20 years of the Brazilian Generics Law

The Brazilian Generics Law – which celebrates 20 years in force – has altered the landscape of the Brazilian pharmaceutical industry by regulating the entry of generics into the market and thus reducing health treatment costs and increasing the nation's access to medicines. Not only has it improved the wellbeing of the population, it is also an efficient mechanism for technology transfer.

Earlier this year, 10 February 2019 marked the 20th year of the Brazilian Generics Law (9787/99). The law has altered the landscape of the Brazilian pharmaceutical industry by regulating the entry of generics into the market and has reduced health treatment costs and increased the nation's access to medicines.

The law defines a generic drug as 'similar to innovator/reference products' – the two products must be interchangeable. They are usually produced after the expiration or waiver of the reference drug's protection or other exclusive rights and must be of proven effectiveness, safety and quality.

Generics may only be registered after the submission of:

- bioequivalence tests, which guarantee that the generic can be absorbed to the same extent and at the same rate as the reference product; and
- pharmaceutical equivalence tests, which guarantee the identical composition of a generic and its branded counterpart.

In the past 20 years, there have been more than 21,000 generic presentations registered before the Brazilian Health Surveillance Agency (ANVISA), representing the main therapeutic classes. According to the Brazilian Association of Generic Drugs Industries (PróGenéricos), this sector expands by more than 10% per year and transacts between $150 and $200 billion worldwide. In Brazil, 79% of the population buy or have bought generic drugs. Further, around one-third of drugs marketed in Brazil are generics. This has generated savings of around R$120 billion since the law entered into force.

The former Industrial Property Code (5,772, of 21 December 1971) did not afford patent protection for pharmaceutical products and process-related inventions.

In 1994 the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs) was signed and provided that all World Trade Organisation (WTO) members should amend their domestic legislations to recognize a minimum standard of IP protection across all technological fields, including pharmaceuticals.

As a WTO member state, as well as to attract foreign investments, in 1996 Brazil amended its legislation and created the Industrial Property Law (9,279/1996), which recognizes patent protection for pharmaceutical products and processes.

Although there is a minimum standard for IP protection, the TRIPs Agreement permits a degree of flexibility for member states with regard to public health measures. For example, Bolar provision, incorporated into the Industrial Property Law in 2001, added Item VII to Article 43: this establishes that performing research and tests for regulatory

approval (e.g., by ANVISA) does not constitute infringement of an original drug's patent rights. This exemption allows manufacturers to develop generic drugs in advance of the original drug's patent expiration.

> *Article 43 - The provisions of the previous article do not apply: (…)*
> *VII. to acts practiced by unauthorized third parties relating to the patented invention carried exclusively to produce information, data and test results to seek market approval in Brazil or abroad, in order to exploit or commercialize the patented product after the term set by article 40 has expired.*

Besides promoting the faster entrance of generics into the market, this flexibility further enables the use of patented information for research purposes. In this case, it is not necessary to obtain authorization from the patent owner.

Conclusion

The Bolar provision streamlines the entry of generics into the Brazilian market soon after the reference product's patent term has expired, as the regulatory approval process can be completed in advance. Further, this flexibility allows both the absorption of knowledge disclosed in the patent and the tacit knowledge related to the invention (i.e., know-how connected with drug manufacture).

In this way, the Generic Law is not only a part of the Brazilian legal system that has improved the wellbeing of the population, it has also had a deep economic influence and is an efficient mechanism for technology transfer.