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IP NEWS

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Federal Circuit: ITC Did Not Err in Denying Non-Respondent's Petition To Rescind Exclusion Order Based on Invalidity Grounds

On July 16, 2020, a Federal Circuit panel of Judges Lourie, Linn, and Wallach, issued an opinion, authored by Judge Lourie, in *Mayborn Grp. Ltd., et al. v. ITC*, Case No. 2019-2077. The panel affirmed the International Trade Commission's (ITC) decision denying Mayborn Group, Ltd. and Mayborn USA, Inc.'s (collectively Mayborn) petition for rescission of a general exclusion order prohibiting importation of products that infringe U.S. Patent No. 8,028,850 (the '850 patent). Slip Op. at 2.

In the ITC proceeding, the complainants asserted infringement of their '850 patent against several respondents, not including Mayborn. *Id.* at 2-3. At the conclusion of its investigation, the ITC determined that two respondents infringed claim 1 of the '850 patent and issued a general exclusion order. *Id.* at 3. The respondents had not raised an invalidity challenge. *Id.* The complainants then notified Mayborn that its products infringed the '850 patent in violation of the exclusion order. *Id.* In response, Mayborn petitioned the ITC to rescind its order pursuant to its power under 19 U.S.C. §1337(k)(1), which allows the ITC to rescind or modify an order if "the conditions which led to such exclusion from entry or order no longer exist." *Id.* at 3-4. Mayborn argued that this requirement was satisfied because claim 1 of the '850 patent is invalid under 35 U.S.C. §§102, 103. *Id.* at 4. The ITC denied Mayborn's petition, holding that a petitioner's asserted discovery of invalidating prior art after issuance of an exclusion order is not a changed condition under §1337(k)(1). *Id.* On appeal, Mayborn argued that the ITC erred in rejecting its petition for rescission, and the ITC argued that Mayborn lacks standing to appeal the ITC's denial of Mayborn's petition because Mayborn continues to import the accused products and thus lacks the requisite injury. *Id.*

The Federal Circuit found that Mayborn had standing to appeal. *Id.* at 5. Any person may petition the ITC for rescission or modification of an exclusion order, provided that there is a case or controversy for which federal courts have jurisdiction under Article III of the U.S. Constitution. *Id.* The court found that Mayborn had shown it suffered injury in fact as a result of the exclusion order because Mayborn imports products that potentially infringe the '850 patent and thus violate the exclusion order. *Id.* at 6.

On the merits, however, the Federal Circuit ruled in favor of the ITC. *Id.* at 8. The ITC may act only pursuant to power granted to it by Congress. Under §1337(b), the ITC may investigate violations of §1337(a) and may conduct proceedings to enforce an existing exclusion order. *Id.* The court explained that the ITC may adjudicate patent validity only when it is raised as a defense by a respondent in the course of an investigation, which did not occur here. *Id.* at 8-9. And, under §1337(d)(1), the ITC must enter an exclusion order upon a finding of a violation unless the public interest weighs against it. *Id.* at 10. The court found that Mayborn did not establish that the public interest favors rescinding or modifying the exclusion order. *Id.* Accordingly, the ITC's denial of Mayborn's petition was affirmed. *Id.* at 11.

Federal Circuit: District Court Did Not Err in Ruling that 'Half-Liquid' Is Indefinite

On July 31, 2020, a Federal Circuit panel of Chief Judge Prost

and Judges Reyna and Hughes, issued an opinion, authored by Chief Judge Prost, in *IBSA Institut Biochimique, S.A., et al. v. Teva Pharms. USA, Inc.*, Case No. 2019-2400. The panel affirmed the United States District Court for the District of Delaware's decision 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. Slip Op. at 2.

IBSA Institut Biochimique, S.A., Altergon, S.A., and IBSA Pharma Inc. (collectively, IBSA) are the assignees of the '390 patent, which claims priority from Italian Patent Application No. M12001A1401 (the Italian Application), written in Italian. 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, which is a soft gel capsule formulation containing the active ingredient levothyroxine sodium. *Id*. Teva Pharmaceuticals USA, Inc. (Teva) sought to market a generic version of Tirosint and filed Abbreviated New Drug Application (ANDA) No. 211369. *Id*. 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, and will not be infringed by Teva's generic product. *Id*. at 2-3. IBSA, after receiving notice of Teva's Paragraph IV certification, filed suit, ultimately alleging infringement of claims 1, 2, 4, and 7-9 of the '390 patent. *Id*. at 3.

The dispute on appeal centered around the construction of "half-liquid," which is recited in claim 1 — the independent claim from which claims 2, 4, and 7-9 ultimately depend. *Id*. IBSA proposed that "half-liquid" should be construed to mean "semi-liquid, *i.e.*, having a thick consistency between solid and liquid." *Id*. Teva argued that the term is indefinite or, alternatively, should be construed as "a non-solid, non-paste, non-gel, non-slurry, non-gas substance." *Id*. The district court held claims 1, 2, 4, and 7-9 invalid as indefinite. *Id*. at 4.

The Federal Circuit began with a review of the intrinsic record, which the parties agreed does not define "half-liquid." *Id*. at 4, 8. One passage of the patent specification states that the "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 …." *Id*. The Federal Circuit agreed with the district court that this and a similar passage indicates a half-liquid is distinct from a gel or a paste. *Id*. Yet because gels and pastes have a thick consistency between a liquid and a solid, they would be included in IBSA's proposed construction. *Id*. at 8-9. This inclusion, the court found, is at odds with the passages and creates uncertainty as to the bounds of a "half-liquid." *Id*. at 9. ISBA pointed to the facts that the Italian Application uses the term "semi-liquido" in the same places where the '390 patent uses "half-liquid" and that a certified translation of the Italian Application prepared for IBSA in 2019 uses "semi-liquid." *Id*. The court disagreed that this indicated the two terms are synonymous. *Id*. at 10. There were a number of differences between the Italian Application and the '390 patent, which were found to reflect an intention to use different terminology. *Id*. Additionally, during prosecution, the applicant had a pending claim reciting "half-liquid," and another claim, depending from that claim, reciting "semi-liquid." This indicated that there is a difference between the two terms. *Id*. at 11.

The Federal Circuit found that the extrinsic evidence also failed to support IBSA's proposed construction. *Id*. at 13. IBSA's expert could not articulate a boundary for "half-liquid" and could not explain how a skilled artisan would know whether certain matter is a "half-liquid." *Id*. at 12. He also testified that "semifluid" and "half-liquid" are not necessarily synonymous and that he was not sure whether his construction of "half-liquid" would include certain types of gels and slurry. *Id*. at 12, 13. Also, most of the dictionaries cited by IBSA did not define "half-liquid" as "semi-liquid." *Id*. at 12. Upon holding that the intrinsic and extrinsic evidence fail to inform, with reasonable certainty, those skilled in the art about the scope of the invention, the district court's judgment was affirmed. *Id*. at 13.

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