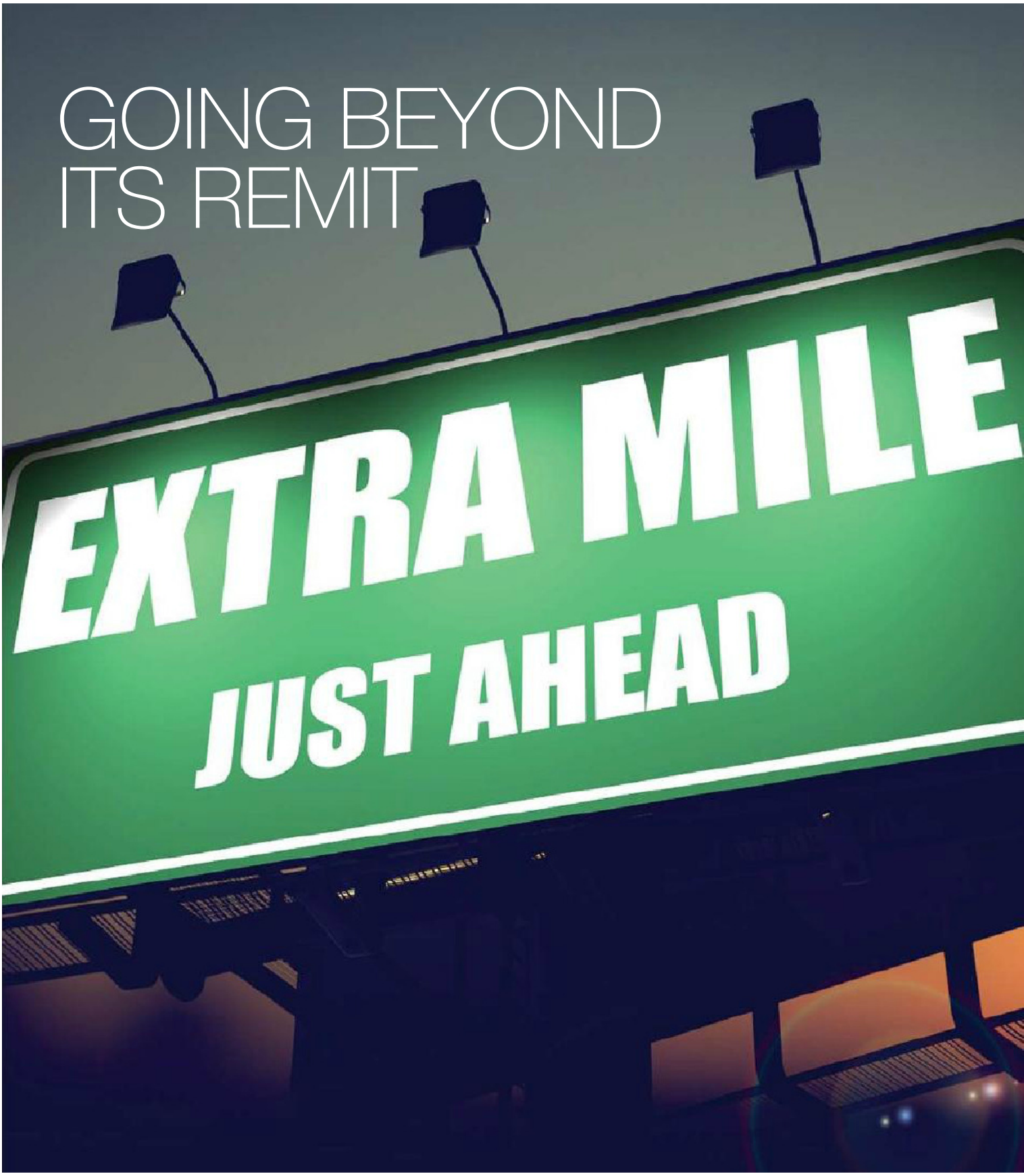
GOING BEYOND ITS REMIT



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A review of ANVISA's role in the prosecution of pharma patent applications and the latest developments reveals ongoing controversies, as Joao Luis Vianna and Maria Claudia Souza report.

The involvement of Brazil's equivalent of the US Food and Drug Administration in Brazil's patent prosecution system was regulated by Law No. 10,196 of February 14, 2001, which amended the Brazilian Patent Law (Law 9,279 of May 14, 1996, IPL) to include Section 229-C: "The granting of patents in connection with pharmaceutical products or processes shall be dependent on prior consent from the National Health Surveillance Agency (ANVISA)."

Until mid-2008, ANVISA analysed patent applications, granting and/or denying approval of such applications, including analysis of patentability requirements, without having formally established any specific regulation defining the criteria/procedures regarding such analysis.

In June 2008, Resolution RDC #45, relative to ANVISA's administrative proceedings on prior consent analysis, was then published, and the number of decisions denying prior consent on the basis of lack of patentability requirement(s) significantly increased, from around 3% (up to June 2008) to 27% by December 2011.

