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Brazil: addressing main challenges in patent prosecution.

For the past few months many articles have appeared in relation to the different challenges that Brazil has in terms of prosecuting patents. These challenges have been present in the country for quite a long time and have been consistently mentioned by the Office of the United States Trade Representative. The 2017 Special 301 Report mentioned the concern for the long delays in the examination of both patent and trademark applications, "with a reported average pendency of nearly two and a half years for trademarks and almost 11 years for patents", as well as for the National Sanitary Regulatory Agency's (ANVISA) duplicate review of pharmaceutical patent applications.

Brazil is currently undergoing a process of addressing these issues. This article aims at providing an overall picture of where the country is and what can be expected.

1. Simplified examination process to grant patent applications

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One of the main issues which is currently being deliberated is the possibility of implementing a simplified process of patent examination to address the above mentioned back-log. On July 27th 2017, the Brazilian Patent Office (INPI) published a public consultation opening a period of gathering opinions from third parties in relation to this simplified process. This period ended on August 31st. No decision has been taken so far and it is understood that deliberations are ongoing. We do not know when to expect a resolution, if any. Apparently there are different interests being considered, although it seems that the project has the support of the Ministry. As of today, anything is possible and there has been no feedback as to what are the provisions forming the framework of the project. However, it seems prudent to affirm, even if only for the sake of argument, that the following options are being considered:

"The INPI is considering different options to reduce its huge back-log. One of them is to accept the granting of applications without substantive examination. The project was made public a few months ago. Comments from interested parties ended have been received and the INPI is now considering all possibilities".

Apparently, the simplified process would not apply to divisional applications or certificates of addition and would concern only those unopposed patent applications whose maintenance fees are up to date and for which no official notification has been previously issued.

According to what would be the first option under consideration, the new process would apply to all patent applications for which a request for examination had been submitted before the date of publication of the Decree and would exclude pharmaceutical and biotechnology patent applications. However, it seems that there may be a second option which would be applied to patent applications filed before 2015. It appears that there may even be a third option which would be applied to all patent applications published at least 30 days before the publication of the corresponding resolution. This is all under discussion.

As the project currently stands, there is a possibility for applicants to opt-out of the process, have their applications examined and, also, interested third parties would have up to 90-days to file pre-grant oppositions after an application is pre-approved for an automatic grant.

Even not knowing what the project is going to be, it already raises many questions and controversy. Discussing them can be a futile exercise of speculation right now, but the importance of the process requires being attentive to the deliberations taking place. We will monitor it and will inform you promptly of any development on this issue.

2. ANVISA's role in patent examinations

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One of the most controversial aspects of prosecuting pharmaceutical patent applications in Brazil was the role that ANVISA had in the examination stage. ANVISA was expected to issue their opinion as to how the application could affect the health system in Brazil but they considered it within their competence to issue also opinions on the patentability of applications.

Last spring, on April 12th, the President of the Patent Office (INPI) and the Director of ANVISA issued a joint communication which essentially conveyed that ANVISA would be entitled to give their opinion as to the patentability of applications, although this opinion would not be binding to the INPI. Apparently, this has been the case so far. ANVISA's opinion is still necessary (which does not help to alleviate the back-log) but it avoids the problem of both institutions reaching different and contradicting opinions.

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Following that resolution, ANVISA issued on August 8th resolution 168/2017 detailing further the process of "prior consent" for pharmaceutical patent applications. Basically, it indicates that ANVISA will only consider if the application is contrary to public health (i.e. if it involves a health risk). If so, a preliminary opinion will be served to the applicant, who will have the opportunity to file arguments in favor of the approval. However, the resolution also indicates that should ANVISA consider that the application has interest regarding drug policies, then an opinion regarding patentability may be issued. This opinion, though, will only be sent to the INPI as a third-party observation.

3. Guidelines for patent applications examination

As you may know, the INPI drafted new guidelines for the examination of patent applicationsin the chemical field and launched a period of public consultation. This period ended on May16th, 2017 and there is still no news on the horizon as to what the definite version is going to be. Waiting for a resolution, it may be useful to highlight some of provisions of the draft, as it was outlined by the INPI:

