Teva's generic product (known as a "Paragraph IV certification"). *See* App. 3a. By making this certification, Teva effectively asked the FDA to approve its generic product for sale in the United States *before* the '390 patent expires. *See* 21 U.S.C. § 355(j)(5)(B)(iii). Absent the certification, Teva would not be eligible for approval of its ANDA until after the '390 patent expires.

As required by statute, Teva notified IBSA of its ANDA and the accompanying Paragraph IV certification. *See* App. 3a. IBSA then sued Teva for patent infringement in the District of Delaware pursuant to 35 U.S.C. § 271(e)(2), which makes submission of an ANDA with a Paragraph IV certification an act of patent infringement. The district court set a schedule for the case that included

a "claim construction" phase, including two briefs from each side, followed by a hearing. *See* App. 17a.

Claim construction is the process that courts use to determine the meaning of the terms used in a patent's claims as a matter of law. *See Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 388 (1996). "[T]he first step in any infringement analysis is claim construction." *Godo Kaisha IP Bridge 1 v. TCL Commc'n Tech. Holdings Ltd.*, 967 F.3d 1380, 1384 (Fed. Cir. 2020). After the claims are construed, the product accused of infringement is compared to the claims to assess whether it falls within the claims' scope. *See Cybor Corp. v. FAS Techs., Inc.*, 138 F.3d 1448, 1454 (Fed. Cir. 1998) (en banc). In construing claim terms, the court is guided by the intrinsic evidence—that is, the patent itself and its prosecution history before the U.S. Patent & Trademark Office leading up to patent issuance. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312-1315 (Fed. Cir. 2005) (en banc). Extrinsic evidence—i.e., any information outside the patent and its file history—is less relevant than intrinsic evidence but may be useful in construing claims. *Id.* at 1317-1318.

During claim construction, the parties disagreed over the proper meaning of the claim term "half-liquid" and submitted the term to the court for construction. IBSA proposed that "half-liquid" be construed as "semi-liquid, i.e., having a thick consistency between a solid and a liquid." App. 4a.

In support, IBSA referred to the Italian Application and its use of "semi-liquido." IBSA explained that the Italian Application is intrinsic evidence because it is part of the '390 patent prosecution history. App. 4a-5a. IBSA demonstrated

that each use of "semi-liquido" in the Italian Application matches the use of "half-liquid" in the '390 patent. App. 4a-5a. IBSA explained that "half-liquid" was therefore an imperfect—albeit literal—Italian-English translation of "semi-liquido." In other words, the inventors' intent was to use the term "semi-liquid." IBSA offered a certified translation of the Italian Application, which confirmed that "semi-liquido" is appropriately translated as "semi-liquid." JA 318. IBSA also pointed out that the English-language treatise that the '390 patent cites for its explanation of manufacturing "half-liquids" discusses the manufacture of "semiliquids." App. 28a.

IBSA also directed the district court to the '390 patent's description of the invention. IBSA explained that the patent's example capsule formulations and lists of chemicals that could be used to make them confirmed that "half-liquids" had the same properties as "semi-liquids." IBSA offered a declaration and testimony from an expert in pharmaceutics, Dr. Chyall, to confirm this. JA 466. Dr. Chyall also explained that a pharmaceutical scientist would readily understand the Italian word "semi-liquido," as used in the Italian Application, to mean "semi-liquid," a well-known term of art. *See* JA 466 at 473, 476-477.

Teva, on the other hand, argued that the term "half-liquid" is indefinite or, in the alternative, should be construed to mean "a non-solid, non-paste, non-gel, non-slurry, non-gas substance." App. 4a. In support of its indefiniteness argument, Teva offered a very short expert declaration from Dr. Khan, the substance of which was as follows:

> The term 'half-liquid' is not a term of art. It does not have an ordinary and customary

> meaning in the art of pharmaceutical formulations, including gel capsule pharmaceutical formulations for oral administration. One of ordinary skill in pharmaceutical formulations, including gel capsule pharmaceutical formulations for oral administration, would not have an understanding of the meaning of the term 'half-liquid,' absent some definition.

JA 385 at 389. Dr. Khan offered no further analysis of the patent's disclosure, its prosecution, or any other relevant literature. *See id.* Nor did he detail any investigation he may have done to arrive at his opinion, which amounts to little more than a naked conclusion of indefiniteness. *See id.*

At his deposition, Dr. Khan conceded that he had not reviewed the Italian Application despite the fact that it is included in the '390 patent's prosecution history. JA 746 at 760. Yet, when shown the Italian Application, he volunteered—unprompted—that he would understand that "semi-liquido" in Italian would mean "semi-liquid" in English. *Id.* at 761.

On June 27, 2019, the district court held a *Markman* hearing. During the *Markman* hearing, the district court expressed skepticism over whether the Italian Application could properly be considered intrinsic evidence, despite the fact that it is included in the '390 patent's prosecution history, since it is not written in English. *See, e.g.*, JA 657 at 32:12-32:15 ("[O]ne of the questions I have . . . is whether. . .the Italian priority application is actually intrinsic evidence."). The district court further explained, "[it] was thinking to [it]self, if you have to translate

something, then it seems hard . . . to believe that it's actually intrinsic evidence." *Id*. at 33:14-16.

The court invited the parties to submit supplemental briefing on the issue of whether the Italian Application should be considered intrinsic evidence. *See* JA 607, JA 657. In response, IBSA provided several examples of Federal Circuit decisions and district court decisions where translations and foreign priority applications were considered by the courts, including in the context of intrinsic evidence. *See, e.g.*, JA 650 at 2 (citing *Abbott Labs v. Sandoz, Inc.*, 566 F.3d 1282, 1289-1291 (Fed. Cir. 2009); *Pioneer Corp. v. Samsung SDI Co.*, No. 2:06-CV-384 (DF), 2007 WL 5688764 (E.D. Tex. Dec. 27, 2007). Teva identified no authority to the contrary. JA 607.

On this record, the district court held the term "half-liquid" indefinite. At the foundation of the district court's conclusion was its decision to "not give the Italian priority application, or Plaintiffs' translation of that application, ***any weight***." App. 28a (emphasis added). The district court explained 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." App. 27a n.3. The district court also reasoned that because differences existed between the Italian Application and the U.S. Application, the U.S. Application was conclusive of the inventors' intent. *See, e.g.*, App. 27a (noting differences in "words and phrases" of the '390 patent specification).

IV. The Federal Circuit's Decision

On appeal, IBSA challenged the district court's decision to subordinate the Italian Application to its U.S. counterpart. IBSA argued that "the Italian Application is the best source to understand the inventors' understanding of their invention" (App. 12a) and that the district court did not properly consider it (*see* App. 13a-14a). IBSA explained that the minor differences between the Italian and U.S. documents that convinced the district court to disregard the Italian Application were simply minor differences in syntax and word choice flowing from a translator's judgment, not evidence of some intent to convey a different meaning or claim a different invention. *See IBSA Institut Biochimique, S.A., et al. v. Teva Pharms. USA, Inc.*, 2019-2400 (Fed. Cir.) Reply Brief for Plaintiffs-Appellants at 22. IBSA pointed out that international obligations codified in U.S. statute required the court to treat the Italian Application as the equivalent of a U.S. filing and give it corresponding weight in the analysis. *See* Op. Br. at 40-41.

The Federal Circuit disagreed with IBSA and reaffirmed the district court's decision not to give the Italian Application any weight. *See* App. 13a n.1. The appeals court reasoned that differences between the Italian Application and U.S. Application indicated that the "discrepant usage of 'half-liquid' and 'semiliquido' between the '390 patent and the Italian Application [was] intentional, implying that the different word choice has a different scope." App. 13a. Additionally, the Federal Circuit held that the U.S. Application's inclusion of the new fourth embodiment within its claims confirmed that the patentees

intended the words of the U.S. Application—even those describing *other* embodiments—to mean something different than the Italian Application. *See id*. at 12a.

The Federal Circuit disagreed with IBSA that discounting the Italian Application subordinated a foreign priority application. App. 13a. The Federal Circuit again reasoned that differences between a foreign priority application and a U.S. application are clear indication of the inventors' intent. *Id*. The Federal Circuit did not address IBSA's arguments regarding the United States' international treaty.

REASONS FOR GRANTING THE PETITION

The United States has agreed to grant comity to the inventors of other nations that are signatories to the TRIPS Agreement and give weight to their foreign priority patent applications. The decision of the district court, affirmed by the Federal Circuit, violated those obligations by excising the Italian Application from its claim construction decision.

I. The United States Must Treat Foreign Inventors the Same as U.S. Inventors and Their Applications.

The United States is a member of the World Trade Organization (the "WTO") and a party to the Agreement on Trade-Related Aspects of Intellectual Property Rights (the "TRIPS Agreement"). Amendment of the TRIPS Agreement, World Trade

Organization.[3] Italy is also a member of the WTO and a party to the TRIPS Agreement. *See id*. (identifying the European Union as a member). With 140 signatories, the TRIPS Agreement is "to date the most comprehensive multilateral agreement on intellectual property." Overview: the TRIPS Agreement, World Trade Organization.[4]

In 1994, Congress enacted the TRIPS Agreement through the Uruguay Round Agreements Act. HR 5110, 103rd Congress (1994). Both the Senate and House Reports confirm the intent of Congress to bring the United States into compliance with the Uruguay Round Agreements, which included the TRIPS Agreement. *See* H.R. Rep. No. 103-826(II) at 2 (1994); S.Rep. No. 103-412 at 4-6, 10 (1994). The Uruguay Round Agreements Act was subsequently codified as 19 U.S.C. § 3511.

Article 3 of the TRIPS Agreement requires that foreign patent applicants be treated in the same manner as U.S. patent applicants, so long as the foreign patent applicant is a national of a WTO member country. TRIPS Agreement, Art. 3. (member countries "shall accord to the nationals of other Members treatment no less favourable than that it

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[3] *Amendment of the TRIPS Agreement,* World Trade Organization, https://www.wto.org/english/tratop_e/trips_e/amendment_e.htm (last visited Feb. 24, 2021).

[4] *Overview: the TRIPS Agreement*, World Trade Organization, https://www.wto.org/english/tratop_e/trips_e/intel2_e.htm (last visited Feb. 24, 2021).

accords to its own nationals with regard to the protection."). This concept is known as "national treatment." Article 3 further specifies that such protection "shall include matters affecting the availability, acquisition, scope, maintenance and enforcement of intellectual property rights as well as those matters affecting the use of intellectual property rights specifically addressed in th[e] Agreement." TRIPS Agreement, Art. 3 n.3.

