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INTERNATIONAL PROPERTY RIGHTS INDEX 2023

ANALYZING THE IMPACT OF MANDATORY LICENSING ON INTELLECTUAL PROPERTY RIGHTS IN COLOMBIA

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INTRODUCTION

Historically, Colombia has been a country stricken by violence and poverty. It ranked 81st out of 167 countries analyzed in the Legatum Prosperity Index, which measures how prosperity is forming and evolving across the world. Since 2011, Colombia has moved down the rankings table by 10 places (Legatum Institute, 2023).

Since the end of 2021, inflation in Colombia has been on the rise. Throughout 2022, inflation began to represent a serious threat to the purchasing power of workers' salaries, reaching the highest value of the century in the country (ICP, 2023).

Among Organisation for Economic Co-operation and Development (OECD) countries, Colombia has one of the highest inflation rates for 2023. During this year, Banco de la República's rate hike policy to control this phenomenon seems to be having an effect, and food prices have had lower increases than last year. However, prices of transportation, clothing, and footwear continue to increase (ICP, 2023).

Considering the economic situation and the difficulties the country has faced in recent years, it is necessary to seek alternatives that have a positive impact on world economic growth and promote poverty reduction and social mobility.

Extensive studies by the World Economic Forum (WEF) show the correlation between a country's intellectual property protection and its economic competitiveness (PRA, 2023).

Innovation plays a pivotal role in the economic development of nations, fostering growth and prosperity. For innovation to succeed, it is essential to count on an effective protection of intellectual property rights and a rule of law that guarantees legal certainty with a stable and predictable regulatory environment, as well as institutional architecture (rules of the game) that encourages creativity and free exchange.

However, in the case of Colombia, a notable scarcity of innovative breakthroughs has been observed. According to the Survey of Technological Development and Innovation (EDIT) of the National Administrative Department of Statistics (DANE) for the period between 2019 and 2020, 70.9% of Colombian companies in the manufacturing industry did not obtain innovations, nor report having any process for obtaining it (Dane, 2020).

Despite the different regulatory efforts that have been made in Colombia regarding the protection of intellectual property rights, the country still has a long way to go. According to the



International Property Rights Index (IPRI) 2023, Colombia has an overall score of 4.6 out of 10, and a 3.8 in the specific category of Intellectual Property Rights (PRA, 2023).

In the Fraser Institute's Economic Freedom Index 2022, Colombia scored 5.13 out of 10 in the protection of property rights (Fraser Institute, 2022). In the Heritage Foundation's Index of Economic Freedom, Colombia's property rights score has been decreasing since 2020, going from 61.1 to 44.9 in 2023, below the world average (Heritage Foundation, 2023).

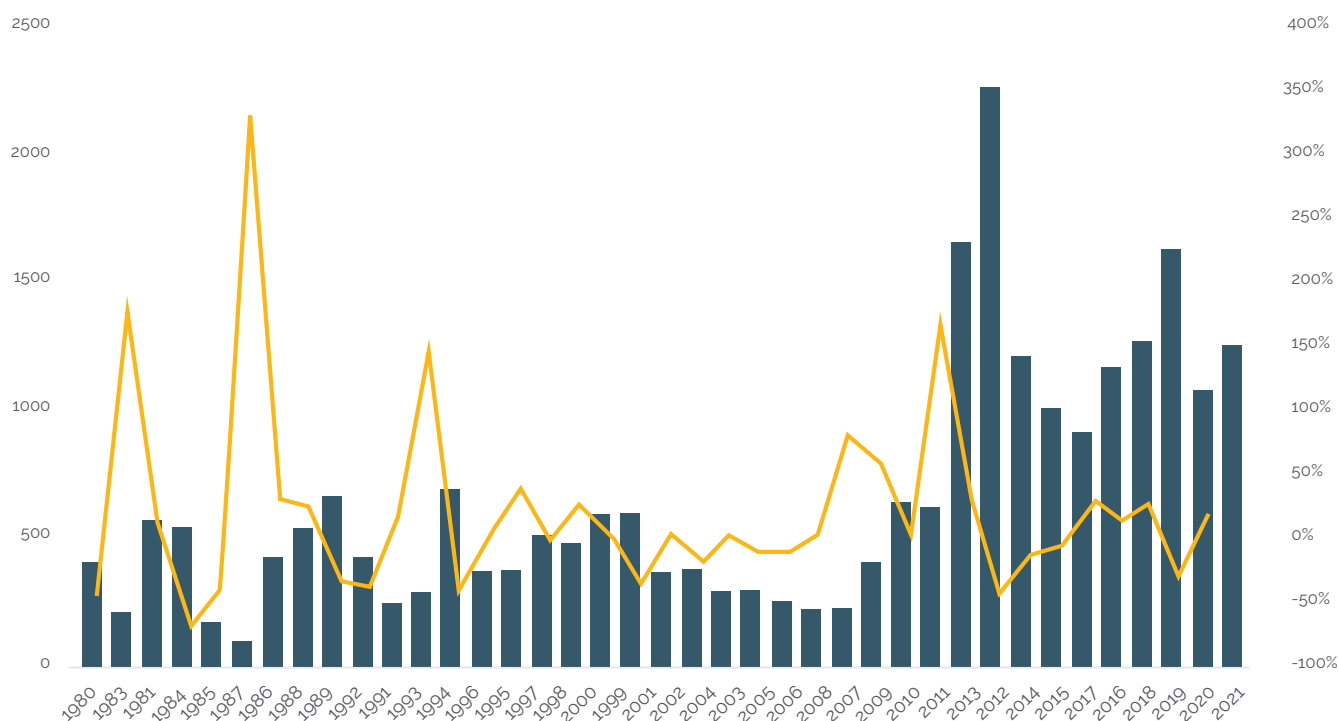
According to the National Council of Economic and Social Policy (CONPES) of the National Planning Department (DNP) in Colombia, "There is still insufficient generation and use of economically valuable Intellectual Property assets, which limits creation, innovation, knowledge transfer and productivity increases". This organization recognizes that among the main problems associated with this is "the low effective defense of intellectual property rights and the lack of knowledge and training on them," (CONPES, 2022).

