V. CHAPTER. CONCLUDING REMARKS

The body of provisions on patents in the WTO TRIPS Agreement clearly seeks to harmonize the general principles that should embody national legislations. Implementation by Member States must always be placed within the context of international trade. Different standards of protection and enforcement have been proven to represent non-tariff barriers to international trade and each of the principles and rules locally governing patents must now be interpreted in light of TRIPS. The present text has aimed to provide an analysis of the TRIPS framework for patents and the implementation of its provisions in Brazilian law. The analysis has been driven by the provisions and context surrounding compulsory licenses for pharmaceutical products, but has also aimed to illustrate the discussions surrounding the accession of Brazil into the international trading system.

Since the WTO negotiations, policy specialists had already foreseen the need to study the impacts of raising IP protection standards in developing countries. Many empirical studies have yet to evaluate such effects, whilst there is a consensus that this should be a case sensitive analysis – such as in the public health area. On the one hand, without patent protections, it is possible that there would not be enough incentive for investment in research and development. Moreover, a lack of patent rights may serve as a non-tariff barrier to trade in addition to being a violation of TRIPS. On the other hand, the absolute right to exclude third parties from using a patented subject matter should be reviewed in a case by case manner, especially in developing countries. The main challenge is to achieve a balance, which assures necessary protections in order to foster technological development yet does not consist in overwhelming protection that creates non-proportional social costs resulting from patent exclusivity. This was the conclusion that derived from the discussions among WTO Member States and is reflected in the Doha Declaration on the TRIPS Agreement and Public Health.

Compulsory licenses should not be regarded as the only way to promote access to medicine. The indiscriminate use of such a mechanism, which would serve to hide structural problems in healthcare systems, should be avoided. For those that defend compulsory licensing, it is a measure that has marginal negative effects on research and development and there is no

evidence that such effects jeopardize other policies such as price control. Any negative effects would be minimal in developing countries, whose markets are less important for industry profits. Increased use of compulsory licenses in developing countries may lead to a reduction in social costs, especially in the patented pharmaceuticals market, while allowing a high level of patent protection to be maintained. Ultimately, the pharmaceutical industry may charge higher prices in developed countries, while practicing price differentiation in order to charge lower prices in developing countries with lower incomes. Furthermore, local industry could benefit as well from transfer of technology, which would allow for drugs to gradually be manufactured locally.

This text has shown that the Brazilian market does not present typical characteristics of a developing country. The Brazilian government plays a strategic role as a major consumer in the pharmaceutical area. In Brazil, universal access to healthcare is constitutionally safeguarded and should be implemented through social and economic policies, which include access to medications distributed by the SUS.

When implementing TRIPS into national legislation, Brazil adopted a rather friendly approach towards higher standards of protection, as the country understood them to be favorable to international trade, from which the Brazilian economy has been benefiting. The country's patent provisions mostly fulfill the minimum standards of protection in TRIPS. For pharmaceutical products and processes, intervention in the patent granting procedure by the ANVISA plays a peculiar role and the question remains why the research-based industry has not questioned the legality of prior consent by the ANVISA on a more general basis – rather than case by case – or even lobbied for the exclusion of the provision from the statute.

However, as a developing country, Brazil has been struggling to balance its interest in protecting technology mostly developed abroad with its interest in fostering local technology while at the same time assuring that social policies are implemented. In the pharmaceutical context, the dispute between these interests is clear. The healthcare system demands more access to medication at cheaper prices and at the same time investments are fostered for innovation by means of private-public partnership with local industry. Investing in innovation could ultimately be translated into protecting such innovation through patents so as to assure a continual investment process. In the compulsory licensing case of efavirenz, the declaration of public interest based on the cost of the drug used in the anti-AIDS

cocktail shows one side of this dichotomy, whereas the public-private partnership for national production of the drug reveals the other.

It is important to consider that compulsory licensing is a measure restricting exclusivity rights derived by a patent, which is a constitutionally safeguarded right in Brazil, and its granting must follow the principle of proportionality. Accordingly, licenses must not only be shaped by the principles of the international treaty, but also follow national mechanisms for controlling legality and constitutionality. Licenses should not be granted when the demands of public interest may be satisfied through different means after balancing all the interests involved. In the case of compulsory licenses for efavirenz, the discussions went beyond compliance with TRIPS or the legality and constitutionality of the measure, which were satisfied in general. In fact, the case concerned how the Brazilian government made use of the available tools and mechanisms to implement a policy making decision. The other cases, such as Abbott's Kaletra and Gilead's Tenofovir, are also examples of such use in the area of public health. The use of the legal mechanisms available as of WTO/TRIPS have also been illustrated by the cross-retaliation in IP rights after Brazil won the case on cotton subsidies against the US in the WTO Dispute Settlement Body.

Another possible solution concerns government control of prices, which could be proposed as a measure to balance the social costs imposed by patents without jeopardizing the patent system and its incentives for investment in research and development. In Brazil, the government controls prices of products that are subject to medical prescription or that are in a more concentrated relevant market. As a major purchaser of drugs, the Brazilian government could also adopt a system that benefits from its power as a big consumer of the drugs. Prices could be based on government control of marginal profits of companies and industry would be obligated to submit accurate data on their profits under the penalty of having their products removed from the government's general purchasing list. Such price control would give the Brazilian government the power to minimize the social costs of patents without creating general suspicion among industry against the country's IP enforcement policies, jeopardizing long-term investments in research and development and the direct transfer of technology into the country. Of course, upon implementing this suggestion, one should take into account that price control administration is not an easy task, especially considering that profit information submitted by the companies may not be accurate and may require extensive negotiations with industry. Also, a deep and careful analysis should be carried out in

relation to the constitutional principle of free enterprise and the restraints that such measures could impose on this freedom. How to best implement this or other alternatives is a challenge that this work leaves up to future studies.