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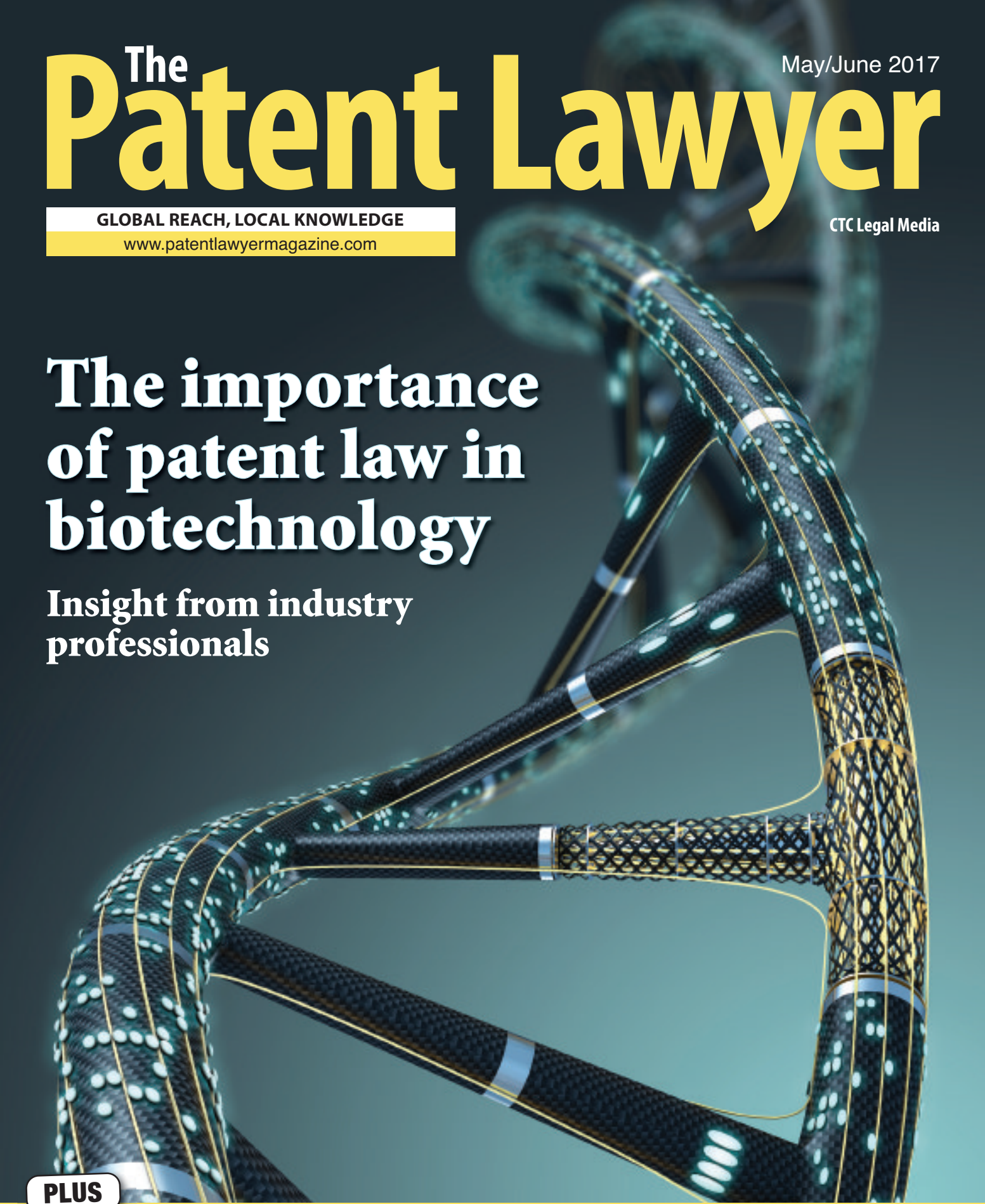

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PLUS

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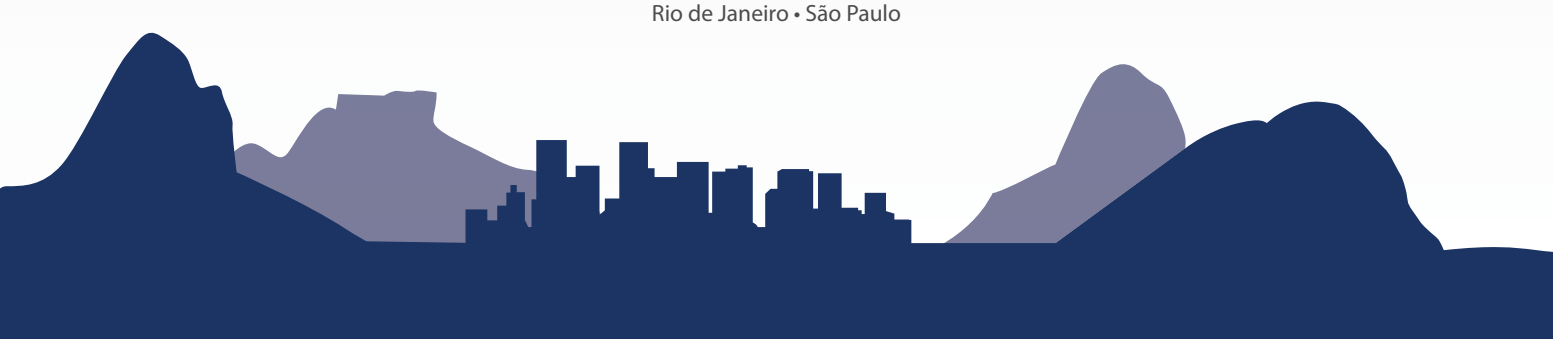

Marisa Moura Momoli

Priscila Kurdian Castanho Afonso

End of deadlock in the protection of pharmaceutical inventions in Brazil

Marisa Moura Momoli and Priscila Kurdian Castanho Afonso, Di Blasi Parente & Associados, outline the recently introduced Joint Ordinance No. 1 that has settled a 15-year long dispute between the BPTO and ANVISA.