One of the most valuable instruments of intellectual property rights protection is patents. This

mechanism serves as a powerful tool in encouraging innovation.

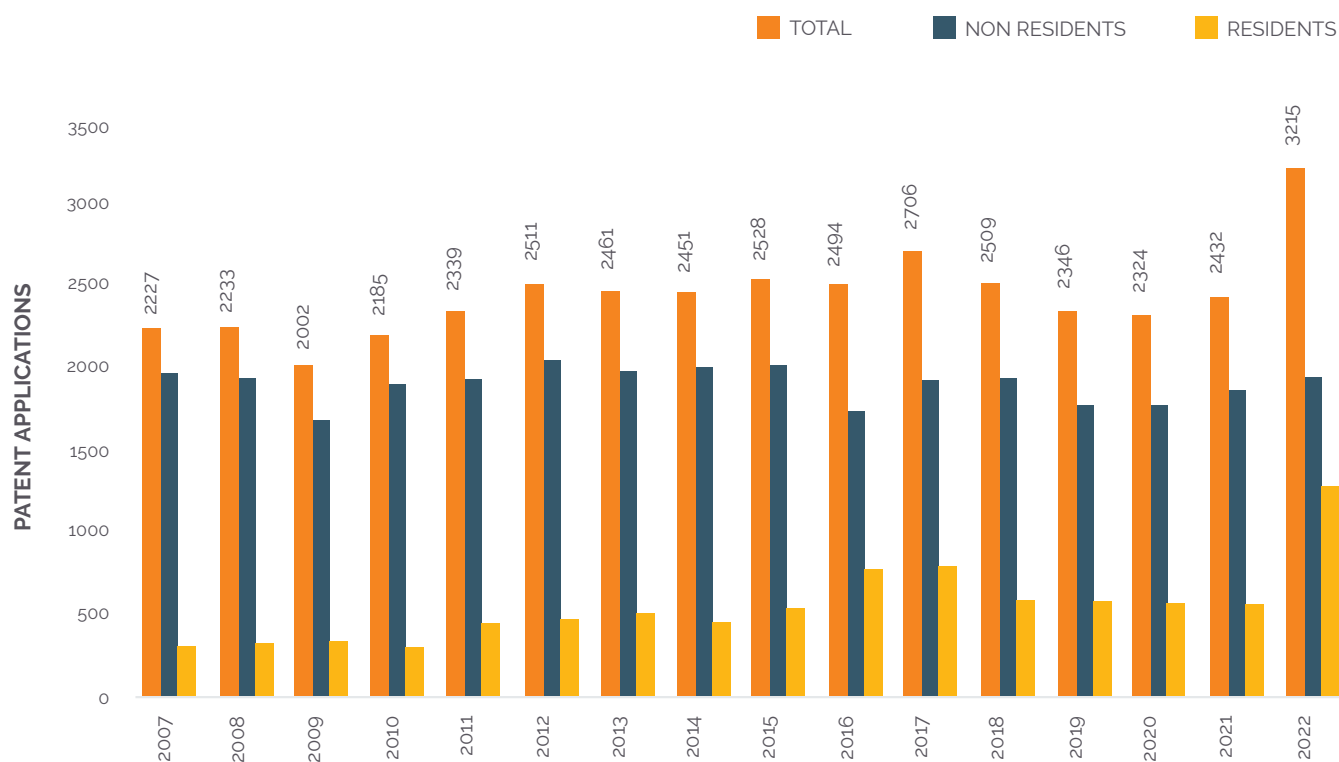
In Colombia, the Superintendencia de Industria y Comercio (SIC) is the authority in charge of protecting competition, personal data and legal metrology. It is also in charge of protecting consumer rights and administering the National Industrial Property System. Thus, the SIC is the main body in charge of collecting, classifying and presenting statistical information related to patent applications in the country.

The insertion of the country to the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) has allowed the country's incursion into world patenting, and there has been a progressive increase in the number of patents in the country as shown in Graph 1. The increase is evident in both national and foreign patents. This is an indicator of a quantitative and qualitative leap in national innovation. This shows the effectiveness of the incentive of the regulatory system on the propagation of novel knowledge, a benefit for middle- and low-income countries of the high investments of developed countries (transfer of foreign R&D, increasing the development of knowledge and access to national medicines).



