Compulsory Use Licenses In Cases Of Pharmaceutical Patents

Patents are exclusive rights granted by the state on a product or a process that usually offers a new way of doing something, or solves a technical problem.

In the patents field, there are the well-known pharmaceutical patents, which have become a fundamental part of Industrial Property, which in turn forms part of the Intellectual Property regime as these are obtained as the result of research that mostly derives from a laboratory, to be marketed later in an exclusive manner by the patent holder, enjoying the holder a monopoly right for a certain period of time (20 years), under a commercial name of registered trademark, allowing positioning itself in the addressed market.

However, nowadays, pharmaceutical patents have become an obstacle to the exercise of the health right and the access to medicines. This is because the patent holder will be the only one who can sell and commercialize such product, being able to place it on the market at a very high price and without the fear of a third party will have a similar product at a lower price.

This situation is affecting developing countries, where the disadvantage of granting a pharmaceutical patent is a monopolistic obstacle opposed to free competition.

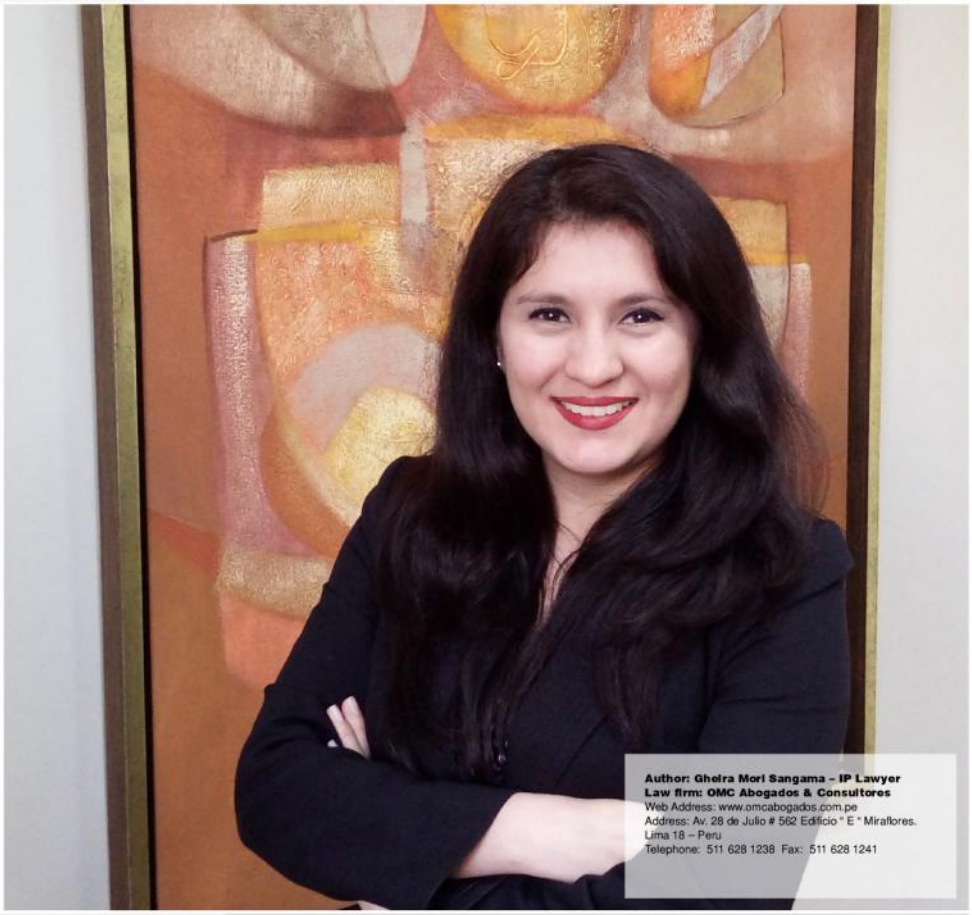
Under these circumstances, in November 2001, the member governments of the World Trade Organization (WTO) adopted by agreement a statement concerning the Trade-Related Aspects of Intellectual Property (TRIPS) and Public Health, known as the Doha Declaration. This Declaration states that TRIPS does not prevent WTO member governments from taking measures to protect public health, reaffirming the right of the member states to make full use of the provisions of the TRIPS, which foresee flexibility to these exclusivity rights.