In addition, the TRIPS Agreement incorporates by reference the Stockholm Act of 14 July 1967 of the Paris Convention for the Protection of Industrial Property (the "Paris Convention"). The Paris Convention—which both the United States and Italy were already a part of—similarly requires that "Nationals of any country of the Union shall, as regards the protections of industrial property, enjoy in all the other countries of the Union the advantages that their respective laws now grant . . . ." Paris Convention, Art. 2 (1967). Moreover, in the United States, it is recognized that "the purpose of the Paris Convention was to have an application made in a foreign country treated as the equivalent of a domestic filing." *Yasuko Kawai v. Metlesics*, 480 F.2d 880, 889 (C.C.P.A. 1973); *see also Bonzel v. Pfizer, Inc.*, 439 F.3d 1358, 1365 (Fed. Cir. 2006) (explaining that the Paris Convention "require[s] a nation's courts to give equal treatment to nationals of other nations. . . .").

II. The United States—through the TRIPS Agreement and Paris Convention—Is Obliged to Recognize a Foreign Priority Date for Applicants of Member Countries.

In addition to treating applicants of member countries and their applications in the same manner, the Paris Convention also grants foreign applicants a right of "priority" to a patent application filed in their home country when they later seek to file a patent application in a different WTO country. *See* Paris Convention, Art. 4 (1967). A priority date establishes the date for assessing "prior art," that forms the basis for determining patent validity. *See, e,g.*, 35 U.S.C. §§ 102, 103.

The obligation to recognize a foreign priority date is essential to establishing the rights of foreign patent applicants. Foreign inventors often file for patent protection in the United States given the strength of the United States patent system and the promise of the United States market. *See* Michael D. Bednarek, *Planning a Global Patent Strategy to Maximize Value: Where to Get the Most "Bang for Your Buck,"* 77 J. PAT. & TRADEMARK OFF. SOC'Y 381, 386 (1995). Similarly, United States inventors often seek to protect their inventions in foreign countries. However, many countries have restrictions that require inventors to first file in their home country, or in the country where the invention was made. *See* WIPO, International applications and national security

considerations.[5] Only later can the inventor applicant file abroad. The United States itself has its own such requirement, codified in 35 U.S.C. § 184.

The system established in the Paris Convention therefore provides for an efficient mechanism by which inventors can seek patent protection in multiple countries, without having to file multiple applications at the same time in order to guarantee a priority date or consider the implications of being required to first file in the inventor's home country.

In order to account for its international obligations, the United States enacted what is today 35 U.S.C. § 119. *See Yasuko Kawai v. Metlesics*, 480 F.2d 880, 883 (C.C.P.A. 1973). Pursuant to 35 U.S.C. § 119, a foreign application filed in a WTO member country becomes, in essence, the equivalent of a U.S. application and must be treated as such. *See* 35 U.S.C. § 119 (such applications "shall have the same effect as the same application would have if filed in this country on the date on which the application for patent for the same invention was first filed in such foreign country, if the application in this country is filed within 12 months from the earliest date on which such foreign application was filed."). Accordingly, commentators have observed that, under these circumstances, the foreign priority application is in fact the crucial documentation of the invention; the

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[5] *International applications and national security considerations*, World Intellectual Property Organization, https://www.wipo.int/pct/en/texts/nat_sec.html (last visited Feb. 24, 2021).

U.S. application, in contrast, is merely a translation. *See* Donald S. Chisum & Stacey J. Farmer (2009) 'Lost in Translation': The Legal Impact of Patent Translation Errors on Claim Scope. In PATENT LAW AND THEORY 289-324 (Toshiko Takenaka ed. 2008) ("With a direct filing of a non-English application, it could be argued that the foreign language application is the U.S. application and the English translation merely evidence of what the application in fact says.").

III. The District Court and Federal Circuit Improperly Subordinated the IBSA Inventors' Italian Application to Its English Translation.

This case concerns four Italian inventors who first filed a patent application in Italy. Within twelve months of the Italian priority date, the applicants filed a U.S. counterpart in English, as required under 35 U.S.C. § 119 and 37 C.F.R. § 1.55.

Other than the addition of the fourth embodiment, the substance of the Italian Application and U.S. Application are nearly identical. In each instance where the Italian Application uses the term "semi-liquido," the corresponding portion of the U.S. Application uses the term "half-liquid." The two terms are otherwise used in the exact same way to describe the exact same things. *See* App. 4a. But, an overly literal translation omitted a term having clear meaning to those in the field ("semi-liquid") and instead inserted a comparatively obscure term ("half-liquid") in its place.

This obvious mistranslation became a hook first for Teva, and then the district court and Federal

Circuit, to ignore the Italian inventors' original word choice of "semi-liquido" in the Italian Application. In doing so, the courts set aside the term the Italian applicants originally used ("semi-liquido") to describe their invention and violated their rights as foreign inventors to be afforded the same privileges as citizens of the United States filing original patent applications in English. 35 U.S.C. § 119.

The Italian Application is a critical piece of evidence for claim construction. Under the TRIPS Agreement, the Paris Convention, and United States law, the Italian Application must be treated as any other U.S. application. *See supra* §§ I; II . Moreover, as part of the prosecution history, the Italian Application is part of the intrinsic evidence—the most critical evidence in claim construction—of the '390 patent. *Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 U.S. 898, 901 (2014) (citing *United States v. Adams*, 383 U.S. 39, 48-49 (1966); *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 741 (2002)). As the originally filed description of the invention, the Italian Application was also evidence of the Italian speaking inventors' intent. *See Phillips*, 415 F.3d at 1317 (explaining that review of the prosecution history during claim construction is useful as it aids in "inform[ing] the meaning of the claim language by demonstrating how the inventor understood the invention."). Put simply, the Italian Application should be considered the true record of the inventors' invention. *See* Chisum, D., "Lost in Translation:" The Legal Impact of Patent Translation Errors on Claim Scope ("With a direct filing of a non-English application, it could be argued that the foreign language application ***is*** the U.S. application

and the English translation merely evidence of what the application in fact says.") (emphasis added). Yet the district court's decision improperly casts aside this evidence.

Underlying the district court's decision was its mistrust of the Italian Application—it was "dubious that Italian-language materials, even if part of the intrinsic record, inform a POSA's understanding of what the patent claims." App. 27a n.3. On its own, that reasoning is directly contrary to the United States' obligations under the TRIPS Agreement. *See supra* §§ I; II. Furthermore, the decision contradicts United States jurisprudence. *See, e.g.*, *Abbott Labs. v. Sandoz, Inc.*, 566 F.3d 1282, 1289-1291 (Fed. Cir. 2009) (considering foreign language priority application as "intrinsic evidence" and "evidence of the inventor's knowledge.").

The district court's inherent suspicion of foreign filings was not its only error. The court also seized on minor differences between the Italian Application and the U.S. Application. *See* App. 27a (noting differences in the "Field of the Invention" and "Prior Art" sections of the '390 patent). The culmination of these errors was the district court giving the Italian Application ***no weight*** at all. App. 28a.

On appeal, the Federal Circuit likewise contravened the United States' international obligations. It dismissed IBSA's arguments that the district court improperly failed to consider the Italian Application and likewise relied on minor differences between the Italian Application and the U.S. Application to arrive at the same sweeping conclusion: the inventors of the '390 patent must have intended their U.S. Application to claim entirely different

subject matter than their Italian Application. App. 10a-11a.

At bottom, both courts concluded that the meaning of "half-liquid" was impossible to ascertain, despite the presence in the prosecution history of an indisputably relevant priority document—the inventors' initial description of their invention in their native language—tying the meaning of "half-liquid" to a well-known and readily understood term of art. When Teva argued that the translator's choice of "half-liquid" rather than "semi-liquid" rendered "half-liquid" meaningless, IBSA rebutted this with the Italian Application. *See* App. 4a-5a. The Italian Application makes the intent of the inventors clear: they intended to claim "semi-liquid" fillings. But the lower courts rejected this undeniably relevant evidence.

The Federal Circuit's decision, taken to its logical conclusion, stands for a rule that if a patent challenger can identify ***any*** differences between a foreign and a U.S. patent application—even the most minor differences arising from a translator's judgment—then the foreign application cannot inform the analysis of the U.S. patent. Rather, the foreign application is passed over in favor of the U.S. application.

This precedent has profound consequences. In this instance, it led the courts to conclude that Teva had offered the necessary clear and convincing evidence of indefiniteness. At the same time, it robbed IBSA of the best evidence of the disputed term's commonly understood meaning, and the inventors' intent.

This practice also directly opposes U.S. law, as courts must treat foreign inventors as they do U.S. inventors, and foreign priority applications as they do U.S. applications. *See supra* §§ I; II. Certiorari is warranted to correct this error.

CONCLUSION

For the foregoing reasons, the petition for certiorari should be granted.

Respectfully submitted,

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March 1, 2021

APPENDIX

APPENDIX A — OPINION OF THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT, FILED JULY 31, 2020

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

2019-2400

IBSA INSTITUT BIOCHIMIQUE, S.A.,
ALTERGON, S.A., IBSA PHARMA INC.,

Plaintiffs-Appellants,

v.

TEVA PHARMACEUTICALS USA, INC.,

Defendant-Appellee.

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

July 31, 2020, Decided

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 U.S. Dist. LEXIS 141404, 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.

Appendix A

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 U.S. Dist. LEXIS 141404, 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 U.S. Dist. LEXIS 141404, 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. 2019 U.S. Dist. LEXIS 141404, [WL] at *4.

The district court then turned to the extrinsic evidence. The court found IBSA's extrinsic evidence "minimally probative" and "unpersuasive." 2019 U.S. Dist. LEXIS 141404, [WL] 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." 2019 U.S. Dist. LEXIS 141404, [WL] 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. 2019 U.S. Dist. LEXIS 141404, [WL] 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, 134 S. Ct. 2120, 189 L. Ed. 2d 37 (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, 116 S. Ct.

1384, 134 L. Ed. 2d 577 (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 U.S. Dist. LEXIS 141404, 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 semi-liquid, 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

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 U.S. Dist. LEXIS 141404, 2019 WL 3936656, at *4 & n.3.

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 U.S. Dist. LEXIS 141404, 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.

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

APPENDIX B — OPINION OF THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE, FILED AUGUST 20, 2019

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

Civil Action No. 1:18-cv-00555-RGA

IBSA INSTITUT BIOCHIMIQUE, S.A.,
ALTERGON, S.A., AND IBSA PHARMA INC.,

Plaintiffs,

v.

TEVA PHARMACEUTICALS USA, INC.,

Defendant.

MEMORANDUM OPINION

August 16, 2019

ANDREWS, U.S. DISTRICT JUDGE:

Presently before me is the issue of claim construction of multiple terms in U.S. Patent No. 7,723,390 ("'390 Patent"). (D.I. 70). I have considered the Parties' Joint Claim Construction Brief and supplemental submissions. (*Id.*; D.I. 97, 98). I heard oral argument on June 27, 2019. (D.I. 94 ("Tr.")).

