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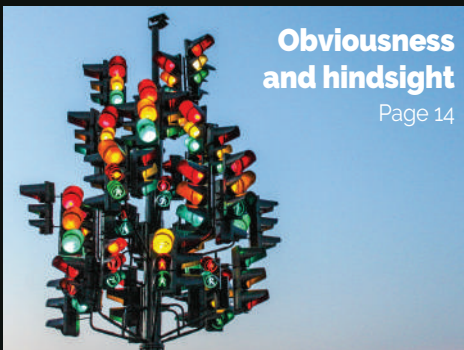
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China's drug Patent Linkage System – is it working?

Dr. Yongqiang Qi, Partner and Patent Attorney at Corner Stone & Partners, evaluates China's drug Patent Linkage System one year on from its implementation to discover some unfortunate failings.



Obviousness and hindsight

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Patent Thickets: change on horizon?

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DEI: disability

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Pain points in the examination of pharmaceutical patents in Brazil

Daniela Fasoli, Partner at Simoes IP Law Firm, reviews analysis from 263 opinions in pharmaceutical patent prosecution cases in Brazil to highlight the greatest problems facing those working to protect their assets.

Prosecuting patent applications in Brazil is a challenge. When the application involves pharmaceutical inventions, the challenge is taken to a different level. Without deeply understanding the history and reasons for the current PTO's strict examination and, most importantly, without staying updated, the results may be frustrating.

Although pharmaceutical inventions share common characteristics with inventions from other fields, there are elements in the prosecution of pharma patent applications in Brazil that are unique. A set of clear criteria to assist in the drafting and prosecution of these applications, considering not only the legislation, but also the PTO's understanding and practice, helps to speed up the examination and offers applicants greater certainty about the possible results of the examination. Therefore, if Brazil is an important country for the object of a patent - and considering that Brazil accounts for approximately 2% of the pharma global market, being the 7th in terms of revenue with a projection of becoming the 5th in 2023 - there are important issues that need to be addressed before even filing in the country.

Due to the differences between the practices of the countries and the radical changes in the treatment of pharma patent applications over the years in Brazil, especially in view of restrictions imposed by the local IP Law, changes in the patent term, interference by the Food and Drug Administration Agency, ANVISA (no longer applicable to new applications) and controversies regarding



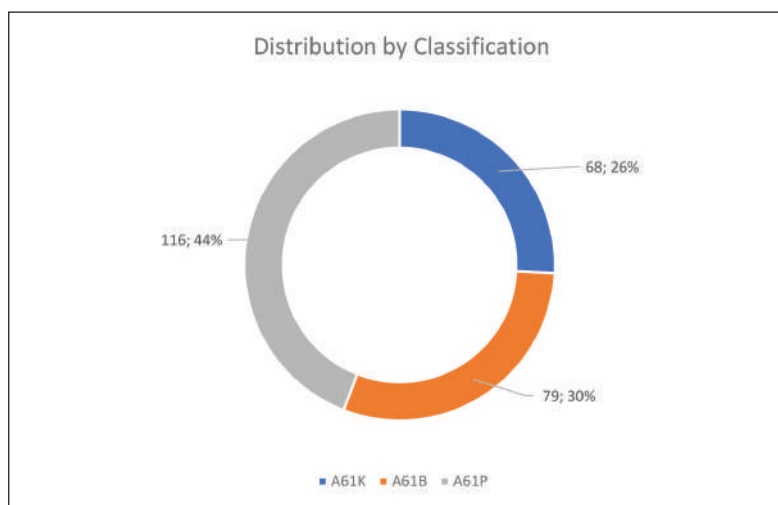
Daniela Fasoli

incremental inventions. Applicants in this technological field face greater obstacles in the drafting and consequent prosecution of their applications when compared to others.

The drafting of pharmaceutical patent applications, especially the set of claims, has a direct impact on the entire examination process - from formal aspects to the final decision - and on the prosecution timeline, with several intermediate opinions, delays and, often, impossibilities of amending the claims to cover the final product of interest in the Brazilian market.

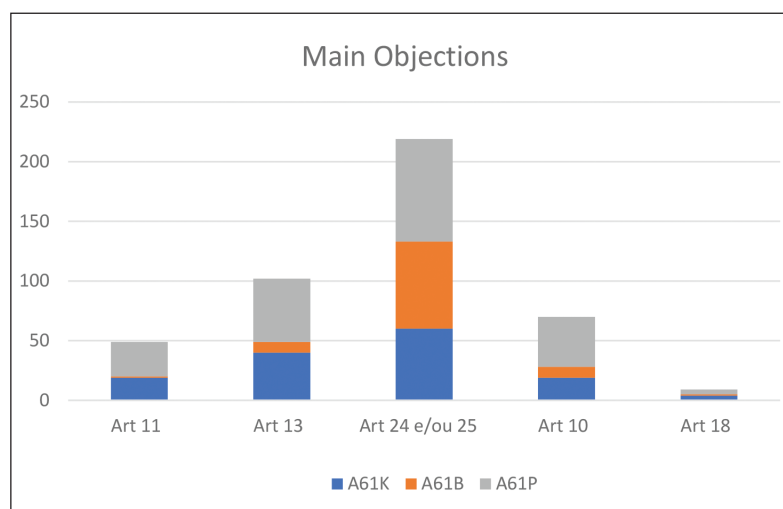
Analyzing office actions

In order to understand how pharma applications are examined, a total of 263 opinions were

