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Learn about the law that will cause billionaire loss to the Ministry of Health and increase the profit of pharmaceutical companies

A study by the Federal University of Rio de Janeiro (UFRJ) estimates that government will waste 3.8 billion BRL in 10 years due to the delay in the evaluation of pharmaceutical patent applications; the market monopoly lasts an average of three years longer in Brazil than in other countries and postpones the entry of generics into the country

Por: Diego Junqueira

"Who owns the patent for this vaccine?", asks the journalist on TV. "The people, I would say. There is no patent," replies the American doctor and scientist Jonas Salk in the famous interview he gave in 1955, after launching the first vaccine against polio, a contagious disease that challenged medicine at the time. "Could you patent the sun?", continued the scientist, who became an inspiration for those who advocate medicines accessible to the population.

The researcher's provocation makes sense. The price of medicines is directly linked to the existence (or not) of a patent – an instrument that guarantees exclusivity in the manufacture and sale of a product. Without competitors, drug prices tend to be higher – which guarantees a greater profit for the pharmaceutical industry.

In Brazil, however, a singularity in the legislation allows the monopoly on a drug to last longer than the world's average, which delays the entry of cheaper generics in the market.

As a result, the Ministry of Health will waste 3.8 billion BRL (US$ 918 million) over the next 10 years with the purchase of nine drugs, indicated for the treatment of cancer, hepatitis C, rheumatism and rare diseases. The expense was estimated by researchers from the Innovation Economics Group at the Federal University of Rio de Janeiro (UFRJ).

While the term of a pharmaceutical patent is 20 years in other countries, in Brazil the average duration is 23 years. There are cases that it extends beyond 28 years. “Brazilian legislation gives companies an extra benefit that was not anticipated [in the international treaty that determined two decades as standard time]”, says economist Julia Paranhos, coordinator of the study.

Article 40

The problem in Brazil revolves around the Industrial Property Law, passed in 1996 under strong lobbying by the pharmaceutical sector. An article of the law authorizes extra time for patents if the National Institute of Industrial Property (INPI) takes more than 10 years to analyze an application. Currently, the agency takes an average of 13 years to complete an analysis of the pharmaceutical sector — which extends the monopoly on a drug to 23 years on average.

One example is dasatinib, used to treat leukemia. In the last five years, the Ministry of Health has spent an average of 69 BRL (US$ 16) for each pill. In India, the generic version is sold for 16 BRL (US$ 4). The similar drug could arrive in Brazil in April 2020, when the patent for dasatinib reaches its 20 years. However, the national market will remain closed until November 2028, because it took INPI 18 years to analyze the order.

The controversial part of the law is under debate in the Supreme Federal Court, where a 2016 action by the Attorney General’s Office calls for an end to the extension of patents in Brazil, but there is no schedule for the trial.

The INPI has granted 683 pharmaceutical patents since 1997, of which 630 (92%) have benefited from the extension over 20 years, according to a survey by the UFRJ research group, which has been investigating the sector for more than 10 years.

Even when the extension does not apply, as in the case of patents applied for before the law came into force, the pharmaceutical industry uses Article 40 to file lawsuits asking for the extension of the monopoly. This is the case of humira (for rheumatoid arthritis and other diseases), from the US

laboratory Abbvie. A lawsuit guarantees the company exclusivity in Brazil until February 2020, although its patent expired in 2017.

As long as a final decision by the courts does not come out, legal uncertainty keeps competitors out of the market. With that, in the last five years, the Ministry of Health transferred 3.7 billion BRL (US$ 894 million) to Abbvie to buy humira. At the end of the three-year extension of the patent, the estimated loss for the Ministry of Health will be 990 million BRL (US$ 239 million), according to the study.

Humira is the highest-revenue drug in the world, with global sales of US$ 19.9 billion in 2018 alone. To get an idea of how the end of the patent impacts its price, in Europe, Abbvie offered 80% discounts after the arrival of the first similar drugs. So, what is the real price of this drug?