Appendix B

I. LEGAL STANDARD

A. Claim Construction

"It is a bedrock principle of patent law that the claims of a patent define the invention to which the patentee is entitled the right to exclude." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (en banc) (citation omitted). "'[T]here is no magic formula or catechism for conducting claim construction.' Instead, the court is free to attach the appropriate weight to appropriate sources 'in light of the statutes and policies that inform patent law.'" *SoftView LLC v. Apple Inc.*, 2013 U.S. Dist. LEXIS 125893, 2013 WL 4758195, at *1 (D. Del. Sept. 4, 2013) (quoting *Phillips*, 415 F.3d at 1324) (alteration in original). When construing patent claims, a court considers the literal language of the claim, the patent specification, and the prosecution history. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 979-80 (Fed. Cir. 1995) (en banc), *aff'd*, 517 U.S. 370, 116 S. Ct. 1384, 134 L. Ed. 2d 577 (1996). Of these sources, "the specification is always highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term." *Phillips*, 415 F.3d at 1315.

"[T]he words of a claim are generally given their ordinary and customary meaning. . . . [This is] the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application." *Id.* at 1312-13. "[T]he ordinary meaning of a claim term is its meaning to [an] ordinary artisan after reading the entire

patent." *Id.* at 1321. "In some cases, the ordinary meaning of claim language as understood by a person of skill in the art may be readily apparent even to lay judges, and claim construction in such cases involves little more than the application of the widely accepted meaning of commonly understood words." *Id.* at 1314.

When a court relies solely on the intrinsic evidence—the patent claims, the specification, and the prosecution history—the court's construction is a determination of law. *See Teva Pharms. USA, Inc. v. Sandoz, Inc.*, 574 U.S. 318, 135 S. Ct. 831, 841, 190 L. Ed. 2d 719 (2015). The court may also make factual findings based on consideration of extrinsic evidence, which "consists of all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises." *Phillips*, 415 F.3d at 1317-19. Extrinsic evidence may assist the court in understanding the underlying technology, the meaning of terms to one skilled in the art, and how the invention works. *Id.* Extrinsic evidence, however, is less reliable and less useful in claim construction than the patent and its prosecution history. *Id.*

"A claim construction is persuasive, not because it follows a certain rule, but because it defines terms in the context of the whole patent." *Renishaw PLC v. Marposs Societa' per Azioni*, 158 F.3d 1243, 1250 (Fed. Cir. 1998). It follows that "a claim interpretation that would exclude the inventor's device is rarely the correct interpretation." *Osram GMBH v. Intl Trade Comm'n*, 505 F.3d 1351, 1358 (Fed. Cir. 2007) (citation omitted).

B. Indefiniteness

"[A] patent is invalid for indefiniteness if its claims, read in light of the specification delineating the patent, and the prosecution history, fail to inform, with reasonable certainty, those skilled in the art about the scope of the invention." *Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 U.S. 898, 901, 134 S. Ct. 2120, 189 L. Ed. 2d 37 (2014); *see also* 35 U.S.C. § 112 ("The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the inventor ... regards as the invention."). A patent claim is sufficiently definite if it is "precise enough to afford clear notice of what is claimed, thereby apprising the public of what is still open to them." *Nautilus*, 572 U.S. at 909 (cleaned up).

"Indefiniteness is a question of law" to which the general principles of claim construction apply. *Eli Lilly & Co. v. Teva Parenteral Meds., Inc.*, 845 F.3d 1357, 1370 (Fed. Cir. 2017). A claim term "is indefinite if its language 'might mean several different things and no informed and confident choice is available among the contending definitions.'" *Media Rights Techs., Inc. v. Capital One Fin. Corp.*, 800 F.3d 1366, 1371 (Fed Cir. 2015) (quoting *Nautilus*, 572 U.S. at 911 n.8).

II. BACKGROUND

The patent-in-suit relates generally to pharmaceutical compositions for thyroid hormones. ('390 Patent at 1:6-7). The patent descends from an Italian priority application. (*See* D.I. 71-1, Exh. O (Italian application); *see also* D.I. 71-1, Exh. P (February 11, 2019 translation of Italian application)).

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The specification discusses only the T3 and T4 thyroid hormones. (*See* '390 Patent at 1:11-16). The body also produces Ti and T2 thyroid hormones. (Tr. at 13:15-20). The numbers (one through four) refer to the number of iodine atoms attached to the base molecule, thyronine. (*Id.*).

The Parties dispute the proper construction of terms in claims 1, 7, and 8:

> 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.

> 7. The pharmaceutical composition according to claim 1, having an *outer coating which simplifies ingestion*.
>
> 8. The pharmaceutical composition according to claim 1, wherein the material of *the capsule contents or the swallowable uniform soft-gel matrix includes a plasticizer to control its hardness*.

('390 Patent, claims 1, 7, 8 (disputed terms italicized)).

III. CONSTRUCTION OF DISPUTED TERMS

1. "thyroid hormones or their [sodium] salts"

a. Plaintiffs' proposed construction:

> Plain and ordinary meaning: "one or more thyroid hormones or their [sodium] salts"

b. Defendant's proposed construction:

> Plain and ordinary meaning: multiple thyroid hormones or sodium salts of multiple thyroid hormones

c. Court's construction:

> "one or more thyroid hormones or their [sodium] salts"

The Parties agree that this claim covers compositions that contain more than one type of thyroid hormone.[1] (*See* D.I. 70 at 3-20). They disagree, however, whether the claim covers compositions that contain only one type of thyroid hormone. (*Id.*).

Defendant argues that "hormones," a plural noun, necessarily means that the claim requires more that one type of hormone. (*Id.* at 5). Thus, it argues, the plain and ordinary meaning is "beyond dispute" and controls the outcome of this claim construction. (*Id.*). I disagree.

The meaning of hormones, in the context of the claim alone, is not so clear. First, if the term is construed only with reference to the language of the claim, there is nothing to indicate to a POSA that the applicant meant multiple types of hormones as opposed to multiple hormone molecules. The Parties do not dispute that, in the overall context of the Patent, the claim is clearly referring to types of hormones. (Tr. at 13:2-6). That understanding, however, is not ascertainable merely by reading the claim. Second, although a plural noun is often used to refer to more than one thing, the plural is also used to capture the singular in everyday speech. To use a modified example of what I suggested during oral argument, when driving through Montana, I have seen signs saying, "Beware of rattlesnakes." (*See id.* at 16:22-17:9). When I saw this, I understood that a single rattlesnake was something to be wary of. The plural is used to capture the singular. Another

1. The analysis for "hormones" and "their [sodium] salts" is the same. Thus, while I discuss only hormones, the conclusions I reach apply equally to both terms.

example (this time adopting the golf theme presented by Defendant during argument), on a golf course there are often signs that say something to the effect of, "Watch for flying golf balls." That sign, of course, means to watch for one or more flying balls—it is using the plural to capture the singular. Thus, I find that the meaning of "hormones" is not readily determined from the claim alone.

Plaintiffs argue that the specification would indicate to a POSA that, in the context of the '390 Patent, "hormones" means one or more. (D.I. 70 at 3-5; 12-17). They support their position by citing multiple instances in the specification where the applicant described his invention as containing, "thyroid hormones, in particular T3 and/or T4." (*Id.*; *see also* '390 Patent at 2:57-63, 4:7-9, 6:13-18, 9:21-27). They also point out that Defendant's construction requires an undisclosed additional thyroid hormone and reads out most of the embodiments described in the specification:

> The '390 patent contains 36 example compositions, but not a single example composition contains T3 or T4 combined with another hormone. Five of the 36 example compositions contain T3 and T4, while the other 31 example compositions contain either T3 or T4, mirroring the "T3 and/or T4" language from the specification. In fact, no other thyroid hormone is mentioned anywhere in the specification.

(D.I. 70 at 12 (citation omitted)). Defendant responds that the "and/or" language of the specification, and the

absence of any embodiment with a hormone other than T3 or T4, does not indicate that a third hormone cannot be present in the composition. (*Id.* at 7-10). At argument, however, Defendant was unable articulate a reason why, based on the disclosure in the specification, the applicant would have claimed compositions that contain only more than one hormone. (Tr. at 14:13-16:9).

I do not find Defendant's position persuasive. It is not reasonable to construe "hormones" as excluding the majority of embodiments of the invention. Nor is it reasonable to read the claims as requiring an undisclosed third hormone when just one of the disclosed hormones is present in the composition. Thus, I find that a POSA reading the specification would conclude, based on the examples in the specification and the repeated use of "thyroid hormones, in particular T3 and/or T4," that "hormones" in the claim refers to one or more hormones.[2]

---

2. Other courts have construed plural nouns as encompassing the singular when, in the context of the patent, such a construction was appropriate. *See, e.g., Yodlee, Inc. v. Plaid Techs., Inc.*, 2016 U.S. Dist. LEXIS 5603, 2016 WL 204372, at *6 (D. Del. Jan. 15, 2016) (construing "list of addresses" as covering a list with just one address); *Flash Seats, LLC v. Paciolan, Inc.*, 2010 U.S. Dist. LEXIS 4181, 2010 WL 184080, at *8-9 (D. Del. Jan. 19, 2010) (construing "asks" as "one or more asks"); *see also Versa Corp. v. Ag-Bag Int'l Ltd.*, 392 F.3d 1325, 1330 (Fed. Cir. 2004) ("[I]n context, the plural can describe a universe ranging from one to some higher number, rather than requiring more than one item."). This indicates that there is no one correct method of claiming a singular. Thus, I do not find Defendant's argument that "a" or "an" is understood in patent law to mean "one or more" to be probative of the proper construction of this claim term. (*See* D.I. 70 at 11). The fact that other patents may use "a" or "an" to communicate "one or more" is not a proper consideration for construing "hormones" in the context of the '390 Patent.

Accordingly, I will construe "thyroid hormones or their [sodium] salts" as "one or more thyroid hormones or their [sodium] salts."

2. "half-liquid"

a. Plaintiffs' proposed construction:

Plain and ordinary meaning: semiliquid, i.e., having a thick consistency between solid and liquid

b. Defendant's proposed construction:

Indefinite.

Alternatively, "a non-solid, non-paste, non-gel, non-slurry substance"

c. Court's construction:

Indefinite.

The Parties agree that the intrinsic record does not define "half-liquid." (D.I. 70 at 24). They disagree, however, whether the term is amenable to construction.

