39 Biotechnology Law Report 452
Number 6, 2020

DOI: 10.1089/blr.2020.29208.phc

# Incorrect Translation Causing a Claim to Be Indefinite Under 35 U.S.C. § 112—A Case Study of *IBSA Institut Biochimique, S.A. v. Teva Pharmaceuticals USA, Inc.*

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## ABSTRACT

*IBSA Institut Biochimique, S.A. v. Teva Pharmaceuticals USA, Inc.*, 966 F.3d 1374 (Fed. Cir. 2020), shows a case of inaccurate translation leading the court to find the asserted claims invalid. The disputed term "half-liquid" was found unclear in terms of whether pastes and gels should fall within or be excluded from the patentee's construction of "half-liquid." This article examines the *IBSA* case and argues that there could have been a chance to avoid such mistake. This article also demonstrates that the translation error is not correctable under 35 U.S.C. § 255.

## I. INTRODUCTION

TIROSINT, A SOFT-GEL CAPSULE DRUG containing levothyroxine sodium, is used to treat patients with hypothyroidism to help them return their thyroid hormone levels to normal, or used to conduct pituitary thyrotropin (thyroid-stimulating hormone, TSH) suppression on patients to prevent thyroid cancer recurrence or the growth of thyroid nodules.[1] Institut Biochimique, S.A. holds a marketing approval of Tirosint.[2] In *Approved Drug Products with Therapeutic Equivalence Evaluations* (Orange Book), two patents are listed for various doses of Tirosint: U.S. Patent Nos. 7,691,411 and 7,723,390 ('390 Patent).[3] Both patents claim pharmaceutical compositions.[4]

**Keywords:** Tirosint, indefiniteness, new abbreviated drug application, semi-liquid, half-liquid

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[1] *See* U.S. Food and Drug Administration (FDA), Tirosint Labeling, at 1, *available at* https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/021924s013lbl.pdf (last visited Aug. 22, 2020); *see also* Mario Tanguay *et al.*, *Pharmacokinetics and Comparative Bioavailability of a Levothyroxine Sodium Oral Solution and Soft Capsule*, 8(4) CLINICAL PHARMACOLOGY IN DRUG DEV. 521, 521–22 (2019) (describing the function of levothyroxine sodium), *available at* https://accp1.onlinelibrary.wiley.com/doi/pdf/10.1002/cpdd.608 (last visited Aug. 22, 2020); Alina Gavrila, *Thyroid Hormone Treatment*, 7(5) CLINICAL THYROIDOLOGY FOR THE PUBLIC 6, 6, *available at* https://www.thyroid.org/wp-content/uploads/publications/ctfp/volume7/issue5/ct_public_v75_6_7.pdf (last visited Aug. 22, 2020).

[2] *See* FDA, Approval Letter for Application No. 021924, at 1, *available at* https://www.accessdata.fda.gov/drugsatfda_docs/nda/2006/021924s000_Approv.pdf (last visited Aug. 17, 2020).

[3] *See, e.g.*, FDA, *Patent and Exclusivity for: N021924*, APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS [hereinafter ORANGE BOOK], https://www.accessdata.fda.gov/scripts/cder/ob/patent_info.cfm?Product_No=013&Appl_No=021924&Appl_type=N (0.013 mg); https://www.accessdata.fda.gov/scripts/cder/ob/patent_info.cfm?Product_No=002&Appl_No=021924&Appl_type=N (0.025 mg) (last visited Aug. 22, 2020).

[4] *See, e.g.*, U.S. Patent Nos. 7,691,411 cols.51–54; 7,723,390 cols.14–16.