Graph 1. Patents in Colombia 1980 - 2021

Source: Elaboration of the author, data from OMPI



Graph 2. Patent Application in Colombia

Source: Elaboration of the author, data from SIC



Notwithstanding the foregoing, by comparing the number of patents applied for by foreigners and those applied for by Colombian nationals, it is possible to corroborate that innovation by Colombian companies continues to be relatively low. The following graph shows the evolution of the number of patent applications in Colombia from 2007 to 2022.

This case study will provide a literature review on patents and compulsory licensing in Colombia. At the moment this is an interesting case study as the Colombian government is in the process of granting a compulsory license through Reso-

lution 881 of 2023. It is very important to highlight to the citizens the great challenges that Colombia has in terms of innovation and how important this issue is for the development of the country. Additionally, it is important to highlight the risks of the issuance of compulsory licenses in economic matters.

Also, in the current political situation in Colombia, the protection of intellectual property rights may be at risk in view of the reform initiatives proposed for the health sector and the discussions on the lifting of patents, regarding the vaccines developed for COVID-19 and its variants.



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PATENT PROTECTION AND ITS IMPORTANCE

Patents are a recognition of the ingenuity of inventors for novel, inventive and industrially applicable developments. This system seeks to safeguard inventions that show a qualitative leap in technology (Andean Court CAN, 2010, 75).

Patents grant inventors exclusive rights to their creations and encourage research processes that lead to innovation and new technologies. Research and innovation processes involve high costs, not only economically but also in human capital and time. In addition, they are high-risk investments because there is a possibility that the project will not result in the expected product, that it will not be sufficiently accepted in the market, and that it will not generate profitability or return on investment. However, thanks to these processes, especially in the field of health, today the world has medicines, devices and diagnostic methods that allow us to fight

disease more efficiently and live with greater dignity.

Despite all these difficulties, mechanisms such as patents allow those who hold a patent to recover their investments, making innovation processes more attractive. According to Fernández de Córdoba, the incentives that exclusivity grants to the inventor seek to achieve a double reward. The first one comes from being the only product on the market, and therefore fixing quantities and prices of the good. The second one, which he recognizes as a moral one, comes from considering it a very personal and non-renounceable right (2001, 34). They also seek to prevent imitation of the invention by third parties, so that companies are not discouraged from investing substantial capital resources over long periods and continue to encourage technological developments (Florez, K., 2023).

However, the legislator's intention with patents is not only for the benefit of the inventor, but the counterpart of this incentive is also the transfer of knowledge through disclosure of the information over a period of time, depending on the type of patent. The obligation to make it public would be by the collective interest. This disclosure can be within nations or between nations, generating cooperation or transfer from those nations more advanced in research to those less advanced (Florez, K., 2023).

According to the World Intellectual Property Organization (WIPO) the owner of a patent may decide who may or may not use the patented invention during the period in which it is protected. He may grant authorization or a voluntary license to third parties to use the invention subject to mutually agreed conditions, and may transfer the right to the invention to a third party, who will become the new owner of the patent (WIPO, n.d.).

The neo-Keynesian, neoclassical and welfare schools of economics support the claim that technological progress is attributable to patents. It has been modeled that, in the absence of patents, innovation would be minimized or could only be effected through the state and subject to narrow purposes, limiting the possibility of spontaneous and expanded innovation (Kath-erin, F., 2023).

"It is clear that without the protection incentives of the patent system, the current level of technology, obtained thanks to huge investments and the certainty of their recovery, would not have been reached" (Mutter, 2006).

Without a patent system that guarantees the protection of the inventor's rights over his invention, there would be no innovation, or worse still, other protection mechanisms would be used

that completely eliminate the transfer of technology. For example, we would resort to industrial secrets whose protection lasts up to ninety years, closing the door for other companies to use the knowledge and replicate it at zero cost (Florez, 2023).

The normative development of the patent is consolidated worldwide, including Colombia, with the ratification of TRIPS by the World Trade Organization (WTO) art. 27 TRIPS). TRIPS establishes that this exclusion right is granted to an invention that demonstrates three elements: novelty, inventive level (non-obvious), and susceptible to industrial application (practical use). Once the patent is granted, its holder obtains exclusive rights to "prevent third parties from making, using, offering for sale, selling or importing" (art. 28 TRIPS) for 20 years. However, it also allows the holder to "assign or transfer his patent rights by succession and to enter into licensing contracts" with others (art. 28c TRIPS) (Florez, 2023).

In Colombia there are various types of patents that include invention patents and utility model patents. The latter are intended for inventions that have an industrial application and have a certain degree of inventive level. Invention patents protect any new product or procedure that meets the requirements of novelty, industrial application and inventive level.

According to the SIC, *"Utility model patents are intended for minor inventions in terms of inventive range. These are the main differences between them: (1) Utility model only contemplates the protection of product inventions; on the other hand, the invention patent protects product and process inventions. (2) The invention protected in the utility model must be new and have industrial application. (3) Period of protection of the utility model is 10 years."* (SIC, s.f.).



On the other hand, patents are not absolute. In Colombia there are some figures that limit this right such as the Bolar exception, enshrined in Decree 729 of 2012, and licensing mechanisms (AFIDRO, 2020).

