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IBSA Institut Biochimique, S.A. v. Teva Pharmaceuticals USA, Inc. (Fed. Cir. 2020)

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Synopsis

Federal Circuit affirmed that a literally translated claim term “half-liquid” is indefinite, and the patent as invalid.

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Synopsis

- IBSA's US Patent 7,723,390 matured from a US Application that claimed priority to an Italian Application, and claimed a thyroid medication in the form of a soft elastic capsule with a shell containing a liquid or half-liquid inner phase, where the term "half-liquid" was a literal translation of Italian "semiliquido".

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Synopsis

Using Supreme Court's Nautilus standard for definiteness that "a patent's claim, viewed in light of the specification and prosecution history, inform those skilled in the art about the scope of the invention with reasonable certainty", the Fed. Cir. ruled that "half-liquid" is indefinite because the plain meaning of the claim, the specification, the prosecution history, and external evidence for "half-liquid" did not inform those skilled in the art about the scope of the invention with reasonable certainty.

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Synopsis

- This seminar will:
- review IBSA's patent claim at issue,
- briefly explore the decisions in the District Court and the Federal Circuit,
- discuss IBSA's subsequent appeal to the Supreme Court, and
- other attempts to remedy the invalidity of IBSA's patent.

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IBSA's Patent (US 7,723,390)

- US Patent No. 7,723,390 ('390 patent) is directed to delivering precise doses of the thyroid hormone levothyrozine, which is delivered via soft gel capsules that improved bioavailability and reduced degradation as compared to conventional tablet forms.
- The '390 patent matured from a US Application that claimed priority to an Italian Application.

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IBSA's Patent (US 7,723,390)

- Claim 1, which is the sole independent claim of the '390 patent, claimed:

- A pharmaceutical composition comprising thyroid hormones or their sodium salts in the form of either:

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IBSA's Patent (US 7,723,390)

- 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

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IBSA's Patent (US 7,723,390)

- 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.

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District Court Case

- The District Court case proceeded in the District of Delaware under Judge Richard G. Andrews, and was decided on August 20, 2019.
- IBSA sells the invention of the ‘390 patent in the US as Tirosint®, that provides precise doses of the thyroid hormone levothyrozine, and which is listed under FDA’s Approved Drug Products with Therapeutic Equivalence Evaluations (the “Orange Book”).

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District Court Case

- Teva filed an Abbreviated New Drug Application (“ANDA”) to sell a generic version of Tirosint®, and submitted a certification that the ‘390 patent is invalid, unenforceable or will not be infringed by Teva’s generic product, and IBSA sued for infringement.

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District Court Case

- “In the District Court, 5 claim terms were disputed, and all but the term “half-liquid” were found to be definite either by way of the District Court providing the claim construction or giving its plain and ordinary meaning.

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District Court Case

- Regarding the term “half-liquid”,
- IBSA proposed the construction of:
- Plain and ordinary meaning: semiliquid, i.e., having a thickness consistency between a solid and a liquid.

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District Court Case

- Teva proposed the construction of:
- Indefinite. Alternately, “a non-solid, non-paste, non-gel, non-slurry substance”.

- The District Court’s construction was:
- Indefinite.

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District Court Case

- The District Court, relied on Supreme Court's holding in Nautilus, Inc. v. Biosig Instruments, Inc., that "[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" in its decision that "half-liquid" is indefinite.

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District Court Case

- The District Court looked at 4 factors.
- 1) Specification (Intrinsic evidence)
- 2) Prosecution History (Intrinsic evidence)
- 3) Extrinsic Evidence
- 4) Reasonably Certain

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District Court Case (Specification)

- The District Court rejected IBSA's argument a "plain and ordinary meaning" construction of "half-liquid" is synonymous with "semi-liquid" based on a person of ordinary skill (POSA) looking at the Italian priority application's use of "semiliquido". The District Court decided that the Italian Priority application is minimally probative, since an external evidence in the form of a new translation that was submitted during litigation had differences in other portions from the US application,

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District Court Case (Specification)

- so that the original translation that became the US application would be most relevant translation for claim construction, and even in the original translations, the original translator was aware of the difference between “half-liquid” and “semi-liquid” when the translator chose to use “half-liquid” instead. Thus, the District Court gave no weight to evidence regarding the disclosure of the Italian priority document.

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District Court Case (Prosecution History)

- The District Court reviewed the prosecution history, and found that IBSA had proposed dependent claims reciting semi-liquid off of claim 1, but then later canceled that claim, without replacing “half-liquid” with semi-liquid. Based on this, the District Court decided that IBSA was aware of the term semi-liquid, but chose not to use semi-liquid in the claims.

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District Court Case (Extrinsic Evidence)

- The District Court decided that use of an 1896 dictionary definition of semiliquid was contrary to the requirement that the meaning of the claim term to POSA should be based at the time of invention.

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District Court Case (Extrinsic Evidence)

- The District Court decided that several patents describing pharmaceutical composition in “half-liquid bases” were of different context and word combinations from the ‘390 patent’s use of the term “half-liquid” which showed that the term “half-liquid” was not a term of art at the time of invention.

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District Court Case (Extrinsic Evidence)

- The District Court decided that, as an expert's opinion that "half-liquid" was synonymous to "semi-liquid" was drawn from a review of the 1896 dictionary definition and the several patents that the District Court found unpersuasive, the expert's opinions was not to be given any weight.