Teva Pharmaceuticals USA, Inc. (Teva) filed an Abbreviated New Drug Application (ANDA) to market a generic version of Tirosint.[5] The ANDA included a Paragraph IV certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that the '390 Patent is invalid or unenforceable and that Teva's generic product will not infringe the patent.[6] In return, IBSA Institut Biochimique, S.A., Altergon, S.A., and IBSA Pharma Inc. (collectively, IBSA) filed a patent lawsuit under 35 U.S.C. § 271(e)(2)(A) against Teva in the United States District Court for the District of Delaware, alleging that claims 1, 2, 4, and 7–9 of the '390 Patent are infringed.[7]

The district court invalidated the disputed claims, because the disputed term "half-liquid" was found indefinite under 35 U.S.C. § 112.[8] On appeal, the Federal Circuit, in *IBSA Institut Biochimique, S.A. v. Teva Pharmaceuticals USA, Inc.*, upheld the indefiniteness decision.[9]

The '390 Patent claimed a right of priority from the Italian Patent Application No. MI2001A1401 in which the specification uses the term *semiliquido* (an Italian word), which the patentee alleged as the origin of the term "half-liquid."[10] The *IBSA* decision implies that if *semiliquido* had been translated into "semi-liquid" instead of "half-liquid," the disputed claims would have been found valid.[11] Thus, this article is intended to answer a question of whether this translation error could have been avoided and can be fixed. Next, this article analyzes the *IBSA* decision in Part II. Then, Part III provides some practical aspects drawn from the *IBSA* case.

## II. ANAYSIS OF *IBSA INSTITUT BIOCHIMIQUE, S.A. V. TEVA PHARMACEUTICALS USA, INC.*

### *A. Governing law*

Following the Supreme Court in *Nautilus, Inc. v. Biosig Instruments, Inc.*,[12] the *IBSA* court adopted a standard that finds a claim "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.'"[13] In addition, the *IBSA* court reviewed the district court's decision on indefiniteness along with governing legal standards and intrinsic evidence *de novo*, but any factual findings about extrinsic evidence relevant to the indefiniteness decision were reviewed for clear error.[14] Finally, the *IBSA* court found no clear error in the district court's factual findings.[15]

### *B. Disputed claim term*

On appeal, claim 1 of the '390 Patent was a representative claim reciting:

> 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.[16]

The patentee construed "half-liquid" as "semi-liquid, *i.e.*, having a thick consistency between solid and liquid," while the defendant interpreted the same term as "a non-solid, non-paste, non-gel, non-slurry substance."[17] Ultimately, the district

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[5]*See IBSA Institut Biochimique, S.A. v. Teva Pharm. USA, Inc.*, 966 F.3d 1374, 1376 (Fed. Cir. 2020).
[6]*See id.*
[7]*See id.* at 1375–76.
[8]*See id.*
[9]*See id.* at 1375.
[10]*See IBSA Institut Biochimique, S.A.*, 966 F.3d at 1377; *see also IBSA Institut Biochimique, S.A. v. Teva Pharm. USA, Inc.*, No. 1:18-CV-00555-RGA, 2019 WL 3936656, at *4 (D. Del. Aug. 20, 2019).
[11]*See IBSA Institut Biochimique, S.A.*, 966 F.3d at 1378–81.
[12]*Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 U.S. 898 (2014).
[13]*IBSA Institut Biochimique, S.A.*, 966 F.3d at 1378 (alteration in original and emphasis added) (quoting *HZNP Meds. LLC v. Actavis Labs. UT, Inc.*, 940 F.3d 680, 688 (Fed. Cir. 2019) (quoting *Nautilus, Inc.*, 572 U.S. at 90)). For the introduction of indefiniteness, please read Ping-Hsun Chen, *Definite Indefiniteness of ''Molecular Weight'' as a Claim Term for Polymer-Related Patents*, 11 J. Bus. Entrepreneurship & L. 207, 217–19 (2018).
[14]*See IBSA Institut Biochimique, S.A.*, 966 F.3d at 1378 (citing *BASF Corp. v. Johnson Matthey Inc.*, 875 F.3d 1360, 1365 (Fed. Cir. 2017)).
[15]*See id.* at 1380–81.
[16]*Id.* at 1376 (emphasis added).
[17]*See IBSA Institut Biochimique, S.A.*, 2019 WL 3936656, at *4.

court found the disputed term indefinite.[18] On appeal, the Federal Circuit affirmed the district court's indefiniteness decision and rejected the patentee's proposed claim construction of "half-liquid."[19]