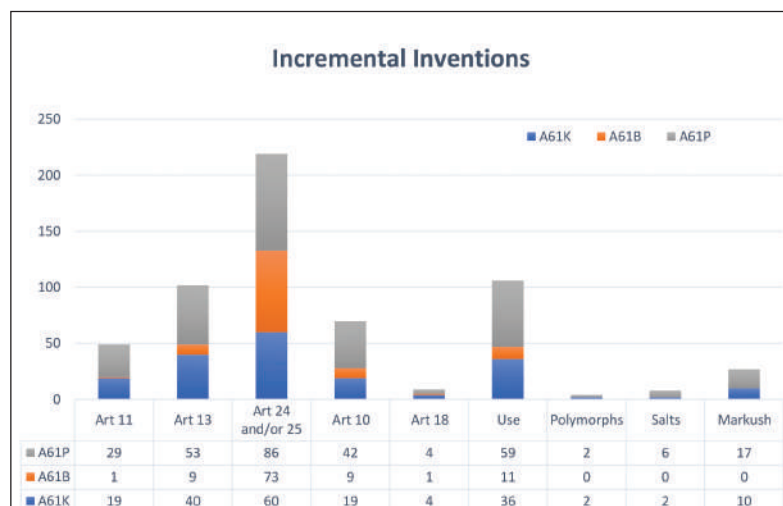


collected and analyzed (most recent opinions available at the BRPTO's website), among which 68 included the A61K classification, 79 the A61B classification and 116 the A61P classification.

Among the main objections found, we have 219 based on lack of support and enablement (articles 24 and/or 25 of the IPL), 102 of lack of inventive step, 70 including the prohibitions of Art 10¹ of the IPL, 49 for lack of novelty, and 9 including the prohibitions of Art 18² of the IPL.



With regard to incremental inventions, the category of "use" being included for containing second medical uses, 106 cases were analyzed with use claims in the set of claims, 27 involving Markush formulas in their set, eight applications claiming salts and four cases involving poly-morphic forms.



Qualitative analysis

A61K and A61P

Most patent applications related to medicines are included in these classifications.

Despite being much discussed and the large amount of literature and guidelines regarding incremental inventions, the total number of

Résumé

Daniela advises global companies on how to protect, defend, enforce, and manage their intellectual property rights. Her practice encompasses all aspects of intellectual property law, including patent drafting and prosecution, IP litigation, validity and infringement opinions, client counselling in intellectual asset management and appeals before the Brazilian Patent and Trademark Office, especially in the fields of pharma, chemistry, biotechnology, oilfield technologies and nanotechnology.

Daniela is often a speaker on panels around the globe discussing topics including the IP landscape in Latin America.

Before joining Simões IP, Daniela worked as a Corporate Director of an international IP Company. She was responsible for managing all IP legal and technical services Departments from 10 countries of Latin America and Europe. As a pharmacist, Daniela also has field experience in the pharma industry.

¹ Article 10 - The following are not considered to be inventions or utility models:
VIII - operating or surgical techniques and therapeutic or diagnostic methods, for use on the human or animal body; and
IX - natural living beings, when found in nature or isolated therefrom, and natural biological processes.

² Article 18 - The following are not patentable:
III - living beings, in whole or in part, except transgenic microorganisms meeting the three patentability requirements - novelty, inventive activity and industrial application - provided for in article 8 and which are not mere discoveries.
Sole paragraph - For the purpose of this law, transgenic microorganisms are organisms, except the whole or part of plants or animals, that exhibit, due to direct human intervention in their genetic composition, a characteristic that can normally be attained by the species under natural conditions.

cases that effectively refer to said inventions was not expressive in the analyzed opinions. The particular analysis of these opinions concluded that there is a tendency towards unspecific objections to the type of invention, and common to other applications on this classification, in particular the lack of enablement and support of the claims.

Precisely, from the reading of the technical opinions issued by the PTO, it is noticed that there is a great difficulty for the applicants to overcome objections related to enablement and support of the claims (Art 24 and 25 of the IP Law). These objections correspond to ~40% of the total of the different types of objections formulated in the opinions analyzed in these classifications.

In the case of national applicants, 81% of all opinions analyzed in the A61K classification and 69% of all opinions analyzed in the A61P classification contained objections based on Articles 24 and 25 of the IPL.