Plaintiffs argue for a "plain and ordinary meaning" construction based on their position that "half-liquid" is synonymous with "semi-liquid." (*Id.* at 21-24). The intrinsic record does not, however, support such an understanding. Plaintiffs argue that a POSA would understand that the

two terms are synonymous based on (1) the Italian priority application's use of "semiliquido," (2) the '390 Patent's specification's use of "half-liquid" in a manner that is consistent with a POSA's understanding of "semi-liquid," and (3) uses of the term "half-liquid" in extrinsic evidence.

The Italian priority application is minimally probative of the meaning of half-liquid. Plaintiffs argue that a POSA would understand, based on the Italian priority application's use of "semiliquido," that half-liquid means semi-liquid.[3] (*Id.* at 21; *see also* D.I. 71-1, Exh. O at IBSATIR-00000576, -579-81). To support their argument, Plaintiffs rely on extrinsic evidence, that is, they commissioned a professional translation of the priority application. (*See* D.I. 71-1, Exh. P (2019 English translation of Italian priority application)). Plaintiffs' retranslation of the Italian priority application is not, however, good evidence of what the applicant meant by "semiliquido." A comparison of Plaintiffs' translation of the Italian application's "Field of Invention" and "Prior Art" sections against those portions of the '390 Patent's specification quickly reveals that the applicant and the translator regularly interpret words and phrases differently. (*Compare* '390 Patent at 1:6-4:51, *with* D.I.71-1, Exh. P at 2-11). The inconsistency between the two translations is likely because translation requires the translator to use judgment. I must assume the applicant used his judgment, and knew what he meant to communicate, when

3. I am quite sure that, for purposes of claim construction, a POSA is not required to be fluent in Italian, and thus I am dubious that Italian-language materials, even if part of the intrinsic record, inform a POSA's understanding of what the patent claims.

he translated the Italian priority application into English for the purpose of filing a U.S. patent application. That translation is significantly more probative of what the applicant meant than a litigation-inspired translation done in 2019. The best evidence of what the applicant meant are the words he chose. Thus, I do not give the Italian priority application, or Plaintiffs' translation of that application, any weight in claim construction.

The specification's use of "half-liquid" similarly does not support redefining that term as semi-liquid. Plaintiffs argue that the applicant's citation to pharmaceutical references that use the term "semi-liquid" means he understood half-liquid as meaning semi-liquid. (D.I. 70 at 21-23). I do not agree with Plaintiffs' conclusion. It seems more likely to me that the applicant's citation to references that use the term "semi-liquid," coupled with his choice to use the term "half-liquid," indicates that he was aware of the term of art and chose not to use it.

The prosecution history provides additional support for the conclusion that the applicant understood "semi-liquid" and "half-liquid" to have different scopes. During prosecution, the applicant proposed a set of claims that included the term "semi-liquid":

> 20. (New) Pharmaceutical composition comprising thyroid hormones or their salts in soft elastic capsules consisting of a shell of gelatin material and containing a liquid or *half-liquid* inner phase or in swallowable uniform soft-gel matrices of gelatin, wherein the

> inner phase of the soft elastic capsule and the swallowable uniform soft-gel matrix comprise ethanol, glycerol, or mixtures thereof.
>
> . . .
>
> 24. (New) The composition according to claim 20, wherein soft elastic capsule includes an inner phase consisting of a paste or a gel comprising gelatin and a liquid or *semi-liquid* vehicle consisting of ethanol, glycerol or a mixture thereof.

('390 Patent File History: Response to Office Action (April 12, 2005) at 3 (D.I. 71-1, Exh. C at IBSATIR-00000776) (emphasis added); *see also* '390 Patent File History: Examiner's Amendment (Jan. 12, 2010) at 3 (D.I. 71-1, Exh. N at IBSATIR-00001016 (allowing original claim 20 to issue as claim 1))). The applicant later amended the application to remove proposed claim 24.[4] ('390 Patent File History: Response to Office Action (Oct. 26, 2006) at 3 (D.I. 71-1, Exh. E at IBSATIR-00000838)). I view this prosecution history as evidence that the applicant did not mean "semi-liquid" when he used the term "half-liquid." He was clearly aware of the term and could easily have used "semi-liquid" in claim 1, the independent claim.

4. Had proposed claim 24 issued, guiding principles of claim construction would have strongly favored "half-liquid" and "semi-liquid" having distinct meanings. *See Amgen Inc. v. Sandoz Inc.*, 923 F.3d 1023, 1031 (Fed. Cir. 2019) ("[D]ifferent claim terms are presumed to have different meanings." (quoting *Helmsderfer v. Bobrick Washroom Equip., Inc.*, 527 F.3d 1379, 1382 (Fed. Cir. 2008)).

He, however, chose not to. He chose to eliminate "semi-liquid" from the claims entirely. Thus, the specification and prosecution history indicate the opposite of Plaintiffs' proposition. Far from showing that the applicant understood the two terms as synonymous, the record indicate that the applicant knew the term "semi-liquid" and intentionally chose not to use it.

The extrinsic evidence identified by Plaintiffs is minimally probative and unpersuasive. Plaintiffs look first to an 1896 definition of "semiliquid" to support their argument that "half-liquid" is a synonym. (D.I. 70 at 30-31). A late 19th-century edition of Webster's International Dictionary defines "semiliquid" as "half liquid; semifluid." (D.I. 71-1, Exh. HH at 1308). I do not find this evidence persuasive as to the meaning of "half-liquid" in the context of the '390 Patent. The purpose of claim construction is to determine the meaning of claim terms to a POSA at the time of the invention. It is important to focus on language at the time of invention because language evolves over time. Thus, a dictionary entry from more than a century prior to the relevant date, defining a term other than the claim term, carries essentially no weight in determining the meaning of the term.

Plaintiffs further point to a handful of patents as support for their argument that a POSA understands the term "half-liquid." They argue, "The cited patents use the term 'half-liquid' without providing any express definition, refuting [Defendant's expert's] claim that one would have been necessary to understand it." (D.I. 70 at 29). I do not find this argument persuasive. The extrinsic

patents identified by Plaintiff are not persuasive evidence of what "half-liquid" means in the context of the '390 Patent. The four pre-priority date patents identified by Plaintiff each describe pharmaceutical compositions in "half-liquid bases." (*See* D.I. 71-1, Exh. Z at 8-9 (Plaintiffs expert's summary of the patents; D.I. 71-1 Exhs. AA-DD (patents identified by Plaintiff)). Notably, the '390 Patent does not mention a "half-liquid base." Plaintiff, however, does not address that issue. It is my opinion that, if a term was not used in the art outside of patents and was used in patents only in combination with another term, it is exceedingly unlikely that the term was a term of art at the relevant date.

Plaintiffs also look to their expert for support of their position that "half-liquid" is a term of art meaning "semi-liquid." (*Id.* at 29-30). Plaintiffs' expert's opinion is, however, drawn exclusively from his review of the patents and dictionary definition that I discuss above. (*See* D.I. 71-1, Exh. Z at ¶¶19-22). He admitted during his deposition that he is not aware of any other support in the art for understanding "half-liquid" to mean "semi-liquid." (D.I. 86 at 164:11-165:12). Thus, as I do not find the sources that Plaintiffs' expert relies on to be anything more than unconvincing data points, I do not give his opinion on this matter any weight.[5]

5. Plaintiffs' expert's declaration is, of course, extrinsic evidence. In essence, the expert's ultimate opinion about the meaning of "half-liquid" is a legal opinion, which is outside his area of expertise. That is why expert opinions on claim construction are usually worthless.

In sum, the intrinsic record indicates that the applicant knowingly chose not to use the term "semi-liquid" and the extrinsic record provides no support for a conclusion that the term "half-liquid" is identical in scope to "semi-liquid." Thus, I will not adopt Plaintiffs' position that "half-liquid" means "semi-liquid."

As the record does not support construing "half-liquid" to mean "semi-liquid," I must consider whether the record discloses a reasonably certain meaning for "half-liquid."

I start with the language of the claim itself. From the claim, a POSA would understand that "half-liquid" does not mean liquid. (*See* '390 Patent, claim 1 (claiming a "a liquid *or* half-liquid inner phase" (emphasis added)). A POSA would also understand, based on the applicant's use of the word "liquid," that a half-liquid is not a solid. It is not clear from the claims, however, what manner of substance qualifies as a half-liquid.

I next look to the specification for guidance on the meaning of "half-liquid." The '390 Patent specification includes "half-liquid" in a list that includes pastes and gels. ('390 Patent at 7:65-8:2 ("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."). A POSA would understand that this language is meant to indicate that a half-liquid is not, or at least is not necessarily, a gel or a paste. A half-liquid

is some category of matter that is not identical to those that may be classified as gel or paste.

The prosecution history is the final piece of intrinsic evidence that I consider when construing a claim term. During the '390 Patent's prosecution, the applicant distinguished at least one type of gel and one type of slurry from the claimed "half-liquid." To overcome an obviousness rejection, the applicant stated that the invention claimed in the '390 Patent "is not a ***macromolecular*** gel-***lattice*** matrix." ('390 Patent File History: Response to Office Action (April 23, 2008) at 4-5 (D.I. 71-1, Exh. I at IBSATIR-00000938-39) (emphasis in original)). In response to another obviousness rejection, the applicant clarified that a liquid or half-liquid is not a "high concentration slurry." ('390 Patent File History: Response to Office Action (Nov. 19, 2008) at 6 (D.I. 71-1, Exh. K at IBSATIR-00000964)). The full scope of the applicant's disclaimers is not clear from my review of the intrinsic record, but it is clear that the applicant disclaimed some portion of the claim's scope that might otherwise qualify as a half-liquid.

Turning now to extrinsic evidence of the meaning of "half-liquid," the record reflects that the Parties' experts do not know what manner of substance meets the half-liquid limitation of the claim. When asked how a person could know that something is not a half-liquid inner phase, Plaintiffs' expert responded that he didn't know. (D.I. 86 at 50:7-14). He also testified that some slurries and some gels may be half-liquid but could not articulate a boundary. (*Id.* at 99:4-18; 123:16-124:4; 129:10-130:2). In his declaration,

Plaintiffs' expert notes that the distinction between the disclaimed macromolecular gel-lattice matrices and high concentration slurries is nuanced. (D.I. 71-1, Exh. Z at ¶ 25). He does not, however, attempt to characterize which substances are half-liquid. (*See id.*).

Defendant's expert's strikingly short declaration states that "half-liquid" does not have a meaning in the art and that the specification does not clarify the term's meaning. (D.I. 71-1, Exh. Y at ¶¶ 18-20). Although his declaration is brief, I do credit Defendant's expert's testimony as he has a great deal of relevant personal experience and education in pharmaceuticals. (*Id.* at ¶¶ 2-8). On balance, considering Plaintiffs' expert's difficulty articulating the boundaries of "half-liquid," I think that, almost by default, Defendant's expert's opinion that half-liquid is not a well-known term in the art must be right.