GUIDELINES FOR EXAMINATION OF CHEMICAL PATENT APPLICATIONS	
Chemical compounds	1- The most accurate format in which to claim a chemical compound is in terms of its chemical structure (general formula), nomenclature (according to the IUPAC rules) or another denomination that defines it unequivocally. Thus, product-by-process claims will only be possible in exceptional cases, when there is no other possible way to define the compound as previously described. 2- In addition, independent claims that define the compound solely by its physical, physicochemical or biological properties will not be accepted. In the same way, claims defining a compound by its use or application will not be accepted. 3- General expressions defining the derivates of a compound (such as stereoisomers, hydrates, solvates, etc.) will not be considered a clear and precise definition thereof. 4- Other generic expressions such as "pharmaceutically acceptable salts", "agriculturally acceptable salts" or "immunologically acceptable salts" will be accepted, since it is considered that: 1) the compound is responsible for the activity; and 2) the person skilled in the art is aware of the salts commonly used in his area of expertise. 5- The technical analysis of patent applications claiming salts, esters and ethers will follow the same guidelines applied to chemical compounds. In these cases, the alternative salt, ester and ether of a known compound will not be considered inventive in case of not having an unexpected technical effect in view of the state of the art. On the other hand, the process of obtaining said compounds will be considered patentable only in cases where the compounds are also considered patentable. Otherwise, an invention only referred to a process of obtaining the salt, ester or ether of a compound will not be patentable for being considered obvious to a skilled person in the art. 6- In addition, a selected chemical compound will only be patentable if it has not been specifically disclosed in the state of the art. In this regard, a general Markush formula will not be considered to specifically disclose all the chemical derivatives comprised thereof. However, in these cases, the evaluation of inventive activity will require the presentation of comparative data between the selected compound and the closest pior art.
Stereoisomers	1- A stereoisomer in the pure form will be only considered to be clearly and sufficiently described if it is application. In this regard, analytical techniques can be used for the characterization of the claimed enantiomer/atropoisomer/diastereoisomer. 2- In addition, stereosiomers should be unambiguously identified, for example by means of their official nomenclature. In this regard, the expression "stereoisomers thereof" in a claim will not be considered a clear and precise identification of the stereosiomers.

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	3- In relation to the process of obtaining the stereoisomer, the particular conditions of the same should be enumerated in the specification, in order to ensure its reproducibility by a skilled person in the art. In this relation, it will be important to disclose the reaction conditions, reagents used or the isolation and purification methods of the stereoisomer obtained by the process, as well as the possible enantiomeric excess obtained and the method of analysis used for its measurement.
Polymorphs	1- For the characterization of a crystalline form, the specification must contain, on the filing date of the application, the identification data obtained by physicochemical characterization techniques of solids. In this relation, monocrystal XRD techniques will be sufficient for the perfect characterization of the crystalline structure of the solid. Other techniques, such as powder XRD, should be associated with other methods of physicochemical identification of solids. 2- Besides, the simple identification of a crystalline form by its designation (for example, alpha or beta form, form I or II) will not be considered a clear and precise definition of the same. 3- Again, in order to guarantee its reproducibility, the conditions of the process of obtaining the crystalline form should be identified in the specification (such as, for example, the solvent(s) used and their concentrations, heating and cooling rates, etc.). 4- With regard to the inventiveness of polymorphs, it needs to be noted that obtaining crystalline solids of a particular compound is considered common practice for improving its physicochemical characteristics. Thus, in order to acknowledge inventive activity, it will be necessary to prove a non-obvious effect or advantage associated with the new crystalline form.
Solvates, clathrates co-chrystals	1- For a clear and sufficient description of solvates, clathrates or co-crystals, the chemical identification of the molecules and stoichiometry will need to be given. For examination purposes, solvates will be considered chemical compounds and crystalline forms (such as clathrates or co-crystals) will have to be physicochemically characterized by the techniques described in the Guidelines in relation to polymorphs. 2- The terms "solvates thereof", "clathrates thereof" or "co-crystals thereof" will not be considered to clearly and precisely identify the compounds per se.
Compositions, formulations and physical forms of compositions	1- Chemical compounds should be defined by their constituents. If this is the case, additional features, such as the physical form or the application characteristics may also be used to further define the claimed compounds.
Combination of chemical compounds	1- In order to be patentable, the combination of the compounds must produce a non-obvious effect which cannot be the mere sum of the individual effects of each compound of the composition.
New uses of known compounds	1- new use of a group of compounds will present unity of invention if all the compounds are structurally related or present the same mechanism of action. In the case of a "Markush formula", it will not be possible to extrapolate the new use of a single compound to all the others, unless tests are used to prove their equivalence.
New medical use	1- Characteristics related to the use of a compound, such as the therapeutic regimen and/or group of patients will not provide novelty to the known use of the compound. In addition, in order to prove inventive activity, the mechanism of action of the compound involved should not be inferred from the mechanism of action already known in the state of the art. Besides, the etiology of the disease should be different from the etiology of the disease already known in the state of the art. Also, the new use should not be deduced from the structure-activity relationship of the compound when compared to structurally related molecules. Finally, the new use cannot be deduced from the use of the compound for the treatment of a symptom of a disease already disclosed in the state of the art, nor can it be deduced from the disclosure of adverse effects of the state of the art for the particular drug. 2- Only in vivo tests are evidence of the new use. In the case of studies performed in animal bodies, the models adopted should present the possibility of extrapolation for the humans or animals to be treated. 3. Also, in the case of a new medical use of a "Markush formula", only the use of the compounds that have been effectively demonstrated in vivo will be considered sufficiently described. It will not be possible to extrapolate the use of a single compound to all others, unless tests are provided proving an equivalence of the achieved effect. 4.The new use should also specify the disease. General disorders, syndromes or symptoms will not be accepted. Defining the condition treated in terms of the mechanism of action, the therapeutic scheme or the group of patients will not be accepted either.

Taking into account the above projects, we can objectively say that the Brazilian institutions are fairly busy. Obviously, there are always different interests to be considered and the result of these deliberations is still uncertain. However, we think it is fair to acknowledge the efforts that Brazil is exploring. We will monitor the outcome of these deliberations and will inform you promptly of any developments. If you have any questions, please do not hesitate to contact us.