### *C. Federal Circuit's reasoning*

The *IBSA* decision can be divided into four parts.[20] First, the Federal Circuit looked to the claim language "to determine whether the meaning of ['half-liquid'] is reasonably clear."[21] The court observed that in claim 1, "[t]he term 'half-liquid' is merely used alongside 'liquid' to describe the inner phase of a soft elastic capsule."[22] Thus, the court concluded that "the claim language clarifies only that a 'half-liquid' differs from a liquid."[23]

In the second part, the Federal Circuit reviewed the patentee's specification-related arguments and concluded that the specification could not define "half-liquid."[24] The court started with the district court's determination that a "half-liquid is not, or at least is not necessarily, a gel or a paste."[25] The court specifically pointed to two portions of the specification indicating that "a 'half-liquid' is an alternative to the other members of the list, including pastes and gels."[26] Because finding that gels or pastes "have a thick consistency between a liquid and a solid" and, therefore, fall within the patentee's definition of "half-liquid," the court opined that such fact "creates uncertainty as to the boundaries of a 'half-liquid.'"[27]

In addition, to support its claim interpretation, the patentee relied on the third embodiment in the specification describing "an SEC capsule containing *an inner phase consisting of a paste or gel* comprising gelatin and thyroid hormones or *pharmaceutically acceptable salts thereof*, in particular *their sodium salts in* a liquid or *half liquid vehicle* . . . ."[28] But, the court agreed with the defendant's critique that the patentee "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.'"[29] Thus, the court concluded that the third embodiment could not outweigh the fact of "half-liquid" serving as an alternative to pastes and gels.[30] Finally, the court held that the patentee's other references to the specification also failed, because they did not help define or clarify boundaries of a "half-liquid."[31]

In the third part, the Federal Circuit considered the prosecution history and rejected the patentee's reliance on an Italian patent application providing a right-of-priority of the '390 Patent.[32] The court acknowledged several differences between the '390 Patent and its Italian counterpart: for instance, the fourth embodiment of the '390 Patent embraced by claim 1 did not appear in the Italian application; the '390 Patent used the term "gel," while the translation of the Italian application did not.[33] Therefore, the court opined that a person of ordinary skill in the art "would likely consider the discrepant usage of 'half-liquid' and 'semiliquido' between the '390 [P]atent and the Italian [a]pplication to be intentional, implying that the different word choice has a different scope."[34]

The Federal Circuit also noticed a piece of the prosecution record showing a pending claim that has the term "semi-liquid" and depends on another claim reciting the term "half-liquid."[35] Since the claim using "semi-liquid" was eventually removed, the court concluded that "the applicant knew the term 'semi-liquid' yet elected to use 'half-liquid' to mean something different."[36]

Finally, in the fourth part, the Federal Circuit examined the extrinsic record, including dictionary definitions, other patents, and expert testimony,

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[18]*See IBSA Institut Biochimique, S.A.*, 966 F.3d at 1375.
[19]*See id.*
[20]*See id.* at 1378–81.
[21]*Id.* at 1378 (alteration in original) (quoting *Berkheimer v. HP Inc.*, 881 F.3d 1360, 1363 (Fed. Cir. 2018)).
[22]*Id.* at 1379.
[23]*Id.*
[24]*See id.*
[25]*Id.* (quoting *IBSA Institut Biochimique, S.A.*, 2019 WL 3936656, at *6).
[26]*Id.* (referring to two passages of the specification: the first one 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[,]" U.S. Patent No. 7,723,390 col.7 l.65–col.8 l.2; and the second one stating "[s]oft capsules (SEC) with liquid, half-liquid, paste-like or gel-like inner phase[,]" *id.* at col.10 ll.38–39).
[27]*Id.* at 1379.
[28]*See* U.S. Patent No. 7,723,390 col.9 ll.15–19 (emphasis added); *see also IBSA Institut Biochimique, S.A.*, 966 F.3d at 1379. Because claim 1 of the '390 Patent uses "a liquid or half-liquid inner phase," it seems that the patentee tried to characterize the "inner phase" of the third embodiment as the claimed "liquid or half-liquid inner phase."
[29]*IBSA Institut Biochimique, S.A.*, 966 F.3d at 1379 (alteration in original).
[30]*See id.*
[31]*See id.*
[32]*See id.* at 1379–80.
[33]*See id.* at 1380.
[34]*Id.*
[35]*Id.*
[36]*Id.*