Taken together, the record is unclear on the meaning of "half-liquid." The intrinsic record teaches us a few things that are not a half-liquid by outlining some of the boundaries of the claim term. The intrinsic and extrinsic records are, however, devoid of any indication of what defines a half-liquid. There is nothing to put a POSA on notice of what a half-liquid is. This 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. Thus, I find that "half-liquid" is indefinite as a matter of law.

3. "uniform soft-gel matrix"

a. Plaintiffs ' proposed construction:

Plain and ordinary meaning: "homogeneous soft-gel matrix"

b. Defendant's proposed construction:

"composition containing active drug particles uniformly dispersed in an unencapsulated gel matrix"

c. Court's construction:

"composition containing active drug particles uniformly dispersed in a single phase with no outer shell that can be distinguished from the bulk of the soft-gel matrix, except for external additive layers like enteric layers or layers facilitating swallowing"

The Parties' dispute on this term is the narrow question of how to properly capture the language used by the applicant in the specification and prosecution history. The Parties agree uniform means uniformly dispersed. (Tr. at 68:13-21). The Parties also agree that external additive layers, like enteric layers or layers to facilitate swallowing, fall within the scope of the term. (*See* Tr. at 79:12-18, 80:11-14). They further agree that the outer layer must have a reason for being there—a defined purpose consistent with the purposes described in the specification. (*See id.* at 77:4-9, 79:4-8).

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The intrinsic record provides two indications of the meaning of "uniform soft-gel matrix." First, the specification describes "uniform soft-gel matrix" as "constituted of a single phase and . . . not provided (except for putative external additive layers like enteric layers or layers facilitating the swallowing) with an outer shell which could be distinguished from the bulk of the soft-gel matrix." ('390 Patent at 9:28-32). Second, to overcome an obviousness rejection during the prosecution of the Patent, the applicant explained that the "uniform soft-gel matrix" embodiment:

> is made up of a single, uniform, gelatinous phase. Thus, in [the] embodiment . . . there is neither a discernible capsule filling as such (as in Veronesi [U.S. Patent No. 5,814,338]), nor an "outer" gelatine layer or an "inner" silicon layer (see claim 1 of Veronesi). Stated in other words, a Veronesi-type multilayer texture is clearly excluded by the very wording "uniform softgel matrix" which appears in claim 1.

('390 Patent File History: Response to Office Action (Oct. 26, 2006) at 5 (D.I. 71-1, Exh. E at IBSATIR-00000840)). Together, the intrinsic record indicates that the distinction between a soft-gel capsule and a soft-gel matrix with an additive layer is the nature of the outer coating. A capsule is filled with the active drug while an additive layer is applied to a fully formed soft-gel matrix. Whether something is a capsule versus an additive layer is, however, a factual question that a POSA can opine on.

The specification clearly sets out what the applicant meant by "uniform soft-gel matrix." The prosecution history does not clearly change or add to that meaning. Thus, I will construe "uniform soft-gel matrix" according to the specification as "composition containing active drug particles uniformly dispersed in a single phase with no outer shell that can be distinguished from the bulk of the soft-gel matrix, except for external additive layers like enteric layers or layers facilitating swallowing"

4. "outer coating which simplifies ingestion"

a. Plaintiffs' proposed construction:

No construction necessary.

b. Defendant 's proposed construction:

"additional outer layer that reduces the friction between the capsule and the patient's esophagus"

c. Court 's construction:

None.

"[T]here no real dispute as to the scope of this claim." (D.I. 70 at 50). It is not clear how the Parties understanding of the term differs, if at all. The Parties only clear dispute is whether "outer coating which simplifies ingestion" should be construed. I find that no construction is necessary.

The plain language of the claim does not lend itself to Defendant's construction. That is, it is not clear that "simplifies ingestion" should be limited to a reduction in friction between the capsule and a patient's esophagus. It is also not clear that "outer coating" requires something "additional" to the outer surface of the capsule described in claim 1.

The specification describes one purpose of an "outer layer," but that description is not lexicography for the term "outer coating." The detailed description of the invention explains:

> Besides (or instead of) possible enteric layers, the capsules or swallowable uniform soft-gel matrices according to the present invention can also be provided with additional outer layers which simplify ingestion, i.e. consisting of excipients which reduce the friction between the capsule and the patient's esophagus.

('390 Patent at 6:49-55). Defendant argues that its construction merely copies the specification's discussion of "layers which simplify ingestion" to clarify an otherwise ambiguous claim term. (D.I. 70 at 48). I do not find Defendant's argument persuasive. It is true that the use of an "i.e." phrase can be strong evidence of an applicant's characterization or definition of her invention. *See SkinMedica, Inc. v. Histogen Inc.*, 727 F.3d 1187, 1200 (Fed. Cir. 2013) ("[A] patentee's use of 'i.e.' signals an intent to define the word to which it refers." (citation omitted)). Where, as here, the applicant uses "i.e." to define

a different term than the one that appears in the claim, the importance of such definitional language is less clear. It is not clear from this passage that the applicant meant to disclaim all ingestion-assisting *coatings* (as opposed to *layers*) other than those that help with swallowing. Thus, I will not construe this term as limited in that way. Instead, I find that no construction of this term is necessary.

5. "the capsule contents or the swallowable uniform soft-gel matrix includes a plasticizer to control its hardness"

a. Plaintiffs' proposed construction:

No construction necessary.

b. Defendant's proposed construction:

Indefinite.

c. Court's construction:

Plain and ordinary meaning.

Defendant argues that this term is indefinite. The crux of its argument is this: "It is unclear how a liquid or half-liquid can be 'hard,' how someone can 'control [the] hardness' of a liquid or half-liquid, or how someone would test to determine if they are 'control[ling] [the] hardness' of a liquid or half-liquid." (D.I. 70 at 52 (alterations in original)). Defendant does note, citing Wikipedia, that "hardness" in the context of a liquid typically relates to

mineral content. (*Id.* at 56). Defendant does not, however, cite any expert testimony or reliable evidence to support its position that hardness has no other meaning or couldn't mean mineral content in the context of the claim. (*See* Tr. at 98:6-15 (explaining that Defendant's expert did not address "hardness")). Defendant's position, appealing to "common sense," does not meet the clear and convincing evidence standard for finding indefiniteness.

As neither Party proposes a construction for this term, I will construe it as having its plain and ordinary meaning. I express no opinion at this time on whether the plain and ordinary meaning makes logical sense in the context of this patent.

IV. CONCLUSION

Within five days the parties shall submit a proposed order consistent with this Memorandum Opinion.

APPENDIX C — DENIAL OF REHEARING OF THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT, FILED OCTOBER 2, 2020

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

2019-2400

IBSA INSTITUT BIOCHIMIQUE, S.A.,
ALTERGON, S.A., IBSA PHARMA INC.,

Plaintiffs-Appellants,

v.

TEVA PHARMACEUTICALS USA, INC.,

Defendant-Appellee.

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

ON PETITION FOR PANEL REHEARING AND REHEARING *EN BANC*

Before Prost, *Chief Judge*, Newman, Lourie, Dyk, Moore, O'Malley, Reyna, Wallach, Taranto, Chen, Hughes, and Stoll, *Circuit Judges*.

Per Curiam.

Appendix C

ORDER

Appellants Altergon, S.A., IBSA Institut Biochimique, S.A. and IBSA Pharma Inc. filed a combined petition for panel rehearing and rehearing *en banc*. The petition was referred to the panel that heard the appeal, and thereafter the petition for rehearing *en banc* was referred to the circuit judges who are in regular active service.

Upon consideration thereof,

It Is Ordered That:

The petition for panel rehearing is denied.

The petition for rehearing *en banc* is denied.

The mandate of the court will issue on October 9, 2020.

For the Court

October 2, 2020
Date

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

APPENDIX D — TREATY AND STATUTORY PROVISIONS

Stockholm Act of the Paris Convention of 14 July 1967

Article 2

[National Treatment for Nationals of Countries of the Union]

(1) Nationals of any country of the Union shall, as regards the protection of industrial property, enjoy in all the other countries of the Union the advantages that their respective laws now grant, or may hereafter grant, to nationals; all without prejudice to the rights specially provided for by this Convention. Consequently, they shall have the same protection as the latter, and the same legal remedy against any infringement of their rights, provided that the conditions and formalities imposed upon nationals are complied with.

(2) However, no requirement as to domicile or establishment in the country where protection is claimed may be imposed upon nationals of countries of the Union for the enjoyment of any industrial property rights.

(3) The provisions of the laws of each of the countries of the Union relating to judicial and administrative procedure and to jurisdiction, and to the designation of an address for service or the appointment of an agent, which may be required by the laws on industrial property are expressly reserved.

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Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C

Article 3

National Treatment

1. Each Member shall accord to the nationals of other Members treatment no less favourable than that it accords to its own nationals with regard to the protection[3] of intellectual property, subject to the exceptions already provided in, respectively, the Paris Convention (1967), the Berne Convention (1971), the Rome Convention or the Treaty on Intellectual Property in Respect of Integrated Circuits. In respect of performers, producers of phonograms and broadcasting organizations, this obligation only applies in respect of the rights provided under this Agreement. Any Member availing itself of the possibilities provided in Article 6 of the Berne Convention (1971) or paragraph 1(b) of Article 16 of the Rome Convention shall make a notification as foreseen in those provisions to the Council for TRIPS.

2. Members may avail themselves of the exceptions permitted under paragraph 1 in relation to judicial and administrative procedures, including the designation of an address for service or the appointment of an agent

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3. For the purposes of Articles 3 and 4, "protection" shall include matters affecting the availability, acquisition, scope, maintenance and enforcement of intellectual property rights as well as those matters affecting the use of intellectual property rights specifically addressed in this Agreement.

within the jurisdiction of a Member, only where such exceptions are necessary to secure compliance with laws and regulations which are not inconsistent with the provisions of this Agreement and where such practices are not applied in a manner which would constitute a disguised restriction on trade.

Appendix D

19 U.S.C.A. § 3511

§ 3511. Approval and entry into force of Uruguay Round Agreements

(a) Approval of agreements and statement of administrative action

Pursuant to section 2903 of this title and section 2191 of this title, the Congress approves--

> **(1)** the trade agreements described in subsection (d) resulting from the Uruguay Round of multilateral trade negotiations under the auspices of the General Agreement on Tariffs and Trade, entered into on April 15, 1994, and submitted to the Congress on September 27, 1994; and
>
> **(2)** the statement of administrative action proposed to implement the agreements that was submitted to the Congress on September 27, 1994.