According to the PRA, Colombia has a score of 5.5 out of 10 in the category of patent protection for 2023. In the Intellectual Patent Index, Colombia is positioned 59th out of 139 countries, and has a score of 3.3026 out of 10, as observed in the results of the Index. The category in which the lowest score for the country can be observed is "Loss of Rights", which is described as follows:

"In some countries, a patent right may be revoked for inadequate working or if the technology is deemed to be in the 'national' interest. The patent restriction score (ranging from zero to one) will be the fraction of these three elements – working requirements, compulsory licensing, and revocation – that are not provided for under the law. It will be important, however, not to penalize countries that revoke a patent if the patent holder's patent is found to be invalid or that issue a compulsory license for abuses by the patent holder. The score should reflect the extent to which rights can be abridged, not the extent to which they are protected unconditionally" (PRI, 2023).



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LICENSING MECHANISMS

The licensing mechanism is used to allow a product, despite being patented, to be produced by competitors who have the capacity to generate a substitute product under certain conditions to meet a specific situation.

Voluntary licenses are those in which the patent holder, on an optional basis, decides to make a transfer of knowledge and provide the possibility for a third party to make use of the patented product (SIC, 2012). In this sense, voluntary licenses respect the autonomy of will and property rights, maintaining the stimulus that a patent represents for research and promoting the transfer of knowledge, even in a more complete and effective way. Through this type of mechanism, it is possible for a transfer of technology to take place before the patent expires, according to the will of its holder (ICP, 2023).

Compulsory licenses, on the other hand, are those in which the patent holder is imposed the duty, by mandate of the State, to release it, in exchange for a royalty. The owner can continue to exploit his patent and the license will be applied only for a certain period of time. This generates great practical problems and represents an indirect violation of intellectual property rights. This opens the door to possible abuses by the States in cases where the legitimate figure is abused for purposes other than those enshrined in the TRIPS Agreement, such as price reduction.

Knowledge and analysis of regulations on mandatory licensing in Colombia is essential to understand the context in which Resolution 881 of 2023 of the Ministry of Health and Social Protection is developed, and its possible impact on the Colombian economy.

COMPULSORY LICENSING IN COLOMBIA

In Colombia, there are several regulations in force regarding compulsory licenses. These regulations range from national law to binding decisions of the Andean Community and international agreements to which Colombia is a party.

Decision 486 of the Andean Community establishes guidelines on the implementation of compulsory licenses in member countries: Bolivia, Ecuador, Peru and Colombia. At the national level, Decree 1074 of 2015 and Decree 670 of 2017 stand out.

At the international level, in addition to the aforementioned TRIPS Agreement of the WTO, Colombia is part of agreements and declarations on intellectual property that refer to voluntary and compulsory licenses, such as the Paris Convention for the Protection of Industrial Property and the Doha agreement, adopted at the WTO Ministerial Conference in 2001, which contains relevant provisions on the legitimate use of compulsory licenses in the field of intellectual property.

Compulsory licenses in Colombia, according to Decision 486, can be granted in cases of national emergency, matters of public importance or health, cases where there is an abuse of a position of power or breaches of competition law, non-commercial public use, and lack of exploitation (AFIDRO, 2020).

The Court of Justice of the Andean Community in preliminary ruling Prejudicial Interpretation 144 -IP-2019, clarified that:

"The industrial property regime of the Andean Community provides that compulsory license may be adopted under the following assumptions:

(i) Due to the lack of exploitation of the patent;

(ii) The existence of reasons of public interest, emergency, or national security; in the presence of anticompetitive conduct, especially abuse of a dominant position; or,

(iii) When the owner of a patent necessarily requires, in order exploiting it, the use of another's patent" (Court of Justice of the Andean Community, 2019).

According to Decree 1074 of 2015 to initiate this process to apply for one of these licenses, the person interested in the application of a compulsory license must apply to the competent authority for a declaration of public interest. This competence will depend on the industry or subject matter of the patent, for example, in the case of medicines and pharmaceutical products, the competent authority is the Ministry of Health.

Decree 670 of 2017 established that, after this request, an Inter-institutional Technical Commit-

tee must be created. This must be, “made up of at least one delegate of the competent Ministry,(...) one delegate of the Minister of Commerce, Industry and Tourism and one delegate of the Director of the National Planning Department, who must examine and evaluate the documents submitted, request the information to be presented by the interested party, request concepts or technical support required from other entities or natural or legal persons and recommend to the competent Ministry the decision to declare or not the existence of reasons of public interest” (ITC, 2022).