Patent Family

The extension of pharmaceutical patents has become standard in Brazil for two reasons: the high number of invention applications submitted by companies and the low number of INPI examiners.

There are currently 319 employees responsible for analyzing inventions from all sectors of the economy. But there are 160,000 pending orders in the queue, or 501 per examiner, according to the INPI. The scenario is worse than in the United States, Europe, Japan, India and Mexico.

The excess of pharmaceutical patent applications was investigated by the Oswaldo Cruz Foundation (Fiocruz), an agency linked to the Ministry of Health. In the case of adalimumab, the study identified 33 requests submitted to INPI by Abbvie and its competitors. Only two orders were granted, one was rejected, eight were filed and 22 remain in the queue.

In addition to piling up INPI's work stack, multiple patent applications for the same active ingredient are a strategy by the pharmaceutical industry to "extend the exclusivity of a product", says pharmacist Roberta Dorneles da Costa, a UERJ researcher and one of the authors of the Fiocruz study.

"The pharmaceutical industry resorts to different strategies to maintain a monopoly. The first step is to create this endless patent network", says Carlos Portugal Gouvêa, professor of commercial law at USP. "Another

strategy is the lawsuits, because while there is no final decision, the competitors are put back", adds Paranhos.

INPI recognizes that the number of examiners is low and that "the delay in analyzing patent applications has led to the extension of the term of protection". The agency said that in July it started a plan to reduce the time it takes to review patents to five years: the goal is to reduce the backlog by 80% by 2021.

When contacted, Abbvie did not comment on the extension of the humira monopoly or on the various patent applications for the drug. The laboratory told Repórter Brasil that the price of the drug has dropped in the past ten years.

The Ministry of Health told Repórter Brasil that it will comment after the study is published.

Negotiating prices

Another drug analyzed by UFRJ is sofosbuvir, indicated for hepatitis C, a disease that affects 71 million people worldwide and kills 400,000 a year, mostly in poor countries. Developed by Gilead, sofosbuvir looks as revolutionary as Salk's vaccine, as it cures hepatitis C in 95% of cases. But the high price charged by Gilead and the barrier to generics keeps the eradication of the disease in a distant future.

In Brazil, the Ministry of Health has spent more than 1.7 billion BRL (US$ 410 million) on sofosbuvir since 2014, paying an average of 258 BRL (US$ 62) per pill, according to UFRJ's survey. In low-income countries, however, it sells for 2.95 BRL (US$ 0,71 – 98% less), while in the United States it reaches 4,000 BRL (US$ 966). The patent application in Brazil was filed in March 2008, but after 11 years the analysis has not yet been completed. UFRJ estimates the extra cost to the Ministry of Health at 346 million BRL (US$ 83 million) for each year of the extension of the sofosbuvir patent.

In defending the extension of patents, Interfarma (representative of foreign companies in Brazil) says that the laboratories do not commercially take advantage of the 20 years of monopoly, since the first 10 years are

dedicated to research and tests to create the drug. The organization says that pharmaceutical investments are high and that the sustainability of the business "requires the maintenance of the right to industrial property".

The president of the Brazilian laboratory with the highest number of patents, however, defends a 20-year duration for the monopoly, "as it is recognized worldwide," says Ogari Pacheco, from Cristália. For Libbs, which financed the UFRJ research, the extension of patents "delays the entry of generics" and "increases SUS (Public Health System) spending a lot". Abifina, a representative of Brazilian pharmaceutical companies, classifies this section of the law as unconstitutional and says that some companies use the law to "artificially extend the term of patents".

For researchers at UFRJ, in addition to showing the need for investments in the INPI, the study indicates that the Brazilian government can spend less on medicines. "It is possible for the Ministry of Health to look for ways to negotiate products and get lower prices," says Paranhos.

"The future is in our hands," said Salk in 1985. "To decide whether to use the science, technology and knowledge we have for the best, rather than the worst."

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