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Double patenting and lack of support: Obstacles or opportunities?

There are still some gaping gray areas in Mexican Patent Law, particularly when it comes to Double Patenting. But within these gray areas lie opportunities to discuss and define an innovative sector of the law. Sergio Olivares Jr and Mauricio Sámano explain...

I. Introduction

In recent years, applicants who seek to protect their pharmaceutical, chemical and biotechnological inventions in Mexico have been forced to deal with two major objections: double patenting and lack of support.

A double patenting objection is raised when an Examiner considers that the matter claimed in a subsequent divisional application is already covered by the parent case, in order to avoid the issuance of more than one patent for the same invention. A lack of support objection is raised when an Examiner considers that the matter contained in the description of a patent application does not enable a person of ordinary skill in the art to carry out the invention that is sought to be protected. In this regard, it

is important to mention that the lack of support criteria which Examiners are now expected to follow has also been changing. We will discuss this further later in this article.

II. Legal framework

II.a) Double patenting

Mexican Industrial Property Law (hereinafter referred to as 'IPL') does not have a specific provision that prohibits double patenting. However, the Mexican Institute of Industrial Property (hereinafter referred to as 'IMPI') applies the criteria applied by most patent systems which is that two patents cannot be granted for the same invention.

The basis for the criteria applied by IMPI is that an applicant has no legitimate interest in the proceedings that lead to the granting of a second patent for the same subject matter if he already possesses one granted patent for said matter. In this regard, it is important to point out that a double patenting objection is raised only in relation to a parent and its divisional application.

Unlike US patent law which expressly defines double patenting and specifically mentions that there are two different types of double patenting rejections ('same invention' type double patenting and 'non-statutory' type double patenting), the IPL does not expressly define double patenting. This can lead to a series of different interpretations with each Examiner giving their specific prohibitions, creating an inherent uncertainty around the double patenting issue.

II.b) Lack of support

The legal basis for a lack of support objection may be found in Sections I and III of Article 47 of the IPL and Section VII of Article 28 of the Regulations to the Mexican Industrial Property Law. Sections I and III of Article 47 of the IPL mention the following:

Résumés

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Sergio joined Olivares in 1987, becoming a partner in 1994 and Chairman of the Management Committee in 2009. He leads the firm with strength and a commitment to transparency, client satisfaction and personal service.

His work at Olivares is extensive, and he has vast experience in the prosecution and litigation of intellectual property rights, particularly trademarks, copyrights, patents and unfair competition. He has specialized his practice in all types of intellectual property law, but works closely with the Patent Group and is highly recommended by leading industry titles and rankings as a leader in IP.

Mauricio Sámano

Mauricio joined Olivares in 2012. His work mainly focuses on prosecuting chemical, pharmaceutical and biotechnological patent applications before the Mexican Institute of Industrial Property. He also has experience in drafting patent applications, patent portfolio management, freedom to operate studies, and providing technical opinions regarding patent infringement. Mauricio has also given lectures in international congresses regarding Mexican patent practice.



Article 47 - The patent application shall be accompanied by...

"I. A description of the invention, which shall be sufficiently clear and complete to be fully understood and, where appropriate, to serve as a guide for a person with average skill in the art to make it; it shall also mention the best method known to the applicant of carrying out the invention, when this is not clear from the description of the invention..."

"III. ...one or more claims, which shall be clear and concise and may not exceed the contents of the description..."

Furthermore, Fraction VII of Article 28 of the Regulations to the Mexican Industrial Property Law specifies that the applicant must indicate the best known method for carrying out the invention and, when appropriate, said indication must be made by means of practical examples or specific applications of the invention. Based on this legal framework, IMPI's current practice requires the applicant to demonstrate by means of practical examples which must be contained in the description, that the claimed matter has a surprising or unexpected effect from that which has been disclosed in the state of the art.

III. Double patenting in practice

Although, as previously mentioned, the IPL does not specifically contemplate a provision prohibiting double patenting, there are certain considerations that Examiners apply when issuing a double patenting objection. Specifically, Examiners analyze the scope of the matter granted in the parent case as well as the scope of the matter that the applicant is pursuing in the subsequent divisional application, and verify whether there is an overlap in the scope of protection. In other words, if the parent case protects a series of chemical compounds and the subsequent divisional application claims a series of chemical compounds wherein some of these compounds fall within the scope of the compounds claimed in the parent case, the Examiner will issue a double patenting objection.

