



Expert Contributor

Infringement of Pharma Process Patents, Recent Mexico Precedents.

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Article 192 Bis 1 of the abrogated Industrial Property Law establishes that, when the patent subject to analysis in an administrative declaration of infringement procedure is a process for obtaining a product, by legal mandate, the burden of proof is reversed, and, consequently, it is the alleged infringer who must prove that the questioned product was manufactured under a process other than the one patented.

The inclusion of this article expressly addresses the Mexican state's obligation to harmonize its domestic legislation with the provisions contained in the International Treaties to which Mexico is a party, primarily in relation to the provisions of Article 34 of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and paragraph 11 of Article 1709 of the North American Free Trade Agreement.

This is due, among other reasons, to the difficulties in accessing technical information and evidence used to produce a product that is presumably the result of applying a patented procedure, without the application of the procedure having been authorized by the patent holder.

Forcing the patent holder, in order to succeed in his infringement action, to prove that the product imported, manufactured, commercialized or used by the defendant has been obtained precisely by applying the patented process and not by using any other process is to place him before a true "impossible proof," since the analysis of the product does not generally provide data to determine the process by which it was manufactured.

Therefore, the difficulty for the holder of a process patent in proving infringement of its patent in a proceeding makes the reversal of the burden of proof necessary to prevent unlawful conducts sanctioned by law from going unpunished due to the alleged infringer's refusal and lack of evidence of "not using the protected process."

This practical problem was precisely what motivated the introduction of the legal concept of "reversal or inversion of the burden of proof for process or procedure patents" in the TRIPS, which implies that

judicial authorities will be empowered to order the defendant to prove that the procedure for obtaining a product is different from the patented procedure, and that the defendant will have the burden of proving that the allegedly infringing product was made by a process other than the patented one, when one of the following normative assumptions is applicable:

1. the product obtained by the patented process is new, or
2. where there is a significant probability that the allegedly infringing product was manufactured using the process and the patent holder has not, through reasonable efforts, been able to establish the process actually used.

However, contrary to what is provided therein, Article 192 Bis 1 of the Industrial Property Law establishes that the reversal of the burden of proof is conditioned to the applicability of the two normative hypotheses detailed above, this to the detriment of the holder of an exclusive right in an infringement action brought before the Mexican Institute of Industrial Property (IMPI), because it requires it to prove two assumptions at the same time when said treaties establish that either of the two must be proven.

This contravention was the subject of analysis by the Supreme Court of Justice in an appeal for review filed by OLIVARES, where the Second Chamber, in a session dated Feb. 7, 2024, resolved to declare the unconstitutionality of Article 192 Bis of the Industrial Property Law under the consideration that the content of international treaties should be privileged, which establish that when the subject matter of a patent is a process in an infringement procedure, the defendant will have the burden of proving that the infringing product was made by a different process, and only compliance with one of these hypotheses should be required in order to reverse the burden of proof, so it will be sufficient for the aggrieved party to demonstrate that one of the two assumptions is met.

Thus, the Second Chamber of the Supreme Court considered that the inclusion of the conjunction “and” in the text of Article 192 Bis 1 is incorrect and contrary to the provisions of Article 34 of the TRIPS and Article 1709 of the North American Free Trade Agreement, regulatory devices where it is expressly stated that the reversal of the burden of proof is applicable as long as one of the circumstances provided for in Sections I and II of the article being challenged is met, making use of the conjunction “or” in both cases.

The new Federal Law for the Protection of Industrial Property, which came into force on Nov. 5, 2020, and which abrogated the Industrial Property Law, corrected this legislative error and, in accordance with the provisions of Article 34 of the TRIPS and paragraph 11 of Article 1709 of the North American Free Trade Agreement, modified the inclusion of the conjunction “and” for the conjunction “or” when referring to said normative hypotheses.

However, there is an underlying failure to comply with a portion of this international commitment, in that the Mexican authorities do not have the power to order the defendant to prove that the procedure for obtaining a product is different from the patented procedure.

That is, the abrogated Article 192 Bis 1 of the Industrial Property Law and the current Article 335 of the Federal Law for the Protection of Industrial Property do not establish, – either expressly or implicitly –, the power of the Mexican authorities to order that, in any process patent infringement

procedure, the defendant must prove that the procedure for obtaining its product is different from the patented procedure.

As we have mentioned at the supranational level, Mexico has agreed not only to the rule of reversing the burden of proof to the defendant, but also to the power of the Mexican authorities to order the defendant to prove that the process for obtaining a product is different from the patented process, when the subject matter of a patent is a process for obtaining a product.

This figure, which is not incorporated in our domestic law, constitutes a protection mechanism for patents that protect manufacturing procedures and that must be analyzed from a double dimension, which consists not only in transferring the burden of proof to the defendant, but in order to make this mechanism effective and materialize it in a trial, it is only possible to do so through an express requirement from the administrative authority to the defendant so that the defendant provides convincing and conclusive evidence that proves that its process is different, regardless of whether the defendant files ex officio evidence as happens in most cases, since through the requirement emanating from the authority, the evidentiary logic changes substantially, because the requirement entails an obligation to comply with it, while the mere allegation and exhibition of exculpatory evidence in the response to the action are arguments presented under convenience, without warning by law and without having the obligation to demonstrate before the authority the substantial differences between the procedures.

This is why there is a clear interrelationship between the reversal of the burden of proof and the requirement to prove that it does not infringe, since the standard or level of proof required in the reversal of the burden of proof will depend functionally on the requirement of the authority and not on the evidentiary will of the defendant.

Hence it can be stated that, as long as there is no obligation in the law that allows the authorities to require the alleged infringer to demonstrate the process under which a product is manufactured, in our patent system will remain the easy defense for this and the cases that follow, when the defendant is the manufacturer of the product itself, despite the fact that the manufacturer knows better than anyone the procedure used, it will exhibit the information that suits the case and will point out that it is an industrial secret, meaning it will not be analyzed under any type of evidentiary standard, because there was no requirement and reversal of the burden of proof and under these circumstances, it will be impossible to prove an infringement of a process patent in Mexico.

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