



Expert Contributor

The Right (Legal Standing) To Claim Nullity of a Pharma Patent

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The decree published in the Official Gazette of the Federation on Sept. 19, 2003, added section IV of article 167 and article 167 bis of the Health Supplies Regulation were added, as well as article 47 bis. In Mexico, the requirement for filing a claim for the nullity of an industrial property right before the Mexican Institute of Industrial Property (IMPI) is to demonstrate that one has a legal standing to do so. In the case of pharmaceutical patents, this is not free, since it derives from the rights protected and safeguarded by the extinct Industrial Property Law (article 188) and the new Federal Law for the Protection of Industrial Property (article 329), relating to the property and exclusive rights of individuals. To ensure legal certainty, their rights can only be challenged by someone who has a legal standing and basis for the claim, for which a legitimate or simple interest is not enough, since said interest applies to other types of acts that affect the community, such as health laws, where said simple, group or legitimate interest is recognized in popular or group actions; however, that is not the case provided for in the Industrial Property Law.

For many years, pharmaceutical companies, mainly in the generics sector, have successfully filed actions to nullify pharmaceutical patents. That is, they were not filed as counterclaims to an infringement action, but directly alleging that their legal standing comes from their belonging to a group or sector, in this case the pharmaceutical sector, based on certain theses supported in this regard by the judiciary, which recognizes the possibility of a substantive study due to belonging to a qualified and relevant group.

In my opinion, such interest, even if it is a group interest, requires proof of direct damage by the act of the authority, since it is not enough to prove involvement in a sector to demonstrate the impact of the act, since the damage, grievance or prejudice in the sphere of rights of the governed is required, because otherwise, the required legal security could not be given to the holder of acquired rights, but

mainly to the holder of an exclusive right protected constitutionally, since any third party, alleging a simple or group interest without any direct damage, could question this right, forcing the holder of the acquired right and with a presumption of validity, to respond and participate in an administrative and contentious procedure instituted with frivolous and unproven interests.

In this regard, the IMPI considered that the legal standing was proven by exhibiting the articles of incorporation in which it was stated that the industrial and commercial activity was related to the pharmaceutical industry, and that this was sufficient to prove a right incompatible with the patent holder in the field of pharmaceutical technology.

Our firm insisted before the courts that the industrial and commercial activity of a pharmaceutical company did not prove the existence of real damage or direct interest in relation to the existence of a certain product or technology protected by a patent in the pharmaceutical field to be considered as a legal standing in terms of the applicable provisions of the Industrial Property Law.

Thus, in 2019, the Specialized Chamber on Intellectual Property of the Federal Administrative Court of Justice (TFJA) ruled that the plaintiff in a patent invalidity action should have demonstrated before IMPI a direct affectation, whether a patent right, an enforceable right, or an expectation of right in relation to the patent in question, a criterion that was confirmed two years later by a Circuit Court on Administrative Matters, which also considered it inappropriate to affirm that all persons or companies dedicated to the pharmaceutical industry could claim the invalidity of a patent without demonstrating real and direct damage derived from the claimed patent.

The above motivated IMPI to modify its criteria when analyzing the defense of lack of legal standing in actions for the nullification of pharmaceutical patents, resolving that they lacked legal standing, which was confirmed consistently by the TFJA Chamber and by several Circuit Courts in Administrative Matters.

However, said determination continued to be the subject of challenges by the affected companies, under the argument that article 188 of the Industrial Property Law, which mandates as a procedural requirement the demonstration of having legal standing to file a patent invalidity action, is unconstitutional as it violates the right of access to effective judicial protection.

In January 2024, the Second Chamber of the Supreme Court resolved to confirm in one of the disputes we handle the criterion of the circuit courts under the consideration that “being a commercial competitor does not generate a legal standing to initiate administrative declaration procedures before IMPI,” specifying that the right of access to judicial protection recognized in the

Constitution is not unlimited for individuals, and that the conditions for resorting to an administrative procedure do not translate into restrictions, but rather, obey a normative system that justifies them, which in turn guarantees the principle of legal certainty for all parties. This means that the legal standing must be evidenced and that by definition it excludes the simple or group interest. This resolution motivated the following jurisprudence to be supported by contradiction: 2nd / J.38 / 2024 (11th). "PATENTS. ARTICLE 188 OF THE INDUSTRIAL PROPERTY LAW, BY ESTABLISHING THE LEGAL STANDING AS A REQUIREMENT TO INITIATE THE ADMINISTRATIVE DECLARATION PROCEDURE AT THE REQUEST OF A PARTY, RESPECTS THE RIGHT TO EFFECTIVE JUDICIAL PROTECTION (LEGISLATION IN FORCE UNTIL 2020)."

Likewise, the First Chamber of the Supreme Court had to hear another of these cases, in which the unconstitutionality of the same article was claimed, alleging, among other things, that said differentiated interest should be assessed because it belongs to the pharmaceutical industry and that through said provision the principle of progressivity is violated.

In this regard, the First Chamber ruled that the principle of progressivity is not violated because the extinct Law of Inventions and Trademarks did not foresee a legitimate interest to be considered regressive to the norm of the Industrial Property Law and that, in fact, the new Federal Law of Protection of Industrial Property, in article 329, maintains the same level of requirement.

Likewise, it considered that being a commercial competitor of the same industry does not generate a legal standing to initiate a procedure for an administrative declaration of invalidity, since it must have tangible effects on the legal sphere of the person requesting it, confirming the constitutionality of article 188 of the Industrial Property Law and, although article 329 of the new law on the subject was not the subject of analysis, it did consider that it contains the same procedural requirement to justify an invalidity action, so it would also be applicable to this new provision.

I share the criterion adopted by both Chambers of the Supreme Court, because, procedurally speaking, it is indisputable in light of the normative bodies analyzed that the exercise of any action necessarily requires the existence of a legally protected legal interest.

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