By the same token, it is important to consider that a selection invention would be an exception to this criteria. Namely, if the applicant demonstrates that a specific chemical compound that is sought to be protected in a divisional application and which falls within the scope of the chemical compounds granted in the parent case, has a surprising and unexpected technical effect which could have not been deduced from the parent case or from any state of the art document, it is very likely that the Examiner will not issue a double patenting objection. In this case, it is possible that the Examiner will request the respective experimental evidence that demonstrates said surprising and unexpected technical effect.

There are certain aspects that the applicant must consider when filing this additional experimental evidence, which will be discussed below.

III.a) How to avoid double patenting

We normally recommend an adequate strategy when filing a divisional application. Namely, the matter claimed in the divisional application must refer to a completely different invention than the one protected in the parent case and the matter of said divisional must also be duly supported and exemplified by the originally filed description. In this respect, it is important to mention that there are specific timelines for filing divisional applications in Mexico.

In case the Examiner issues a restriction requirement, the applicant is required to submit the divisional application simultaneously with the response to the office action in which the Examiner issued said restriction requirement. Examiners support this practice under the interpretation of Article 44 of our Domestic Patent Law¹, which establishes the strict compliance of the restriction requirement. The failure of complying with said restriction requirement will result in the abandonment of the application. However, it is worth noting that the interpretation of Article 44 is still under discussion.

In the case of voluntary divisional applications, the Mexican Industrial Property Law does not specifically contemplate said voluntary divisional applications. Nevertheless, pursuant to article 4-G(2) of the Paris Convention², the applicant has the opportunity of voluntarily filing a divisional application as long as the parent case is pending. Therefore, the applicant can file voluntary divisional applications at any time before the grant of the application. In this respect, it is important to note that the date of grant is that in which the final fees

¹ If the application does not meet the provisions of the previous Article (unity of invention), the Institute shall notify the applicant in writing so that within a period of two months, he may divide it into several applications, retaining as the date of each one that of the initial application and that of any recognized priority. If, on expiration of the period allowed, the applicant has not divided the application, it shall be considered abandoned.

Where the applicant complies with the provisions of the previous paragraph, the divisional applications shall not be published as provided for in Article 52 of this Law.

² Due to a reform made on June, 2011 on Mexico's Constitution, Human Rights International Treaties have a superior hierarchy than domestic laws. Since Mexico's Supreme Court considered that Intellectual Property treaties are Human Right treaties, Intellectual Property treaties such as the Paris Convention or the PCT have a superior hierarchy than our domestic laws.

of the pending application have been paid. Some Examiners however, consider that the date of grant is that in which the Notice of Allowance is issued.

Notwithstanding, from our point of view said appreciation is incorrect because the application is still pending as long as the final fees have not been paid.

If a divisional application is rejected because the notice of allowance of its parent case has been issued, the applicant can challenge this decision through two possible venues: a revision recourse filed before IMPI itself and/or a nullity appeal which is filed before a court of law, specifically before the Federal Court of Tax and Administrative Affairs (FCTA).

With this in mind, it is important to consider that if the applicant has not decided which matter he wishes to pursue in the divisional application, it is possible to file the original PCT set of claims in said divisional and, afterwards, once he has defined the matter he seeks to pursue, the applicant can file a voluntary amendment before the issuance of the first office action. Typically, the first office action for a divisional application issues from around 8 to 14 months after the filing date of said divisional and thus, the applicant has plenty of enough time to define the matter they seek to pursue in said divisional application.

Likewise, in practice, double patenting objections can be addressed by making a pre or post grant amendment in the earlier case (parent case). Therefore, Mexican Patent Law is open to the possibility of making post-grant amendments, but the only possible amendments which can be made to an issued patent are corrections of obvious errors or limitations in the scope of the granted matter.

IV. Lack of support in practice

Mexican Examiners commonly issue 'lack of support' objections as 'lack of clarity' objections. Under domestic practice, Mexican Examiners commonly mention in an office action that the description lacks clarity and that it is insufficient to allow a person of ordinary skill in the art to carry out the invention.