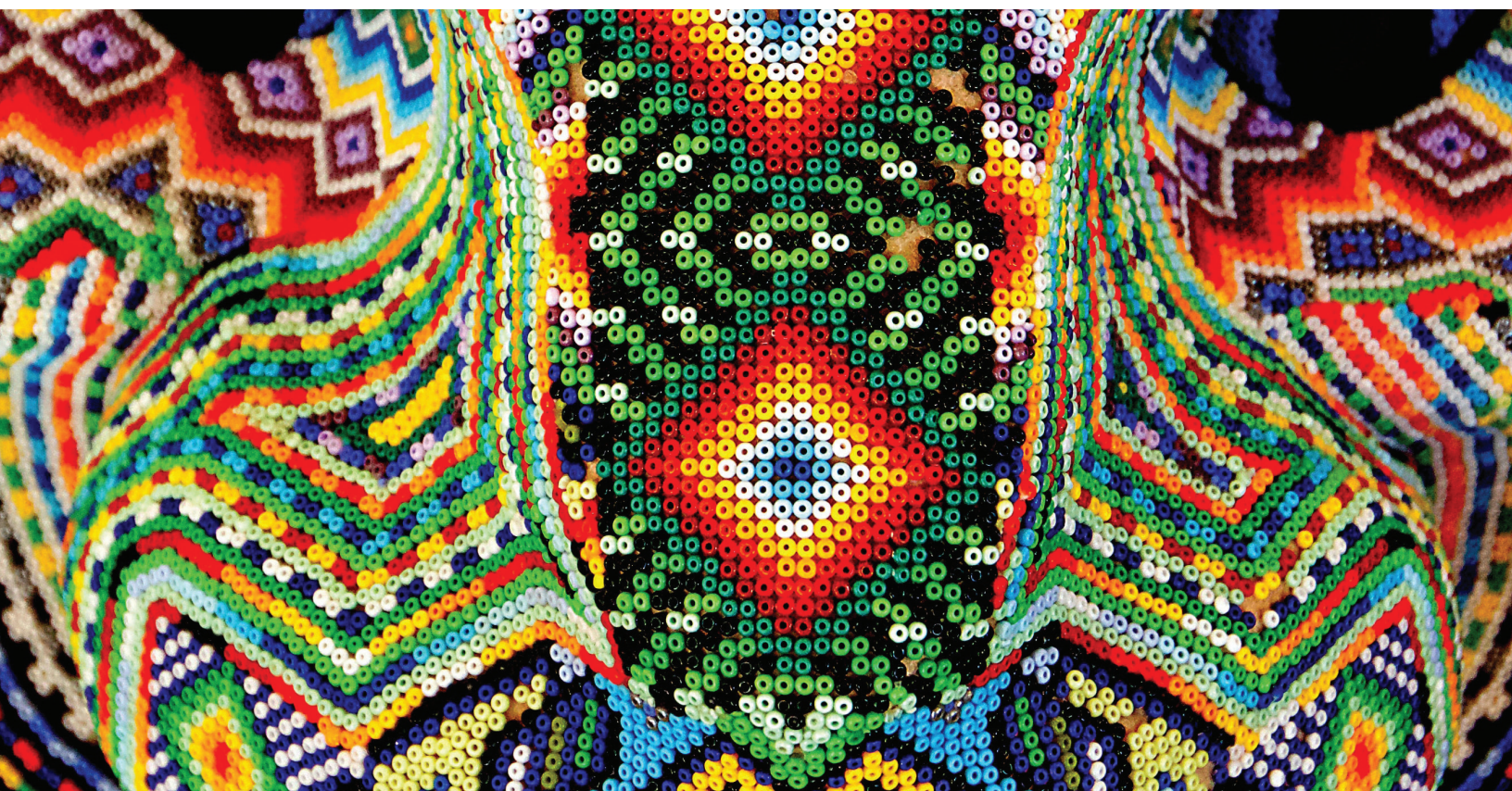
If the existence of reasons of public interest is proven, it is up to the SIC to advance the process to grant the compulsory license.

Within the pharmaceutical industry in Colombia, some processes have been advanced to

request compulsory licenses, as in the 2008 case of Kaletra, a drug for Human Immunodeficiency Virus (HIV), and as in the 2022 case of Action Antivirals, used for the treatment of hepatitis C.

In 2016, the Ministry of Health and Social Protection initiated another case in which an attempt was made to initiate a process to grant a compulsory license on the patent of the drug Glivec developed by Novartis. For this purpose, a declaration of public interest was made. However, so far no compulsory license has been granted in the country.

On June 2, the Ministry of Health and Social Protection issued a resolution to begin the process for a declaration of public interest as the first step towards an eventual compulsory license.



RESOLUTION 881 OF 2023

Resolution 881 of 2023 from the Ministry of Health and Social Protection sets out “the administrative procedure for declaring the existence of reasons of public interest to submit the patents of medicines whose active ingredient is Dolutegravir (DTG) to compulsory licensing” (Ministry of Health and Social Protection, 2023).

According to the Spanish Association of Pediatrics (n.d.), Dolutegravir is a drug indicated for the treatment of HIV infection in combination with other antiretroviral drugs.

In 2019 the World Health Organization (WHO) recommended the use of DTG as the preferred first- and second-line treatment for all populations, including pregnant women and women of reproductive age.

The Resolution established that, “Human Immunodeficiency Virus (HIV) is an infection that has infected nearly 84 million people worldwide in the last 40 years and claimed the lives of more than 40 million people. (...) According to the Public Health Surveillance System SIVIGILA, the incidence of cases of Human Immunodeficiency Virus -HIV- in Colombia has presented a progressive increase in Colombian citizens, rising from 14,064 cases in 2018 to 18,410 in 2022”.

It also expresses that the price regulated by the National Commission on Drug Prices and Medical Devices for the commercial presentation of DTG is COP \$401,574, and that the same presentation of the generic version has a cost of COP \$11,147.

There are currently four (4) patents on pharmaceutical compositions whose active ingredient is Dolutegravir that can be found on the resolution.

As apparent from the preceding section and reiterated in the resolution, the commencement of the current administrative proceeding does not imply a definitive or conclusive determination regarding the analysis. This is only the first stage, which is followed by the committee meeting to verify the existence of all the necessary requirements for the application of the compulsory license.