These exclusive rights that are granted to the holder of a pharmaceutical patent may be limited through compulsory licenses, which are regulated in the TRIPS when one or more of the following assumptions occur:

a) There is a national emergency
b) There is an extreme urgency or its public use is necessary
c) The product is not in the market.

Thus, the Compulsory Licenses allow the State to exploit a patented invention without the authorization of the holder and under the previously highlighted conditions or under the conditions that the member states are free to determine to grant such licenses with the purpose of putting the public interest to the exclusive rights of the private sector granted by the patent.

In Peru, both Andean Decision 486 and Legislative Decree No. 1075 also regulate Compulsory Licenses. However, despite the fact that since 2014, the associations of patients



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and social organizations of Peru have asked the State to issue a Supreme Decree declaring the public need of the compulsory license on the antiretroviral Atazanavir , used for the treatment of approximately 65 thousand people suffering from HIV in our country, the Peruvian State chose to sign an agreement with Bristol Myers Squibb , obtaining a reduction of 35% in the purchase of half a million tablets of the aforementioned antiretroviral . Nevertheless, this agreement has not solved the economic problem of the Ministry of Health since although it has been possible to obtain a discount for the acquisition of said antiretroviral, the granting of a compulsory license for reasons of public interest or non-commercial public use would have allowed the Peruvian State to acquire said product from other pharmaceutical companies at a lower price, by putting the products within the reach of citizens who are in need of said medicine.

One of the reasons the State did not resort to the use of compulsory licenses, is that although the Andean Regulations and the Legislative Decree cover said concept; in the mentioned rules, the specific guidelines for its application are not established. However, regarding this, it should be noted that even the TRIPS provides a scope of application of compulsory licenses, said rule does not specifically list the reasons to justify them, and that on the other hand, the Doha Declaration confirms that countries have the freedom to determine the reasons for the granting of compulsory licenses as well as to determine circumstances of extreme urgency, and that crisis affecting public health, such as HIV/AIDS, tuberculosis, malaria and other epidemics can be considered situations of that nature.

A close case corresponding to a member country of the Andean Community is Colombia, this case was presented in 2013, with the so-called case imatinib or Glivec, which is a very advanced medicine for certain types of cancer. Since its very expensive price, the Colombian Ministry of Health decided to invoke the compulsory license to lower its price. In that situation, the pharmaceutical company Novartis strongly opposed, and as in Peru, the transnational company had the support of the Ministry of Commerce that faced its own Ministry of Health; however, against all odds, the Colombian Ministry of Health used the compulsory license and the imatinib lowered its price by 44%.

Analyzing the case, and taking into account the purpose of compulsory licenses, we believe that the Peruvian State could have made a better management of it, since through this concept it could have guaranteed the access to medicines that are important for health in the country, and achieving savings of 75%; in addition to allowing the coexistence of all products on the market, and allowing the patent owner laboratory to have benefits as it would have received a fair payment for each generic product sold.

Therefore, we conclude that compulsory licenses have long been recognized as the most effective method to deal with the negative effects that patents may have on the public welfare, and it is fair in these situations that decisions such as those of the Andean Community, the Doha Agreements and the FTA itself with the United States, establish the possibility of declaring the compulsory license when the public interest is at stake.

1. *Atazanavir is a retroviral used for the treatment of patients with HIV diagnosis.*
2. *Owner of the pharmaceutical patent ATAZANAVIR until 2019.*
3. *http://larepublica.pe/politica/202597-licencia-obligatoria-hubiera-permitido-75-de-ahorro-en-atazanavir*