(b) Entry into force

At such time as the President determines that a sufficient number of foreign countries are accepting the obligations of the Uruguay Round Agreements, in accordance with article XIV of the WTO Agreement, to ensure the effective operation of, and adequate benefits for the United States under, those Agreements, the President may accept the

Uruguay Round Agreements and implement article VIII of the WTO Agreement.

(c) Authorization of appropriations

There are authorized to be appropriated annually such sums as may be necessary for the payment by the United States of its share of the expenses of the WTO.

(d) Trade agreements to which this Act applies

Subsection (a) applies to the WTO Agreement and to the following agreements annexed to that Agreement:

(1) The General Agreement on Tariffs and Trade 1994.

(2) The Agreement on Agriculture.

(3) The Agreement on the Application of Sanitary and Phytosanitary Measures.

(4) The Agreement on Textiles and Clothing.

(5) The Agreement on Technical Barriers to Trade.

(6) The Agreement on Trade-Related Investment Measures.

(7) The Agreement on Implementation of Article VI of the General Agreement on Tariffs and Trade 1994.

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(8) The Agreement on Implementation of Article VII of the General Agreement on Tariffs and Trade 1994.

(9) The Agreement on Preshipment Inspection.

(10) The Agreement on Rules of Origin.

(11) The Agreement on Import Licensing Procedures.

(12) The Agreement on Subsidies and Countervailing Measures.

(13) The Agreement on Safeguards.

(14) The General Agreement on Trade in Services.

(15) The Agreement on Trade-Related Aspects of Intellectual Property Rights.

(16) The Understanding on Rules and Procedures Governing the Settlement of Disputes.

(17) The Agreement on Government Procurement.

(18) The International Bovine Meat Agreement.

Appendix D

EXECUTIVE ORDERS

EXECUTIVE ORDER NO. 13042

<Apr. 9, 1997, 62 F.R. 18017>

Implementing for the United States Article VIII of the Agreement Establishing the World Trade Organization Concerning Legal Capacity and Privileges and Immunities

By the authority vested in me as President by the Constitution and the laws of the United States of America, including section 101(b) of the Uruguay Round Agreements Act (Public Law 103-465) [this section] and section 1 of the International Organizations Immunities Act (22 U.S.C. 288), I hereby implement for the United States the provisions of Article VIII of the Agreement Establishing the World Trade Organization.

Section 1. The provisions of the Convention on the Privileges and Immunities of the Specialized Agencies (U.N. General Assembly Resolution 179 (II) of November 21, 1947, 33 U.N.T.S. 261) shall apply to the World Trade Organization, its officials, and the representatives of its members, provided: (1) sections 19(b) and 15, regarding immunity from taxation, and sections13(d) and section 20, regarding immunity from national service obligations, shall not apply to U.S. nationals and aliens admitted for permanent residence; (2) with respect to section 13(d) and section 19(c), regarding exemption from immigration restrictions and alien registration requirements, World

Trade Organization officials and representatives of its members shall be entitled to the same, and no greater, privileges, exemptions, and immunities as are accorded under similar circumstances to officers and employees of foreign governments, and members of their families; (3) with respect to section 9(a) regarding exemption from taxation, such exemption shall not extend to taxes levied on real property, or that portion of real property, which is not used for the purposes of the World Trade Organization. The leasing or renting by the World Trade Organization of its property to another entity or person to generate revenue shall not be considered a use for the purposes of the World Trade Organization. Whether property or portions thereof are used for the purposes of the World Trade Organization shall be determined within the sole discretion of the Secretary of State or the Secretary's designee; (4) with respect to section 25(2)(II) regarding approval of orders to leave the United States, "Foreign Minister" shall mean the Secretary of State or the Secretary's designee.

Sec. 2. In addition and without impairment to the protections extended above, having found that the World Trade Organization is a public international organization in which the United States participates within the meaning of the International Organizations Immunities Act, I hereby designate the World Trade Organization as a public international organization entitled to enjoy the privileges, exemptions, and immunities conferred by that Act, except that section 6 of that Act [section 288c of Title 22, Foreign Relations and Intercourse], providing exemption from property tax imposed by, or under the

authority of, any Act of Congress, shall not extend to taxes levied on property, or that portion of property, that is not used for the purposes of the World Trade Organization. The leasing or renting by the World Trade Organization of its property to another entity or person to generate revenue shall not be considered a use for the purposes of the World Trade Organization. Whether property or portions thereof are used for the purposes of the World Trade Organization shall be determined within the sole discretion of the Secretary of State or the Secretary's designee. This designation is not intended to abridge in any respect privileges, exemptions, or immunities that the World Trade Organization otherwise enjoys or may acquire by international agreements or by congressional action.

WILLIAM J. CLINTON

THE WHITE HOUSE,

April 9, 1997.

Appendix D

PROCLAMATIONS

PROCLAMATION NO. 6763

<Dec. 23, 1994, 60 F.R. 1007, as amended by Proc. No. 6780, Mar. 23, 1995, 60 F.R. 15849; Proc. No. 6857, Dec. 11, 1995, 60 F.R. 64817; Proc. No. 6948, Oct. 29, 1996, 61 F.R. 56385>

To Implement the Trade Agreements Resulting from the Uruguay Round of Multilateral Trade Negotiations, and for Other Purposes

1. On April 15, 1994, the President entered into trade agreements resulting from the Uruguay Round of miltilateral trade negotiations ("the Uruguay Round Agreements"). In section 101(a) of the Uruguay Round Agreements Act ("the URAA") (Public Law 103-465; 108 Stat. 4809) [subsec. (a) of this section], the Congress approved the Uruguay Round Agreements listed in section 101(d) of that Act [subsec. (d) of this section].

2. (a) Sections 1102(a) and (e) of the Omnibus Trade and Competitiveness Act of 1988, as amended ("the 1988 Act") (19 U.S.C. 2902(a) and (e)), authorize the President to proclaim such modification or continuance of any existing duty, such continuance of existing duty-free or excise treatment, or such additional duties, as he determines to be required or appropriate to carry out any trade agreements entered into under those sections.

(b) Accordingly, I have determined that it is required or appropriate in order to carry out the Uruguay Round

Agreements, which were entered into under sections 1102(a) and (e) of the 1988 Act (19 U.S.C. 2902(a) and (e)), that I proclaim the modifications and continuances of existing duties, duty-free treatments, excise treatments, and additional duties set forth in the Annex to this proclamation.

3. (a) Section 111(a) of the URAA [section 3521(a) of this title] authorizes the President to proclaim such other modification of any duty, such other staged rate reduction, or such other additional duties beyond those authorized by section 1102 of the 1988 Act (19 U.S.C. 2902) as the President determines to be necessary or appropriate to carry out Schedule XX--United States of America, annexed to the Marrakesh Protocol to the General Agreement on Tariffs and Trade 1994 ("Schedule XX").

(b) Accordingly, I have determined that it is necessary or appropriate to carry out Schedule XX to proclaim such other modifications of duties, such other staged rate reductions, and such other additional duties, beyond those authorized by section 1102 of the 1988 Act (19 U.S.C. 2902), as are set forth in the Annex to this proclamation.

4. Section 111(d) of the URAA [section 3521(d) of this title] requires the President to proclaim the rate of duty set forth in Column B of the table set forth in that section as the column 2 rate of duty for the subheading of the Harmonized Tariff Schedule of the United States ("HTS") that corresponds to the subheading in Schedule XX listed in Column A.

5. (a) Section 22(f) of the Agricultural Adjustment Act ("the Adjustment Act") (7 U.S.C. 624(f)), as amended by section 401(a) (1) of the URAA, provides that, as of the date of entry into force of the Agreement Establishing the World Trade Organization ("the WTO Agreement"), no quantitative limitation or fee shall be imposed under that section with respect to any article that is the product of a World Trade Organization member, as defined in section 2(10) of the URAA [section 3501(10) of this title].

(b) Section 401(a)(2) of the URAA [set out as a note under section 624 of Title 7, Agriculture] further provides that, with respect to wheat, amended section 22(f) of the Adjustment Act (7 U.S.C. 624(f)) shall be effective on the later of the date of entry into force of the WTO Agreement or September 12, 1995.

(c) Accordingly, I have decided that it is necessary to provide for the termination of all quantitative limitations and fees previously proclaimed under section 22 of the Adjustment Act (7 U.S.C. 624), other than those for wheat, as provided in the Annex to this proclamation.

6. (a) Section 404(a) of the URAA [section 3601(a) of this title] directs the President to take such action as may be necessary in implementing the tariff-rate quotas set out in Schedule XX to ensure that imports of agricultural products do not disrupt the orderly marketing of commodities in the United States.

(b) Section 404(d)(3) of the URAA [section 3601(d)(3) of this title] authorizes the President to allocate the in-quota

quantity of a tariff-rate quota for any agricultural product among supplying countries or customs areas and to modify any allocation, as he determines appropriate.

(c) Section 404(d)(5) of the URAA [section 3601(d)(5) of this title] authorizes the President to proclaim additional U.S. note 3 to chapter 17 of the HTS, dealing with imports of sugar, together with appropriate modifications thereto, to reflect Schedule XX.

(d) Section 405 of the URAA [section 3602 of this title] directs the President to cause to be published in the **Federal Register** the list of special safeguard agricultural goods and, if appropriate, to impose price-based or volume-based safeguards with respect to such goods consistent with Article 5 of the Agreement on Agriculture annexed to the WTO Agreement, and authorizes the President to exempt from any safeguard duty any goods originating in a country that is a party to the North American Free Trade Agreement ("the NAFTA").

7. Presidential Proclamation No. 6641 of December 15, 1993 [108 Stat. 5134], implemented the NAFTA with respect to the United States and, pursuant to sections 201 and 202 of the North American Free Trade Agreement Implementation Act ("the NAFTA Act") (19 U.S.C. 3331 and 3332), incorporated in the HTS the tariff modifications and rules of origin necessary or appropriate to carry out or apply the NAFTA. Certain technical errors were made in the Annexes to that proclamation. I have determined that, in order to reflect accurately the intended tariff treatment and rules of origin provided for in the NAFTA,

it is necessary to modify certain provisions of the HTS, as set forth in the Annex to this proclamation.

8. Presidential Proclamation No. 6455 of July 2, 1992 [set out as a note under section 3202 of this title], implementing the Andean Trade Preference Act ("the ATPA") (19 U.S.C. 3201 *et seq.*), provided duty-free entry for all eligible articles, and duty reductions for certain other articles that are the product of any designated beneficiary country under that Act. Through technical error, the tariff treatment of ethyl alcohol, ethyl tertiary-butyl ether, and mixtures containing these products was incompletely stated. Accordingly, I have decided that it is appropriate to modify the provisions of subchapter I of chapter 99 of the HTS to provide fully for the tariff treatment of such products under the ATPA.