After a long period of more than 15 years, the deadlock between the Brazilian Patent and Trademark Office (BPTO) and Brazilian Health Surveillance Agency (ANVISA) seems to have finally ended. The situation began in 2001 when an amendment to the Brazilian Industrial Property Law (Law n° 9,279/96) established that the granting of patents for pharmaceutical products and processes would depend upon prior consent from ANVISA.

From 2001 to 2012, applications related to pharmaceutical products and processes were initially analyzed by the BPTO and then by ANVISA. That resulted in the subject-matter of the applications being submitted to both the BPTO and ANVISA for patentability examinations. Upon agreement between the ANVISA and the BPTO decisions, the application would return to the BPTO, and it would be deemed allowed for granting. However, when the institutions disagreed on the approval of a patent application, it would return to the BPTO and, in practical terms, it was neither granted nor re-examined by the BPTO. No procedure had been adopted by the BPTO for these cases. ANVISA used to perform a new prior art search, and often ANVISA's technical opinions would differ from the BPTO on some subject-matters, such as Swiss-Type, hybridoma, and Polymorphs. ANVISA would issue an opinion contesting the set of claims granted by the BPTO, and the patent application was then stopped without any chance to be examined by the BPTO.

During that time, the Brazilian Attorney General (AGU) issued two opinions confirming that the examination of patent applications concerning patentability matters was not the role of ANVISA and that ANVISA should proceed exclusively with public health analysis. However, the AGU further established that, in cases where the subject-matter of the patent application under analysis could be used in at least one therapeutic destination related to the Brazilian Unified Health System (SUS), ANVISA would be allowed to analyze the patentability of said application.

In 2012, aiming to promote better communication between the BPTO and ANVISA, a group including representatives of ANVISA, the BPTO, the AGU, and other relevant government representatives was created. The main goal of this group was to discuss criteria and procedures to be adopted for the analysis of pharmaceutical products and processes. Because of this discussion, the BPTO changed the initially established procedure and the applications related to pharmaceutical products and processes were then to be sent to ANVISA prior to the BPTO conducting its technical examination. In cases where ANVISA provided consent, the application would then be examined by the BPTO, so as to evaluate whether it was acceptable for patentability. When ANVISA denied prior consent, the application was definitely removed from the active records by the BPTO.

This measure was expected to reduce the BPTO backlog, as the applications which were not accepted by ANVISA

> *"These same principles will be applied to applications that had the administrative instance closed at ANVISA."*

Résumés

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would return to the BPTO only for purposes of being definitely removed from the active records. However, despite having solved a problem for the BPTO, the Applicant would still be harmed, as after having its application removed from the active files, no actions for reinstating such application would be possible unless the Applicant decided to file a lawsuit in this regard.

In order to end the controversy between ANVISA and the BPTO, the Joint Ordinance No. 1 was published on April 12, 2017, mainly establishing the following points:

- ANVISA's prior consent is still required, in accordance with Law No. 9,279 (Article 229-C of BIPL);
- After the formal examination carried out by the BPTO and the request for examination, the application will be sent to ANVISA;
- ANVISA will analyze applications in the light of public health. Applications comprising a pharmaceutical product or process that present a health risk resulting from a substance of which use has been prohibited in the country will be considered contrary to public health. If ANVISA denies consent, the application will be forwarded to the BPTO for definitive removal from the active records;
- In the case of patent applications containing a pharmaceutical product or process of interest to the Unified Health System (SUS), ANVISA may issue an opinion, including patentability analysis, which will be considered only as information for aiding the technical examination to be carried out by the BPTO. The BPTO may use its discretion for accepting ANVISA's opinion in the analysis thereof, but it is not a mandatory procedure;
- In the other cases that neither evidence a public health risk nor are of interest to the Unified Health System (SUS), ANVISA will automatically provide prior consent, and those applications will be returned to the BPTO, so as to have the patentability examination started.

"If ANVISA denies consent, the application will be forwarded to the BPTO for definitive removal from the active records."

Another important provision of this new Ordinance is that these same principles will be applied to applications that had the administrative instance closed at ANVISA. Accordingly, patent applications which were previously denied consent will now be analyzed by the BPTO, taking into account ANVISA's opinion on patentability only as information for aiding the technical examination.

Joint Ordinance No. 1 is not merely about finally ending a deadlock between the BPTO and ANVISA, but this new procedure is expected to provide many benefits over the next few years in Brazil. It is expected to:

i) encourage the protection of new inventions;
ii) raise legal security for national and foreign companies;
iii) decrease the number of patent applications involved in lawsuits, since applications stopped at ANVISA will now be analyzed by the BPTO, without the need of judicial recourse; and
iv) reduce the backlog of patent applications in Brazil. The BPTO is also taking additional steps to reduce the backlog in Brazil including the hiring of more than 200 new examiners and the establishment of measures by the BPTO to expedite the examination of patent applications, such as green patent program, neglected diseases program, BR priority program, fast-track examination for applications filed by micro-enterprises, USPTO-BPO PPH and JPO-BPO PPH. Joint Ordinance No. 1 is one more step toward achieving a more efficient process for patent protection in Brazil.