and found nothing supportive to the patentee's claim construction.[37] The court criticized that the patentee only provided a non-scientific dictionary which defines "the term 'semi-liquid' as a 'Half liquid; semifluid[,]'" while the patentee's expert contrarily stated that "'semifluid' and 'half-liquid' are not necessarily synonymous."[38] Regarding those extrinsic patents, the court found that the use of "half-liquid" was in the context of "half-liquid bases" and "half-liquid polyols" different from the '390 Patent and, therefore, could not help define "half-liquid."[39] The patentee's experts also failed to clarify the scope of "half-liquid."[40]

As a result, the Federal Circuit opined that the intrinsic and extrinsic evidence both provided no clue for the boundaries of "half-liquid" and that the district court did not err in determining that the disputed claims were indefinite.[41]

## III. PRACTICAL IMPLICATIONS

### *A. A lesson for patent application*

A certified copy of the Italian Patent Application No. MI2001A1401, which serves as a basis for the right of priority of the '390 Patent, was submitted to the U.S. Patent and Trademark Office (USPTO) under 35 U.S.C. § 119 and became part of the prosecution history.[42] Claim 12 of the MI2001A1401 application corresponded to claim 12 of U.S. Patent Publication No. US 2003/0050344 A1 issued as the '390 Patent, while the MI2001A1401 application used "*semi-liquido*" in substantially the same place as the '390 Patent used "half-liquid."[43] But various differences between the '390 Patent and MI2001A1401 led the Federal Circuit to conclude that the term "half-liquid" was intentionally not to mean "*semi-liquido*."[44]

The term "half-liquid" appeared not only in the '390 Patent, but also in other English applications claiming a priority right based on the MI2001A1401 application.[45] Thus, the use of "half-liquid" in the '390 Patent was not clearly a "mistake."

The fact that the patentee construed "half-liquid" as "semi-liquid" indicates that the patentee considered the term "half-liquid" as an incorrect translation of *semi-liquido* that should have been translated into "semi-liquid." The question then is whether this incorrect translation could be avoided.

Under 37 C.F.R. § 1.52(d), a patent application "may be in a language other than English."[46] An English language translation of the non-English language application, a statement that the translation is accurate, and a required fee are required to submit to the USPTO within a designated period to satisfy the filing requirements.[47] During such period, a patent attorney can review the translation to see whether it uses correct scientific or technical terms.

In *IBSA Institut Biochimique, S.A.*, the patentee presented a professional translation of the MI2001A1401 application, but the translation was considered merely as extrinsic evidence by the district court.[48] Although the translation showed a passage "an internal phase consisting of a liquid, a *semi-liquid*, a paste, an emulsion or a suspension[,]" it did not prevent the Federal Circuit from denying the patentee's claim construction.[49] Had the patentee chosen such professional translation to file with the USPTO, the indefiniteness issue would not have existed. Instead, the patentee filed an inaccurate English version of the MI2001A1401 application. Unfortunately, such inaccurate version became superior over the original MI2001A1401 application and resulted in the indefiniteness of the asserted claims.

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[37] *See id.* at 1380–81.
[38] *Id.* at 1381.
[39] *See id.*
[40] *See id.*
[41] *See id.*
[42] *See* Certified Copy of Foreign Priority Application (received Oct. 18, 2002), at 1, in Patent Application Information Retrieval for U.S. Patent No. 7,723,390, archived at https://drive.google.com/file/d/1AVTjR_y-nEwMNhJEjCNN1-w6oULu3ZPQ/view?usp=sharing (last visited Aug. 31, 2020) [hereinafter Italian Patent Application No. MI2001A1401].
[43] *See* Italian Patent Application No. MI2001A1401, *supra* note 42, at 25 (reciting "liquido o semi-liquido"); *see also* U.S. Patent Publication No. US 2003/0050344 A1 claim 12 (reciting "liquid or half-liquid").
[44] *See IBSA Institut Biochimique, S.A.*, 966 F.3d at 1379–80; *see also IBSA Institut Biochimique, S.A.*, 2019 WL 3936656, at *4 ("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.").
[45] *See* European Patent Application Publication No. EP1291021 (A2) claims 11, 12, archived at https://drive.google.com/file/d/13ueLzDR4IPcyLPs8J3R83mr625N5HiVn/view?usp=sharing (last visited Aug. 31, 2020).
[46] 37 C.F.R. § 1.52(d).
[47] 37 C.F.R. § 1.52(d)(1).
[48] *See IBSA Institut Biochimique, S.A.*, 2019 WL 3936656, at *4.
[49] *See IBSA Institut Biochimique, S.A.*, 966 F.3d at 1380 (emphasis added).