9. Section 242 of the Compact of Free Association ("the Compact") between the United States and Palau provides that, upon implementation of the Compact, the President shall proclaim duty-free entry for most products of designated freely associated states. Such duty-free treatment, pursuant to the Compact of Free Association Approval Act ("the Compact Act") (Public Law 99-658; 100 Stat. 3672, 48 U.S.C. 1681 note), is subject to the limitations of section 201 of the Compact Act and sections 503(b) and 504(c) of the Trade Act of 1974 ("the 1974 Act") (19 U.S.C. 2463(b) and 2464(c)). In Presidential Proclamation No. 6726 of September 27, 1994 [set out as a note under section 1931 of Title 48, Territories and Insular Possessions], I proclaimed that the Compact would enter into force on October 1, 1994. In order to accord such

duty-free treatment to products of Palau, I have decided that it is necessary and appropriate to modify general note 10 to the HTS to designate the Republic of Palau as a freely associated state. Further, I have decided that it is appropriate to modify general note 4(a) to the HTS, which enumerates designated beneficiary countries for purposes of the Generalized System of Preferences, to delete Palau from the list of non-independent countries and territories.

10. Presidential Proclamation No. 5759 of December 24, 1987, imposed increased rates of duty on certain products of the European Community ("EC"), in response to the EC's implementation of the Council Directive Prohibiting the Use in Livestock Farming of Certain Substances Having a Hormonal Action. Austria, Finland, and Sweden have indicated that they will become member states of the EC on January 1, 1995. Accordingly, to clarify that the increased rates of duty imposed by Proclamation No. 5759 continue to apply to the EC in its capacity as a foreign instrumentality, it is necessary to amend the HTS to indicate that the duties are to be imposed on products of the EC, including products of all new and future member states, and not just on products of countries that were members of the EC in 1987 and that were listed in the HTS for illustrative purposes

11. Additional U.S. note 24 to chapter 4 of Schedule XX provides for a delay in the effective date, or prorating, of the expansion of tariff-rate quotas for cheeses above the existing quota quantities provided for in subchapter IV of chapter 99 of the HTS that will result from the implementation of United States commitments under the

Uruguay Round Agreements, in the case of countries or areas that implement their market access commitments on a date later than the effective date of Schedule XX. The current members of the European Community (Belgium, Denmark, France, the Federal Republic of Germany, Greece, Ireland, Italy, Luxembourg, the Netherlands, Portugal, Spain, and the United Kingdom), Austria, Poland, Sweden, and Switzerland all have indicated their intention not to implement their market access commitments until July 1, 1995. Accordingly, I have determined, pursuant to my authority under sections 111(a) and (b) of the URAA and section 1102 of the 1988 Act (19 U.S.C. 2902), that it is appropriate not to make available the amounts specified in section K of the Annex to this proclamation until July 1, 1995.

12. Section 604 of the 1974 Act (19 U.S.C. 2483) authorizes the President to embody in the HTS the substance of the relevant provisions of that Act, of other acts affecting import treatment, and actions thereunder, including the removal, modification, continuance, or imposition of any rate of duty or other import restriction.

NOW, THEREFORE, I, WILLIAM J. CLINTON, President of the United States of America, acting under the authority vested in me by the Constitution and the laws of the United States of America, including but not limited to section 604 of the 1974 Act (19 U.S.C. 2483), section 1102 of the 1988 Act (19 U.S.C. 2902), sections 201 and 202 of the NAFTA Act (19 U.S.C. 3331 and 3332), and title I and title IV of the URAA [Title I and Title IV of Pub.L. 103-465; see Tables for classification], do hereby proclaim:

Appendix D

(1) In order to provide generally for the tariff treatment being accorded under the Uruguay Round Agreements, including the modification or continuance of existing duties or other import restrictions and the continuance of existing duty-free or excise treatment provided for in Schedule XX, the URAA, and the other authorities cited in this proclamation, including the termination of quantitative limitations and fees previously imposed under section 22 of the Adjustment Act (7 U.S.C. 624), the HTS is modified as set forth in the Annex to this proclamation.

(2)(a) The modifications to the HTS made by sections A (except with respect to paragraphs thereof specifying other effective dates), C, E, and IJ of the Annex to this proclamation shall be effective with respect to goods entered, or withdrawn from warehouse for consumption, on and after January 1, 1995;

(b) The modifications to the HTS made by sections B, D(1)-(5), F, G, H, and L of the Annex to this proclamation, and by those paragraphs of section A specifying effective dates other than January 1, 1995, shall be effective with respect to goods entered, or withdrawn from warehouse for consumption, on and after the dates set forth in such sections of the Annex;

(c) The modifications to the HTS made by section D(6) of the Annex to this proclamation shall be effective with respect to goods entered, or withdrawn from warehouse for consumption, on and after the dates set forth in such section, unless the United States Trade Representative (USTR) announces that the scheduled

staged duty reductions set forth in such Annex section are being withheld because other major countries have not afforded adequate entity coverage under the Agreement on Government Procurement annexed to the WTO Agreement, and so advises the Secretary of the Treasury and publishes this information in a notice in the **Federal Register**;

(d) The modifications to the HTS made by section D(7) of the Annex to this proclamation shall be effective with respect to goods entered, or withdrawn from warehouse for consumption, on and after the date announced by the USTR in a notice published in the **Federal Register** as the date on which other major countries have afforded adequate entity coverage under the Agreement on Government Procurement annexed to the WTO Agreement; and

(e) Section K of the Annex to this proclamation, providing for a delay in implementation of the expansion of tariff-rate quotas of cheeses, applies during the period January 1, 1995, through June 30, 1995, unless the USTR determines that it is in the interest of the United States for any such delays to apply to a different period and publishes notice of the determination and applicable period in the **Federal Register.** The USTR also is authorized to prorate over the applicable period any of the quantities that may be imported.

(3) The USTR is authorized to exercise my authority under section 404(d)(3) of the URAA [section 3601(d)(3) of this title] to allocate the in-quota quantity of a tariff-rate quota for any agricultural product among supplying countries or

customs areas and to modify any allocation as the USTR determines appropriate.

(4) The Secretary of Agriculture is authorized to exercise my authority to make determinations under section 405(a) of the URAA [section 3602(a) of this title] and to publish those determinations in the **Federal Register**.

(5) Effective January 1, 1995, in order to clarify that the additional duty provided for in subheadings 9903.23.00 through 9903.23.35, inclusive, of the HTS shall apply to new member states of the European Community, the superior text to those subheadings is modified as provided in the Annex to this proclamation. The USTR is authorized to alter the application of the increased duties imposed by Presidential Proclamation No. 5759, as modified herein, by further modifying the superior text to those subheadings so that it reflects accurately all member states of the European Community or any successor organization. Notice of any such modification shall be published in the Federal Register.

(6) Whenever the rate of duty in the general subcolumn of rates of duty column 1 of the HTS is reduced to "Free", all rates of duty set forth in the special subcolumn of column 1 shall be deleted from the HTS.

(7) The USTR, the Secretary of Agriculture, and the Secretary of the Treasury are authorized to exercise my authority under the statutes cited in this proclamation to perform certain functions to implement this proclamation, as assigned to them in the Annex to this proclamation.

(8) Paragraphs (1)-(4), (6), and (7) shall be effective on January 1, 1995, unless the USTR announces prior to that date that the WTO Agreement will not enter into force on that date.

(9) All provisions of previous proclamations and Executive orders that are inconsistent with the actions taken in this proclamation are superseded to the extent of such inconsistency.

IN WITNESS WHEREOF, I have hereunto set my hand this twenty-third day of December, in the year of our Lord nineteen hundred and ninety-four, and of the Independence of the United States of America the two hundred and nineteenth.

WILLIAM J. CLINTON

Appendix D

PROCLAMATION NO. 6780

<Mar. 23, 1995, 60 F.R. 15845>

To Implement Certain Provisions of Trade Agreements Resulting from the Uruguay Round of Multilateral Trade Negotiations, and for Other Purposes

1. On April 15, 1994, I entered into trade agreements resulting from the Uruguay Round of multilateral trade negotiations ("the Uruguay Round Agreements"). In section 101(a) of the Uruguay Round Agreements Act ("the URAA") (Public Law 103-465; 108 Stat. 4814) (19 U.S.C. 3511(a)), the Congress approved the Uruguay Round Trade Agreements listed in section 101(d) of that Act.

2. Pursuant to section 101(b) of the URAA, I decided to accept the Agreement Establishing the World Trade Organization ("the WTO Agreement") on behalf of the United States, and I determined that the WTO Agreement entered into force for the United States on January 1, 1995.

3. (a) Sections 1102(a) and (e) of the Omnibus Trade and Competitiveness Act of 1988, as amended ("the 1988 Act") (19 U.S.C. 2902(a) and (e)), authorize the President to proclaim such modification or continuance of any existing duty, such continuance of existing duty-free or excise treatment, or such additional duties, as he determines to be required or appropriate to carry out any trade agreement entered into under these sections.

(b) Section 111(a) of the URAA (19 U.S.C. 3521(a)) authorizes the President to proclaim such other modification of any duty, such other staged rate reduction, or such other additional duties beyond those authorized by section 1102 of the 1988 Act (19 U.S.C. 2902) as the President determines to be necessary or appropriate to carry out Schedule XX--United States of America, annexed to the Marrakesh Protocol to the General Agreement on Tariffs and Trade 1994 ("Schedule XX").

(c) Section 103(a) of the URAA (19 U.S.C. 3513(a)) authorizes the President to proclaim such actions as may be necessary to ensure that any provision or amendment made by the URAA that takes effect on the date that any of the Uruguay Round Agreements enters into force with respect to the United States is appropriately implemented on such date.

4. Proclamation 6763 of December 23, 1994, implemented the Uruguay Round Agreements, including Schedule XX, with respect to the United States; and incorporated in the Harmonized Tariff Schedule of the United States ("the HTS") tariff modifications necessary and appropriate to carry out the Uruguay Round Agreements and certain conforming changes in rules of origin for the North American Free Trade Agreement ("NAFTA"). Certain technical errors, including inadvertent omissions, were made in that proclamation. I have determined that it is necessary, to reflect accurately the intended tariff treatment provided for in the Uruguay Round Agreements and to ensure the continuation of the agreed NAFTA rules of origin, to modify certain provisions of the HTS, as set forth in the Annex to this proclamation.

5. (a) One of the Uruguay Round Agreements approved by the Congress in sections 101(a) and 101(d) of the URAA (19 U.S.C. 3511(a) and (d)) is the Agreement on Trade-Related Aspects of Intellectual Property Rights ("the TRIPs Agreement").