Under IMPI's criteria, 'lack of support' has been changing throughout the years, since previously the Examiners considered that the matter claimed in an application was supported by the mere mention of said matter in the description. Nowadays, mostly in pharmaceutical patent applications³, Examiners strictly apply Fraction VII of Article 28 of the Regulations to the Mexican Industrial Property Law and require that the applicant demonstrates by means of experimental evidence or practical examples that the matter sought to be protected in the claims of the application has a surprising or unexpected effect with respect to that disclosed in the state of the art.

In Mexico, continuations in part do not exist, since it is not possible to add any type of information to the description of a patent application and the only possible amendments that can be made to the description of an application are to correct obvious or typographical errors. This represents a problem for pharmaceutical inventions since, in most cases, the clinical trials were still being developed at the time of the filing of the application and thus, the applicant does not necessarily have all the experimental evidence needed to decide which would be the preferred embodiment of the invention. For example, the ideal dose of a certain substance for treating osteoporosis could have been 50 mg twice a week. But once the clinical trials were finished, the ideal dosage may have turned out to be 100 mg twice a month. Since the IPL does not allow the inclusion of additional information in the description, a claim that claims the 100 mg twice a month dosage theoretically would not be supported in the description. This appears to be a severe disadvantage for applicants who seek to protect pharmaceutical inventions in Mexico.

However, there is a practice that the vast majority of the Mexican Examiners apply in cases when the description is insufficient to support the scope of the claimed matter. In these cases, the Examiners accept the submission of additional experimental evidence in order to demonstrate that the claimed matter is duly supported by means of working examples and provides a surprising and unexpected effect with respect to that disclosed in the state of the art documents. Said additional experimental evidence can be filed as an annex to the response to an office action and IMPI does not request a specific format for the submission of said additional experimental evidence. This practice is becoming more and more common in IMPI and represents a clear advantage for the applicant. However, the applicant must take into consideration that the IPL is completely silent about the submission of additional experimental evidence and that, thus far there are no judicial precedents about this particular issue.

V. Opportunities or disadvantages

It is clear that double patenting and lack of support objections represent a challenge for applicants who seek to protect their pharmaceutical, biotechnological or chemical inventions in Mexico, particularly because there are still many gray areas in Mexican Patent Law with respect to these two issues. However, grey areas also represent opportunities to create important judicial precedents which are relevant in patent practice.

It is true that up to now there have been no judicial precedents that speak of double patenting and lack of support. However, we can establish an analogy with another area in which an important judicial precedent was created. Specifically, one example of a situation where an apparent disadvantage due to gray areas in our domestic Patent Law has turned into an opportunity to have an interesting judicial precedent is when Mexico's Federal Court for Tax and Administrative Affairs (FCTA) made a distinction for the first time between computer programs *per se* and computer-implemented inventions. In this case, a patent application was denied because, according to IMPI, it sought to protect a computer program which is not considered patentable matter according to Section IV of Article 19 of the IPL. However, Mexican Patent Law does not provide a definition of a computer program and much less does it define a computer-implemented invention. After reviewing the case, the FCTA decided to overrule IMPI's previous decision of denying the patent application because they concluded that the matter claimed in said application was in fact a computer-implemented invention and not a computer program *per se*. The importance of the FCTA's decision⁴ was such that, after said decision, IMPI started to make a distinction between computer-implemented inventions and computer programs *per se* and, as a result of this, applicants who seek to protect computer-implemented inventions in Mexico enjoy a more expedite granting of their applications.

Therefore, we believe that the current uncertainty that exists in Mexico with respect to double patenting and lack of support could transform into an opportunity to create a judicial precedent and, thus, provide IMPI with some guidance as to when a double patenting objection can be issued and the regulation of the acceptance of additional experimental evidence to overcome a lack of support objection.

³ Currently, Olivares is among the top three IP firms in Mexico in pharmaceutical patent prosecution and the top Mexican IP firm in pharmaceutical patent litigation.

⁴ On June 2013 in the case IMPI vs. Microsoft, the FCTA ruled in favor of Microsoft and rejected IMPI's previous decision of denying Microsoft's patent application. This case was handled by Olivares' litigation team and was the first judicial precedent in Mexico which made a clear distinction between computer-implemented inventions and computer programs *per se*.