Therefore, *IBSA Institut Biochimique, S.A.* teaches a lesson for the patent application of a non-English priority application: incorrect translation provided by a foreign applicant is always a concern. A patent attorney should take advantage of foreign-language filing under 37 C.F.R. § 1.52(d) to buy time for reviewing accuracy of the translation.

### *B. ''Half-liquid'' as a problematic claim term*

The *IBSA* decision confirms that "half-liquid" is a problematic claim term, because its scientific definition is not clear.[50] However, the term "half-liquid" is not new in the patent world. A very long time ago, in *Eskimo Pie Corp. v. Levous*, the Third Circuit described the claimed invention as "a new process for the manufacture of small hollow bodies of chocolate, cocoa, sugar, gelatine, albumen or the like, filled with a liquid or pasty mass," and found that "[t]he process consists in that the filling, which can also be *half liquid* or gelatinous, is left to freeze in suitable moulds . . . ."[51]

A few patents or applications also use "half-liquid" as a claim term.[52] For example, in U.S. Patent Application Publication No. 2010/0183691 A1 entitled "Use of Titanium Metal Fine-Particles for Increasing the Effect of Germicidal Medicines Used for Human Skin Dermatosis, Skin Infection and Traumatism," claim 12 recites "[t]he use as claimed in claim 11 wherein the medicine will be in style of liquid, *half-liquid*, cream, powder or spray powder as per the style of medicine carrier or substrate."[53] But, like the '390 Patent, the specification of the 2010/0183691 application does not define the meaning of "half-liquid," but merely repeats the language of claim 12.[54] Under *IBSA Institut Biochimique, S.A.*, these patents or applications are more likely to be held invalid because of the indefiniteness issue.

A patentee "can 'act as his own lexicographer to specifically define terms of a claim contrary to their ordinary meaning.'"[55] The patentee's own definition of a claim term may resolve the scope of such term. For instance, in *Abraxis Bioscience, Inc. v. Mayne Pharma (USA) Inc.*, the disputed claim term "edetate" could mean "a salt of ethylenediaminetetraacetic (EDTA) acid" or "all anions derived from EDTA," while the Federal Circuit found that the specification there clearly stated that "[b]y the term 'edetate' we mean ethylenediaminetetraacetic acid (EDTA) and derivatives thereof . . . ."[56] Contrarily, the '390 Patent provides no definition of "half-liquid."[57]

Therefore, avoiding the term "half-liquid" may be the best choice for practitioners. Otherwise, a patent drafter has to carefully describe the meaning of "half-liquid" in the specification to clear the indefiniteness issue.

### *C. Incorrect translation as an uncorrectable error*

The final question is whether the term "half-liquid" can be fixed by post-grant amendment. 35 U.S.C. § 255 allows the director of the USPTO to issue a certificate of correction for "a mistake of a clerical or typographical nature, or of minor character, which was not the fault of the [USPTO], appear[ring] in a patent[,]" if "a showing has been made that such mistake occurred in good faith" and "the correction does not involve such changes in the patent as would constitute new matter or would require reexamination."[58] So, can "half-liquid" be changed to "semi-liquid"? The answer is probably no.

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[50]*See id.* at 1381.

[51]*Eskimo Pie Corp. v. Levous*, 35 F.2d 120, 121 (3d Cir. 1929) (emphasis added).