(b) Section 104A of title 17, United States Code, as amended by section 514 of the URAA, provides for copyright protection in restored works. Section 104A(h), as amended, provides that the date of restoration of a restored copyright shall be the date on which the TRIPs Agreement enters into force with respect to the United States, if the source country is a nation adhering to the Berne Convention or a World Trade Organization (WTO) member on such date.

(c) Article 65, paragraph 1, of the TRIPs Agreement provides that no WTO member shall be obliged to apply the provisions of this Agreement until one year after the date of entry into force of the WTO Agreement. The date of entry into force of the WTO Agreement with respect to the United States was January 1, 1995.

(d) The statement of administrative action, approved by the Congress in section 101(a)(2) of the URAA (19 U.S.C. 3511(a) (2)), provides that, "in general, copyright will be restored on the date when the TRIPs Agreement's obligations take effect for the United States."

(e) Accordingly, I have decided that it is necessary and appropriate, in order to implement the TRIPs Agreement and to ensure that section 514 of the URAA is

appropriately implemented, to proclaim that the date on which the obligations of the TRIPs Agreement will take effect for the United States is January 1, 1996.

6. (a) Section 902(a)(2) of title 17, United States Code, authorizes the President to extend protection under chapter 9 of title 17, United States Code, to mask works of owners who are nationals, domiciliaries, or sovereign authorities of, and to mask works, which are first commercially exploited in, a foreign nation that grants United States mask work owners substantially the same protection that it grants its own nationals and domiciliaries, or that grants protection to such works on substantially the same basis as does chapter 9 of title 17, United States Code.

(b) Australia, Canada, Japan, Switzerland, and the Member States of the European Community provide adequate and effective protection for mask works within the meaning of 17 U.S.C. 902(a)(2), and have been subject to interim protection under 17 U.S.C. 914. Consequently, I find that these countries satisfy the requirements of 17 U.S.C. 902(a)(2), and are to be extended full protection under chapter 9 of title 17, United States Code, effective on July 1, 1995.

(c) In addition, 17 U.S.C. 902(a)(1)(A)(ii) provides that mask work owners who are nationals, domiciliaries, or sovereign authorities of a foreign nation that is a party to a treaty affording protection to mask works to which the United States is also a party are eligible for protection under chapter 9 of title 17, United States Code. The TRIPs

Agreement, which requires all WTO members to provide protection equivalent to that provided under chapter 9 of title 17 on the basis of national treatment, is such an agreement. Because the United States is a member of the WTO and thus of the TRIPs Agreement, and because the TRIPs Agreement will be effective for the United States on January 1, 1996, all other WTO members will become eligible for full protection under chapter 9 of title 17, United States Code, on January 1, 1996.

7. Section 491 of the Trade Agreements Act of 1979, as amended ("the 1979 Act") (19 U.S.C. 2578), requires the President to designate an agency to be responsible for informing the public of the sanitary and phytosanitary standard-setting activities of each international standard-setting organization. I have decided to designate the Department of Agriculture as the agency responsible for providing the public with this information.

8. (a) The March 24, 1994, Memorandum of Understanding on the Results of the Uruguay Round Market Access Negotiations on Agriculture Between the United States of America and Argentina ("the MOU"), submitted to the Congress along with the Uruguay Round Agreements, provides for "an appropriate certificate of origin" for imports of peanuts and peanut butter and peanut paste from Argentina.

(b) Proclamation 6763 proclaimed the Schedule XX tariff rate quotas for peanuts and peanut butter and peanut paste. However, that proclamation did not specify which agency should implement the MOU.

(c) Section 404 of the URAA (19 U.S.C. 3601) requires the President to take such action as may be necessary to ensure that imports of agricultural products do not disrupt the orderly marketing of commodities in the United States.

(d) Accordingly, I have decided to delegate to the United States Trade Representative ("the USTR") my authority under section 404 of the URAA to implement the MOU, through such regulations as the USTR, or, at the direction of the USTR, other appropriate agencies, may issue.

9. Section 604 of the Trade Act of 1974, as amended (19 U.S.C. 2483) ("the 1974 Act"), authorizes the President to embody in the HTS the substance of the relevant provisions of that Act, of other Acts affecting import treatment, and actions thereunder, including the removal, modification, continuance, or imposition of any rate of duty or other import restriction.

NOW, THEREFORE, I, WILLIAM J. CLINTON, President of the United States of America, acting under the authority vested in me by the Constitution and the laws of the United States, including but not limited to section 301 of title 3, United States Code, section 902(a)(1) and (2) of title 17, United States Code, section 604 of the 1974 Act, as amended (19 U.S.C. 2483), section 491 of the 1979 Act, as amended (19 U.S.C. 2578), section 1102 of the 1988 Act, as amended (19 U.S.C. 2902), title I of the URAA (19 U.S.C. 3511-3551), and section 404 of the URAA (19 U.S.C. 3601), do hereby proclaim that:

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(1) To more completely implement the tariff treatment accorded under the Uruguay Round Agreements, the HTS is modified as set forth in the Annex to this proclamation.

(2) The obligations of the TRIPs Agreement shall enter into force for the United States on January 1, 1996.

(3) Australia, Canada, Japan, Switzerland, and the Member States of the European Community shall be extended full protection under chapter 9 of title 17, United States Code, effective on July 1, 1995. In addition, as of January 1, 1996, full protection under chapter 9 of title 17, United States Code, shall be extended to all WTO Members.

(4) The Secretary of Agriculture is designated, under section 491 of the 1979 Act, as amended (19 U.S.C. 2578), as the official responsible for informing the public of the sanitary and phytosanitary standard-setting activities of each international standard-setting organization.

(5) The USTR is authorized to exercise my authority under section 404 of the URAA (19 U.S.C. 3601) to implement the MOU with Argentina, through such regulations as the USTR, or, at the direction of the USTR, other appropriate agencies, may issue.

(6) In order to make conforming changes and technical corrections to certain HTS provisions, pursuant to actions taken in Proclamation 6763, the HTS and Proclamation 6763 are modified as set forth in the Annex to this proclamation.

(7) All provisions of previous proclamations and Executive orders that are inconsistent with the actions taken in this proclamation are superseded to the extent of such inconsistency.

(8) This proclamation shall be effective upon publication in the **Federal Register.**

IN WITNESS WHEREOF, I have hereunto set my hand this twenty-third day of March, in the year of our Lord nineteen hundred and ninety-five, and of the Independence of the United States of America the two hundred and nineteenth.

WILLIAM J. CLINTON

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MEMORANDA OF PRESIDENT

Memorandum on the Uruguay Round Agreements

<Dec. 23, 1994, 60 F.R. 1003>

Memorandum for the United States Trade Representative

Subject: Acceptance of the WTO Agreement

Being advised that Canada, the European Community, Mexico, Japan, and other major trading countries have committed to acceptance of the Uruguay Round Agreements, I have determined that a sufficient number of foreign countries are accepting the obligations of those Agreements, in accordance with article XIV of the Agreement Establishing the World Trade Organization (WTO Agreement), to ensure the effective operations of, and adequate benefits for the United States under, those Agreements.

Pursuant to section 101(b) of the Uruguay Round Agreements Act (Public Law 103-465; 108 Stat. 4809) [subsec. (b) of this section] and section 301 of title 3, United States Code [section 301 of Title 3, The President], I hereby direct the United States Trade Representative, or his designee, to accept the Uruguay Round Agreements, as described in section 101(d) of that Act [subsec. (d) of this section], on behalf of the United States in accordance with article XIV of the WTO Agreement.

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You are authorized and directed to publish this memorandum in the Federal Register.

WILLIAM J. CLINTON

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35 U.S.C.A. § 112

§ 112. Specification

Effective: September 16, 2012

(a) In General.--The 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, and shall set forth the best mode contemplated by the inventor or joint inventor of carrying out the invention.

(b) Conclusion.--The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the inventor or a joint inventor regards as the invention.

(c) Form.--A claim may be written in independent or, if the nature of the case admits, in dependent or multiple dependent form.

(d) Reference in Dependent Forms.--Subject to subsection (e), a claim in dependent form shall contain a reference to a claim previously set forth and then specify a further limitation of the subject matter claimed. A claim in dependent form shall beconstrued to incorporate by reference all the limitations of the claim to which it refers.

(e) Reference in Multiple Dependent Form.--A claim in multiple dependent form shall contain a reference, in the

alternative only, to more than one claim previously set forth and then specify a further limitation of the subject matter claimed. A multiple dependent claim shall not serve as a basis for any other multiple dependent claim. A multiple dependent claim shall be construed to incorporate by reference all the limitations of the particular claim in relation to which it is being considered.

(f) Element in Claim for a Combination.--An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.

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35 U.S.C.A. § 282

§ 282. Presumption of validity; defenses

Effective: September 16, 2012

(a) In General.--A patent shall be presumed valid. Each claim of a patent (whether in independent, dependent, or multiple dependent form) shall be presumed valid independently of the validity of other claims; dependent or multiple dependent claims shall be presumed valid even though dependent upon an invalid claim. The burden of establishing invalidity of a patent or any claim thereof shall rest on the party asserting such invalidity.

(b) Defenses.--The following shall be defenses in any action involving the validity or infringement of a patent and shall be pleaded:

> **(1)** Noninfringement, absence of liability for infringement or unenforceability.
>
> **(2)** Invalidity of the patent or any claim in suit on any ground specified in part II as a condition for patentability.
>
> **(3)** Invalidity of the patent or any claim in suit for failure to comply with--
>
> > **(A)** any requirement of section 112, except that the failure to disclose the best mode shall not be a basis on

which any claim of a patent may be canceled or held invalid or otherwise unenforceable; or

(B) any requirement of section 251.

(4) Any other fact or act made a defense by this title.

(c) Notice of Actions; Actions During Extension of Patent Term.--In an action involving the validity or infringement of a patent the party asserting invalidity or noninfringement shall give notice in the pleadings or otherwise in writing to the adverse party at least thirty days before the trial, of the country, number, date, and name of the patentee of any patent, the title, date, and page numbers of any publication to be relied upon as anticipation of the patent in suit or, except in actions in the United States Court of Federal Claims, as showing the state of the art, and the name and address of any person who may be relied upon as the prior inventor or as having prior knowledge of or as having previously used or offered for sale the invention of the patent in suit. In the absence of such notice proof of the said matters may not be made at the trial except on such terms as the court requires. Invalidity of the extension of a patent term or any portion thereof under section 154(b) or 156 because of the material failure--

(1) by the applicant for the extension, or

(2) by the Director,

to comply with the requirements of such section shall be a defense in any action involving the infringement of a patent during the period of the extension of its term and shall be pleaded. A due diligence determination under section 156(d)(2) is not subject to review in such an action.