The private sector has publicly spoken out against the approval of this application, arguing that, “To date, in no situation has respect for intellectual property been an obstacle to a comprehensive response to HIV. In Colombia, so far, there have been no cases in which patients have stopped receiving a specific treatment as a result of patent exclusivity. Therefore, it is important to emphasize that compulsory licenses are a tool for exceptional and temporary use” (AFIDRO, 2023). VI.

ECONOMIC IMPLICATIONS OF COMPULSORY LICENSING

During the event, *“The role of the Court of Justice of the Andean Community in the protection of intellectual property”*, held on October 19, 2022 by the Universidad del Bosque, the International Trademark Association and the Court of Justice of the Andean Community - CAN in Bogotá, Judge Luis Rafael Quintero expressed that the use of compulsory licenses in times of crisis poses a dilemma that arises in those contexts due to the tension that arises between economic and commercial rights of the owners vs. the human rights that could be compromised at that juncture” (Quintero, 2022).

In these scenarios, it is necessary to determine whether the use of compulsory licenses constitutes a certain, effective and proven solution to the current crisis. In general, the use of compulsory licensing, in addition to meeting the high standards for determining the conditions for the granting of compulsory licenses, must be accompanied by a holistic analysis of the situation considering capacities, challenges, and possible consequences (SIC, 2012).

Philip Stevens, founder of the Geneva Network points out that, *“when it comes to making a drug, a patent alone is generally insufficient. Modern vaccines and drugs are complex and cannot be easily copied or reverse engineered with a patent alone. Successful licensees require a technology package that includes, among others, patents, knowledge, teaching, skills and other technical assistance”* (Stevens, 2023). Compulsory licenses would thus make public possibly insufficient

information that could compromise the quality of products, putting people at risk.

On the other hand, as mentioned by Judge Luis Rafael Quintero (2022), it is important to take into account the capacity and infrastructure that in many cases is necessary for the development of innovation. If there is no installed capacity that allows, on the basis of a patent, to replicate a drug or medical input, not only would the safety of the drug or medical input be affected, but also innovation would be discouraged without a clear purpose. Even if patents were to be lifted, there is no clarity about the capacity to develop all generics in a responsible and effective manner (Quintero, 2022).

In addition to the difficulties already mentioned, application of compulsory licenses has consequences on investors' confidence due to legal uncertainty, even moreso when there are other more suitable mechanisms to ensure access to medicines without the need to infringe on intellectual property rights. Below are some of the economic consequences:

1. Mandatory licensing may have a chilling effect on foreign investment.

The granting of compulsory licenses without having strong technical grounds that justify its application may be seen as an indirect expropriation of intellectual property rights, which could affect foreign investment in the country.



The Colombian Constitutional Court in its Decision C-750 of 2008 states that indirect expropriations within the framework of international trade, "refers to an act or a series of acts of a party that has an effect equivalent to that of a direct expropriation without the formal transfer of the title or the right of ownership to the State, since it is to compensate a kind of loss of profit of an investor, who had expectations of profit in an economic sector, which were frustrated by the new regulation" (Constitutional Court, 2008).

Intellectual Property Rights (IPR) protection is a critical consideration for foreign investors when deciding to invest in a country. Companies and investors rely on strong IPR protection to ensure that their innovations and creations are safeguarded, and that they can reap the benefits of their investments.

It is necessary to take into account that the country already is not attractive for global investment. According to the 2001 A.T. Kearney Foreign Direct Investment (FDI), Colombia is not in the ranking of the 25 best countries for FDI in the world. Most of the reasons allude to legal insecurity. The country ranks 177th out of 190 countries in the specific indicator of contract compliance (Florez, K. 2023).

2. Compulsory licenses may discourage investment in research and development, as patent holders may perceive that their investment will not be adequately protected.

Mandatory licensing is a double-edged sword. While it can promote access to essential technologies, it may also reduce the incentives for inventors to invest in research and development (R&D). The fear of losing control over their inventions and the potential for reduced financial returns can discourage inventors from pursuing groundbreaking innovations.

In particular, the importance of the pharmaceutical patent has been defended more vigorously over other innovation sectors. According to Correa (1999), in the drug and biotechnology sector the patent is more important because its investment in R&D is high and imitation is cheap, while in other sectors of more mature technologies (e.g. food) or where imitation is very risky or costly (e.g. semiconductors), it is relatively less important.

When the compulsory licensing mechanism is used arbitrarily, disregarding the economic rights that derive from obtaining a patent, it



discourages the research and development of new technologies, as well as the cooperation processes for their transfer. These usually have high costs in money and time, in addition to being high-risk investments.

3. Lifting patents does not imply local industry development.

International experience shows that this mechanism would not lead to the development of the local industry. A compulsory license without the productive and technological capacity of licensees would lead to their being easily co-opted by multinational generic industries such as those existing in China and India (Urbina, 2018).

Countries have often wanted to use compulsory licensing as a mechanism to reduce drug prices. However, there is no guarantee that this will happen. Issuing a compulsory license does not automatically guarantee faster access to medicines or improved prices.

"There can be no confusion in the use of tools proper to intellectual property law, to modify the prices of a product" (Cardona, 2016). In Colombia, there are other mechanisms. Taking into account the existence of these mechanisms in cases where the purpose is to reduce the price, the need to make use of tools of a totally different regime to that of drug prices, such as compulsory licensing, is not legally clear (Cardona 2016).