[52]*See, e.g.*, U.S. Patent No. 3,212,996 claim 15 ("15. The process of treating spent sulfite liquor derived from the calcium sulfite pulping of hemlock wood chips which comprises, . . . , concentrating the so-treated spent sulfite liquor to about half solids and half liquid . . . ."); U.S. Patent No. 7,552,844 claim 15 ("15. The coupling arrangement according to claim 1, wherein the contents of the package (1) are liquid or half-liquid foodstuffs, such as, for example, ketchup, mustard, mayonnaise, dressing or similar."); U.S. Patent Application Publication No. 2010/0183691 A1 claim 12; U.S. Patent Application Publication No. 2012/0064207 A1 claim 4 ("4. The method of claim 1, wherein the cooking object is made of a liquid material or a half liquid material, . . . ."); U.S. Patent Application Publication No. 2012/0132817 A1 claim 17 ("17. A process according to claim 16, wherein the step of covering the chips includes compression-moulding the encapsulating layer in a half-liquid phase within a mould.").

[53]U.S. Patent Application Publication No. 2010/0183691 A1 claim 12 (emphasis added).

[54]*See* U.S. Patent Application Publication No. 2010/0183691 A1 ¶¶ 0015, 0016, 0026, 0027.

[55]*Abraxis Bioscience, Inc. v. Mayne Pharma (USA) Inc.*, 467 F.3d 1370, 1376 (Fed. Cir. 2006) (quoting *Chef Am., Inc. v. Lamb–Weston, Inc.*, 358 F.3d 1371, 1374 (Fed. Cir. 2004)).

[56]*See id.* at 1374 (quoting U.S. Patent No. 5,714,520 col.4 ll.51–52).

[57]*See IBSA Institut Biochimique, S.A.*, 966 F.3d at 1379.

[58]*See* Markus Nolff, *The Patent Provisions of TPP: An Endpoint or Should Be Just a Mere Starting Point for More and Better Patent Protection in a Revised NAFTA*, 100 J. PAT. & TRADEMARK OFF. SOC'Y 103, 115 (2018) ("35 USC §255 allows for correction of applicant's mistake.").

The use of "half-liquid" in the '390 Patent is intentional, so the term "half-liquid" is neither clerical nor typographical.[59] Hence, a mistake of minor character is the closest category the term "half-liquid" may fall within.

The Federal Circuit has defined a mistake of minor character as "exclud[ing] mistakes that broaden a claim."[60] The *IBSA* court found that a "half-liquid" is an alternative to pastes and gels.[61] On the other hand, the *IBSA* patentee interpreted "semi-liquid" as something "having a thick consistency between solid and liquid" and, therefore, found to include pastes and gels.[62] Thus, the scope of "semi-liquid" is larger than that of "half-liquid." The term "half-liquid" cannot be corrected as "semi-liquid" under 35 U.S.C. § 255.

## IV. CONCLUSION

*IBSA Institut Biochimique, S.A.* teaches that "half-liquid" is not a proper term for describing the inner part of a soft elastic capsule for claim drafting purposes. The use of "half-liquid" might result from the *IBSA* patentee's mistranslation of the Italian term *semiliquido* that was supposed to be translated as "semi-liquid." Although 35 U.S.C. § 255 allows correction of applicant's mistake, the *IBSA* error cannot be fixed because variations between the '390 Patent and its Italian counterpart indicates the use of "half-liquid" was intentional. To avoid such error, an applicant may file an application in a foreign language under 37 C.F.R. § 1.52(d) to gain time for reviewing correctness of the later-filed translation.

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[59] *See IBSA Institut Biochimique, S.A.*, 966 F.3d at 1380; *see also Superior Fireplace Co. v. Majestic Prod. Co.*, 270 F.3d 1358, 1369 (Fed. Cir. 2001) ("The phrase 'clerical or typographical nature' is not explicitly defined in § 255, so we first look to the plain meaning and common understanding of the phrase. A standard dictionary defines 'clerical' as relating to an office clerk or office work, and defines 'typographical' as relating to the setting of type, printing with type, or the arrangement of matter printed from type." (citing WEBSTER'S NEW WORLD DICTIONARY OF THE AMERICAN LANGUAGE 116, 646 (David B. Guralnik ed., Warner Books 1982))).

[60] *Superior Fireplace Co.*, 270 F.3d at 1375.

[61] *See IBSA Institut Biochimique, S.A.*, 966 F.3d at 1379.

[62] *See id.*