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District Court Case (Reasonably Certain)

- From the review of the specification, the prosecution history, and the extrinsic evidence such as the dictionary, and the expert testimony, the District Court decided that the POSA is unable to know that is meant by a “half-liquid” with reasonable certainty.

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District Court Case (Conclusion and ruling)

- Based on these analyses, the District Court found that asserted claims 1, 2, 4, and 7-9 were held indefinite on the grounds that IBSA's construction lacked support on the intrinsic evidence and there was no basis in the prosecution history to construe the claims as IBSA argued.

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Federal Circuit

- The Federal Circuit case proceeded under Judges Prost, Reyna and Hughes, and was decided on July 31, 2020.

- In IBSA's appeal of the District's Court's decision that "half-liquid" was indefinite, the Federal Circuit affirmed the District Court's decision, even after analyzing the intrinsic and extrinsic evidences de novo.

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Federal Circuit

- First, the Federal Circuit turned to the language of the claim, and noted that the term “half-liquid” is used alongside a liquid, so that the claim language only clarifies that a “half-liquid” differs from a liquid.

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Federal Circuit

- Second, the Federal Circuit turned to the Specification, and noted that the specification describes a soft capsule containing 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 the possible excipients in suspension or solution, to make a determination that half-liquid is not, or at least not necessarily a gel or a paste.

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Federal Circuit

- Further, the Federal Circuit found that use of the disjunctive ‘or’ showed that the list including the half-liquid is a series of alternatives, and since pastes or gels have a thick consistency between a solid and a liquid, IBSA’s claim construction would be at odds to the list as being alternatives and create uncertainty.

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Federal Circuit

- Third, the Federal Circuit turned to the prosecution history, and noted that differences existed between the US Application and the Italian Application, such as the presence of the term “gel” in the US application, but lack thereof in the Italian Application, and the scope of claim 1 in the US Application reciting an embodiment that is not disclosed in the Italian Application,

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Federal Circuit

- so that the Federal Circuit confirmed the District Court's decision that the changes to the US Application can be seen as intentional, and that use of the term "half-liquid" in the US Application can be implied as intentional.

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Federal Circuit

- Regarding IBSA's argument that weighing the discrepancies unfairly subordinate a foreign priority application and amounts to refusal to a foreign priority document, the Federal Circuit disagreed, noting that Abbott Labs v. Sandoz, Inc, decided that, when discrepancies between a foreign priority document and the US filing exits, it may be proper to view the discrepancies as intentional.

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Federal Circuit

- Further, the Federal Circuit noted the proposal of a new dependent claim reciting “semi-liquid” which was ultimately canceled during prosecution, was additional evidence of “half-liquid” being different from “semi-liquid”.

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Federal Circuit

- Fourth, the Federal Circuit turned to external evidence in the form of expert testimony and four patents, and decided that the expert was unable to articulate the boundary of what constitutes a “half-liquid”, and the four patents used “half-liquid” in a different context from that of the ‘390 patent so that the four patents did not help define “half-liquid” in the ‘390 patent context.

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Federal Circuit

- Based on the review of the internal and external evidences, the Federal Circuit held that there was no clear error in District Court's decision that "half-liquid" is indefinite, and the District Court's decision was affirmed.

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Writ of Certiorari to the Supreme Court

- IBSA has petitioned to the U.S. Supreme Court for Writ of Certiorari, seeking grant to announce a rule that the US is obligated under the Agreement on Trade-Related Aspects of Intellectual Property Rights (the TRIPS agreement) that,

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Writ of Certiorari to the Supreme Court

- *foreign language 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.*

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Writ of Certiorari to the Supreme Court

- IBSA frame the question as:
- 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.

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Writ of Certiorari to the Supreme Court

- IBSA articulated the reasons for granting the petition as:
- 1) Given, the US must treat foreign inventors the same as US inventors their application under treaty obligations, and

- 2) given, the US-through the TRIPS agreement and Paris Convention-is obligated to recognize a foreign priority date for Applicants of member countries,

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Writ of Certiorari to the Supreme Court

- 3) the District Court and the Federal Circuit improperly subordinated the IBSA inventor's Italian Application to its English translation, when use of "half-liquid" rather than "semi-liquid" was a mistranslation, and other than one additional embodiment in the US Application reciting an embodiment that is not disclosed in the Italian Application, the US Application and the Italian Application are nearly identical, especially the location in the specification of the US Application for the term "half-liquid" to that of the Italian Application for the term "semi-liquido".

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Writ of Certiorari to the Supreme Court

- Thus, the Italian Application is a critical piece of evidence for claim construction, and should be treated as intrinsic evidence for purposes of prosecution history, especially since under the TRIPS agreement and Paris convention, it is the Italian Application that should be treated as the true record of the inventor's invention.

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Writ of Certiorari to the Supreme Court

- Using differences between the US and Italian Applications as intent to claim a different invention in the US was erroneous by the Federal Circuit.

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Other Remedies

- After the adverse decision in the Federal Circuit, IBSA attempted to remedy the situation by the following:

- 1. Certificate of Correction filed in the ‘390 patent to replace every occurrence of “half-liquid” with “semi-liquid” based on support from Italian Priority Application.
- Result – Accepted.

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Other Remedies

- 2. Filing of a Reissue Application.
- Based on error by reason of the patentee claiming more or less than he had the right to claim in the patent.
- Inclusion of new claims 11-15 that remove the alternatives that recite “half liquid”.

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Other Remedies (Reissue Application-New claim 11)

- 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.]]
- Result – Pending.

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Questions?

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