Countries that have established compulsory licensing for reasons of public interest have not strengthened their domestic industry. By contrast, some of them continue to show a deficit in the trade balance of medicines (Chamber of Commerce of Guayaquil, 2019), accounting that compulsory licensing did not lead to health sovereignty, but rather deepened the gap between imitation and national innovation.

CONCLUSIONS

As stated by the Property Rights Alliance (PRA):

“Weak IPR protection is a major obstacle to international technology licensing and reduces direct investment. (...)”

Smart regulation must be flexible and in line with the dynamics of innovation, with mechanisms that facilitate cooperation, public-private partnerships and information exchange. (...)”

Patents and intellectual property rights are important tools that enable innovators to select qualified partners to manufacture high-quality

products and help ensure broad access to current and future assets” (PRA, 2021).

Concerning intellectual property rights, there is a strong positive correlation between the top 15 countries in the Global Innovation Index 2022 (GII) of the World Intellectual Property Organization (WIPO) and the top 15 countries in the International Property Rights Index (IPRI) 2022 of the PRA, which shows that innovation is supported by a strong defense and protection of intellectual property (ICP, 2023). To achieve productive and social development driven by innovation, it is essential to safeguard intellectual property rights.

COUNTRY	GLOBAL INNOVATION INDEX	INTERNATIONAL PROPERTY RIGHTS INDEX
SWITZERLAND	1st	3rd
UNITED STATES	2nd	8th
SWEDEN	3rd	7th
NETHERLANDS	5th	5th
SINGAPORE	7th	2nd
GERMANY	8th	10th
FINLAND	9th	1st
DENMARK	10th	4th
JAPAN	13th	6th
CANADA	15th	9th

Table 1: Relation Between Innovation and Property Rights Protection

Source: Author's elaboration, Global Innovation Index and IPRI data.

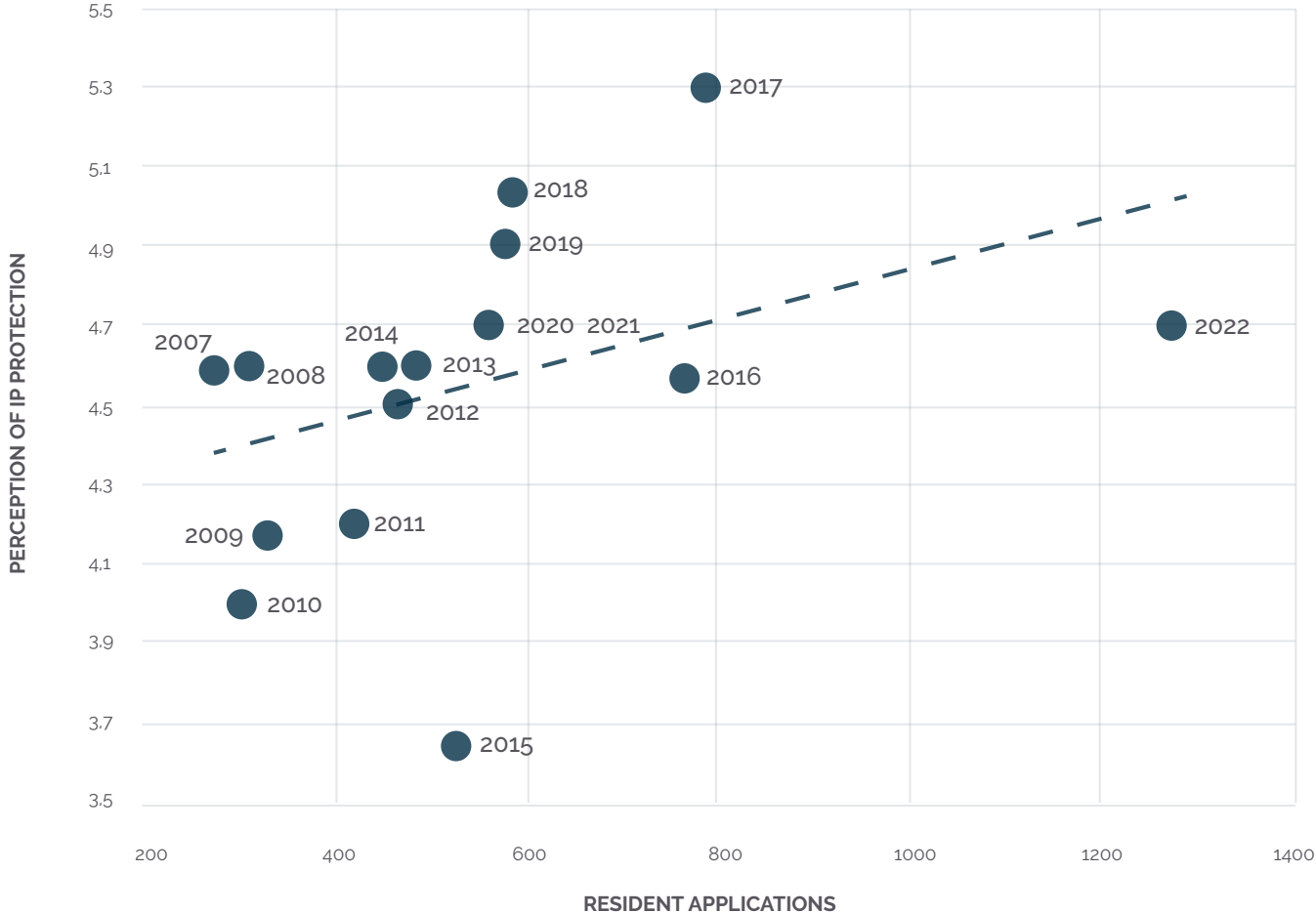
In the Colombian case, for 2022 the country ranked 63/132 in the GII, and 74/129 countries according to the IPRI. It has a score of 5.5 out of 10 in the category of patent protection for 2023.