The legitimacy of ANVISA's role in the examination of pharma patent applications has been extensively contested. According to the understanding of the Attorney General's Office (AGU), upon complying with the dispositions of Section 229-C, ANVISA should limit its analysis to public health factors and not examine patentability issues.

However, contrary to the AGU's determination, ANVISA went on issuing technical reports questioning patentability, grounded basically on the circular reasoning that applications lacking patentability requirements would be contrary to public health, since they would ultimately limit the access of the population to medicaments, especially those included in the programmes of the National Public Health System (SUS).

This contentious matter was discussed by a governmental working group, which issued a report recommending an inversion in the patent applications' examination procedure pathway: once a pharma application was filed, the Brazilian patent office (INPI) would first make a formal examination and then forward the application to ANVISA. After ANVISA's decision consenting, or not, to the granting of the patent, the case would be sent back to the INPI. If ANVISA's consent was granted, the INPI would continue with the examination on its merits.

Although general principles of public health were suggested in such a report as the basis for the health-based assessment to be made by ANVISA, the agency continued to carry out substantive examinations of patent applications. Conversely, in the accompanying letters sent to ANVISA with each patent application, the INPI claimed (and still claims) that ANVISA's analysis should be limited to a sanitary-oriented control.

In October 2012, ANVISA published a proposal for changes to Resolution RDC #45/2008, by means of a public consultation, opening a 60-day period for the submission of comments/suggestions on the proposed changes. The main change suggested by ANVISA was the introduction of a new meaning for "prior consent", defining it as analysis aiming to verify whether the subject matter of a pharma

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patent application is contrary to public health, allegedly following AGU's determinations.

Further to this, Resolution RDC #21/2013 was published in the Brazilian *National Gazette* in April 2013, replacing several dispositions of previous Resolution RDC #45/2008. According to this new resolution, ANVISA's analysis would be made "in light of public health". However, in truth, the text submitted for public consultation at the end of 2012 was not significantly altered: prior consent should not to be granted to pharma applications posing health risks or being "of interest to the SUS" and lacking patentability criteria.

According to ANVISA, a health risk would exist whenever an application is classified as being "of interest to the SUS". This happens with substances listed as one of the strategic products according to Ordinance of the Ministry of Health #3,089/2013, or pertaining to any therapeutic indication recited in the ordinance.

ANVISA's *modus operandi* has sparked further controversy between ANVISA and the INPI, as the former was by then denying prior consent on applications already considered by the INPI as being eligible for allowance.

Over the past few years, several lawsuits have been filed against the agency, claiming that ANVISA's decisions are illegal as there is no legal provision giving the agency legal authority to (re) examine patentability requirements. Indeed, such an attribution is not listed as one of ANVISA's responsibilities in Law #9,782/99, which created the agency.

Some of these lawsuits sought to have ANVISA's analysis based solely on public health factors, in keeping with the opinion raised by AGU. In one particular case, ANVISA was obliged to annul the denial of prior consent based on analysis of patentability requirements, and to issue a report strictly grounded on whether or not the subject matter of the application would place human health at risk.

ANVISA then issued a second opinion, stating that it was not possible to reach conclusions on efficacy and the absence of health risks for all possibilities of pharmaceutical formulations encompassed by the pending claims, but only for those specifically defined and for which marketing approval had been granted by the agency.

The applicant was then requested to narrow the scope of the claims to those formulations that were covered by the sanitary registration of this product, for which efficacy and safety had been attested. In other words, in practice, a kind of reversed linkage was created: pharma patents can be granted only for drugs which have already been approved by ANVISA for marketing in Brazil.

Obviously, the above approach adopted by ANVISA would not be feasible for all cases analysed under Section 229-C of the IPL, since an application does not necessarily cover a pharmaceutical product for which marketing approval has been requested, not to mention that patent linkage is in no way foreseen by Brazilian legislation.

In spite of having had the definition that prior consent analysis should be made in light of public health, in keeping with AGU's determinations, until now ANVISA continues to analyse patentability requirements in cases involving substances strategic to SUS.

Some understand that ANVISA focuses on those applications covering medicaments of great interest to SUS, possibly those purchased by the government, when the issuance of a patent would, allegedly, impair the access of the population to therapeutic treatments.

Ordinance #1,065/2012 states that the INPI should shelve applications if ANVISA decides on the denial of consent. However, up to now, no application has been shelved by the INPI on these grounds.

In fact, the prosecution of applications falling within this situation generally remains halted, for an undetermined period of time, possibly due to the lack of legal basis in Brazil's patent law for the INPI to decide on the shelving of an application.

Besides, once the examination fees are paid, the applicant would have the right to have its application examined by the INPI's examiners. The shelving of an application with no examination of its merits by the INPI may be understood as illegal, and may possibly infringe principles of the Brazilian Constitution.

We can conclude that ANVISA's intervention on the examination of pharma applications remains highly debatable. In situations where ANVISA denies consent indefinitely, a remedy that is likely to continue to be used is to bring the case for discussion before the courts. ■

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