Objections referring to novelty and/or inventive step, in the case of foreign applicants, had similar results to the international phase of said applications - that is, both objections and responses and consequent result/decision, in most cases, were identical compared to examinations carried out in other jurisdictions, especially Europe. This means that the PTO's understanding and practice are similar to the European ones, which makes it easier for international applicants to prosecute their applications in Brazil. No new prior art references were found in any of the analyzed cases, being the references cited in the examination the same cited in the examination of foreign counterparts. The difference is only noticeable in specific cases, in which third party observations were submitted. In a few of the observations, new prior art was cited and subsequently considered by the PTO.

In the case of national applicants, it seems more difficult to file counter arguments to objections regarding novelty and inventive step.

In the A61K classification, 62% of patent applications from domestic applicants had issues related to novelty and/or inventive step versus only 25% for foreign applicants.

A possible explanation for this fact is that the prosecution that took place in other jurisdictions encourages applicants to adapt their patent applications accordingly. This is emphasized nowadays, due to the creation of preliminary opinions.

“ There are elements in the prosecution of pharma patent applications in Brazil that are unique. ”

A61B

As expected, the profile of inventions and, consequently, of the objections formulated by the PTO during the prosecution of patent applications in the A61B classification is different from that found in the opinions of the A61K and A61P classifications.

As such inventions are mostly objects (“medical devices”), no incremental inventions are included. Only a few uses have been identified and, for most, it is only the simple use of the apparatus.

Despite the different profile of the inventions, surprisingly, the results found after a qualitative evaluation of the opinions is quite similar to that found for the A61K and A61P classification cases. Here too, there is a great difficulty for the applicants to overcome objections related to the sufficiency of description and support of the claims (Art 24 and 25 of the IPL). These objections correspond to 92% of the total of the different types of objections formulated in the opinions analyzed in these classifications.



Clarity & enablement

"Clarity and precision" and/or "enablement" are the points that generate most problems in the prosecution of patent applications in the pharmaceutical area, corresponding to more than twice the number of objections to the second most frequent problem (inventive step) in the analyzed opinions.

The difficulty is not unique to the Applicants. In the PTO's technical opinions, a confusion can be seen between the application of articles 24 and 25 by the examiners. Most of the analyzed opinions pointed to the use of both articles, cited together.

According to Art 24 of the IPL, the object of the patent application must be sufficiently described in the specification, in a clear and complete way, in order to allow its reproduction by a skilled person and must contain sufficient conditions that guarantee the reproduction of the invention and, when applicable, indicate the best way of execution.

Art 25 of the IPL, in turn, establishes that the claims must be based on the specification, characterizing the particularities of the application, and defining, in a clear and precise way, the subject matter of protection.

Specifically for pharma cases, the Patent Application Examination Guidelines - Block II - Patentability, established by Resolution No. 169 of 07/15/2016, makes some punctual references to the matter in chapters VI (Markush-type Claims) and VII (Compositions).

According to item 6.9 of chapter VI - Markush-type claims, the sufficiency of description of a group of inventions represented by a Markush formula would only be satisfied if it allowed each invention in the group to be executed by a skilled person, based on the specification, and not just some of the alternatives present in the claims. In this case, it would not be correct to extrapolate that compounds with substituents belonging to different chemical classes could be obtained by the same preparation method, since the nature of the reactions would be different. The PTO goes on to state that the specification should include clear examples of how different substitutes foreseen in the Markush could be incorporated into the final product. This text, as written, has led many examiners to adopt a rather strict stance and led to a practice of requesting limitations of these claims containing Markush formulas to the illustrative examples.

In chapter VII - Compositions, the terms "clarity and precision" are used in item 7 to rule the use of qualitative and quantitative definitions of compositions. In addition, Article 25 is also cited to justify that independent composition claims defined solely by their use, form of

“**This is usually forgotten by the examiners and attention should be paid to the matter when replying to Office Actions in Brazil.**”

administration or mechanism of action would not be accurate, causing the matter to be unclear. It is important to note, however, that item 7.10 establishes that dependent claims may limit the scope claimed in its independent claim by establishing the use, form of administration or mechanism of action of the composition. This is usually forgotten by the examiners and attention should be paid to the matter when replying to Office Actions in Brazil.

Conclusion

The examination of patent applications involving pharmaceutical inventions in Brazil is, in fact, peculiar. Although much is said about incremental inventions in the country, as shown above, the reality is that, despite being very interesting to discuss, they correspond to a minority of the cases.

The problem for pharma applicants prosecuting in Brazil lies in the details. It is essential to pay attention as early as the drafting of the application. Examples of claimed embodiments must be faithfully included in the specification, as well as preferred ranges of variables used in the involved methods.

During examination, submitting strategic amendments and knowing when and how to contest objections especially based on the PTO's guidelines is of fundamental importance and should be an attentive and specific practice.

Knowing how to navigate this sea makes all the difference when prosecuting pharma applications in Brazil.

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