Using the data available at the SIC, included in Graph 1, that shows the number of patents filed year by year from 2007 to 2022, it was identified that in Colombia, patent applications have been on the rise; and although they have been led by non-residents, the gap between the number of patents filed by non-residents and those filed by residents has been decreasing. Thus, in 2007 for every patent filed by a resident, 7 were filed by non-residents. In 2014, this ratio was 1 to 4;

in 2022 it was 1 to 2. This indicates that patent filings by Colombian residents have been on the rise.

A correlation exercise using Pearson's correlation coefficient showed that between 2007 and 2022 there has been a medium-low, although direct (positive), relationship between the number of patents filed by residents and the country's IPRI IP protection perception score. Graph 3 show this correlation graphically:

The fact that, in the study period, higher scores on the perception of intellectual property protection are consistent with a higher volume



of patent filings indicates that the perception that intellectual property rights are protected is an incentive to file patent applications for new innovations.

Between 2017 and 2000, the IPRI showed an increase in the protection of property rights, which generated an environment of confidence for more and more people to apply for patents. Colombians are increasingly motivated to innovate because they have the perception that the law protects their discoveries and innovations with property rights. However, it is important to note that by 2022, protection decreased.

A compulsory license may break with this environment of trust and discourage the accelerated increase in patent applications. In addition to the decline shown by the Index in recent years, the imposition of a compulsory license may be detrimental to innovation in the country.

It is said that through compulsory licenses, knowledge would be disseminated in order to produce more stocks. However, this position is adverse to Colombia's progress and is based on a naive conception of the problem. A compulsory license would not bring more innovation, but less. It would discourage not only new knowledge projects in Colombia and their patentability, but would also discour-

age research and development of new drugs, processes that have saved the country in difficult situations such as the pandemic for Covid - 19 (ICP, 2023).

The intellectual property expert, Mónica Bonett, stated on the podcast of the law firm Posse Herrera Ruíz, that compulsory licenses in Colombia have been requested due to a price issue that has been interpreted in the light of public interest. However, she expressed that in the country there are other mechanisms specifically developed for the control of drug prices, different from compulsory licenses, that do not compromise intellectual property rights. She assures that patents and drug prices are not necessarily related; this is more an issue of access to medicines and health plans. There are countries where drugs are cheaper, and the patent system is extremely strong (2023).

Taking into account the importance of intellectual property rights protection and incentives for innovation and research, which generates conditions for development and welfare, we present the following public policy recommendations that could be implemented by governments of developing countries, instead of promoting compulsory licensing, due to the numerous negative consequences that this may entail.

RECOMMENDATIONS

The success of innovation processes requires the strengthening of an institutional framework that encourages and facilitates an environment of economic freedom, investment, competition, value generation, knowledge transfer and voluntary cooperation between different actors, whether public or private. These incentives are the ones that allow an optimal development of the processes of identification, production, dissemination, use and integration of knowledge in the productive and social transformation of the country.

In this sense, it is essential to strengthen legal security and intellectual property and enhance a series of enabling mechanisms at the institutional level such as:

- » A solid institutional architecture that guarantees legal security and certainty regarding the rules of the game with respect to innovation;
- » The strengthening of intellectual property rights protection strategies;
- » The availability and diversity of financial instruments for investment in innovation;
- » The conditions and capacities for the use of and access to information and communication technologies, particularly the interconnection and interoperability of information systems;

- » The establishment of a system of quality higher education, with criteria of relevance in accordance with the new realities of work in innovation environments;
- » The promotion of business associativity schemes around the development of innovation-based clusters; and,
- » The facilitation of conditions for the establishment of regional and local productive alliances between companies, universities and state entities.

Also, implement a system of voluntary licenses instead of compulsory licenses, generating a positive incentive for innovation and knowledge transfer. To this end, it is important to remember that voluntary licenses, which are derived from a negotiation process between the parties, allow not only the release of the patent but also the transfer of know-how, which makes the generics and drugs developed on the basis of this information safer and more efficient.

Promote and strengthen mechanisms for competitiveness and transfer of knowledge and technology. Some of the forms under which knowledge and technology transfer takes place are the sale and transfer of property licenses, collaboration agreements, the generation of new companies, personnel training, among others.

The Ministry of Science, Technology and Innovation indicates that knowledge and technology transfer processes are usually the space in which governments contribute to innovation. It also states that these require “a system of interconnected public and private institutions to create, store and transfer information, knowledge, skills and competencies”.

In this sense, it is essential to strengthen the institutions that generate knowledge, such as universities, to promote cutting-edge scientific research. To this end, it is necessary to promote public-private alliances and international cooperation, as well as institutional articulation between international pharmaceutical companies, which have extensive production capacities, and national universities.

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