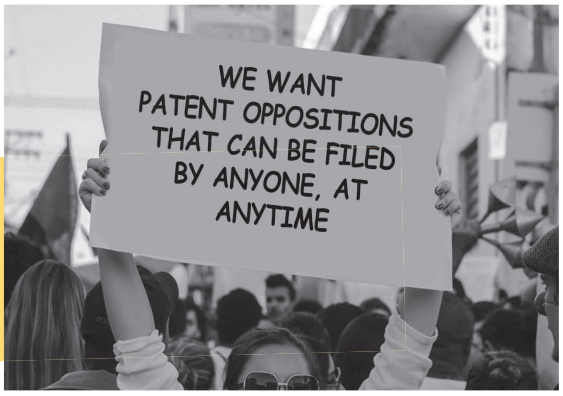
WORKING GROUP ON INTELLECTUAL PROPERTY

de olho nas patentes

Saúde é um direito, não mercadoria!

In Brazil, health is a universal right that must be guaranteed by the State, and not a commodity accessible only when the patient can afford it. However, trade rules, such as intellectual property, may prevent the exercise of the right to health, as they create monopolies (through patents) on health goods, making access to them more difficult. Brazil has failed to adopt some measures to protect the public interest that could minimize the negative impact of patents. The right to health is vulnerable. But human rights are undeniable, patents are not. There is an opportunity for the National Congress to improve the patent law now!



The topic is: participation of third parties in patent application examination

A patent is a title granted by the state, which gives the owner a temporary monopoly for the exploitation of an invention in its territory. It is up to each country to grant or to refuse a pat application in accordance with the criteria set nationally. When defining how patent applications are examined, countries may adopt mechanisms that allow third party involvement in the process. **This participation can take place before or after the grant of the patent, through administrative or judicial proceedings.**

The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) of the World Trade Organization (WTO) states that a country may have administrative procedures of patents annulment and/or opposition (article 62.4), leaving countries to decide which mechanisms will be provided. TRIPS also states that any administrative decision may be challenged in the judiciary (article 62.5).

In Brazil, Law 9.279/96 (Industrial Property Law - IPL) states that any person may file a lawsuit to challenge the validity of a patent already granted (article 56). At the administrative level, the LPI currently establishes that any person can start an annulment proceeding within six months of the grant of the patent (article 51). **This administrative process must follow all the guarantees of due process of law, including contradictory and the need to justify decisions**. Thus, after the grant of the patent, Brazilian law provides the possibility of opposition at the administrative level, although the period of six months can be considered short. However, as regards the questioning of a patent application before it is granted, the IPL adopted the model of "Assistance to examination" (article 31), in which parties may submit documents and information to assist the examiner's decision, but with no requirement for the examiner to consider such information in his/her decision.

Why is it important for health?

The grant of a patent may have negative effects on access to health goods. A patent confers a temporary monopoly to its owner, which can prevent other public and private laboratories to produce the product (article 42 LPI). Therefore, the patent owner may set higher prices, which could compromise public budgets and hamper the sustainability of public policies on access to medicines or even the purchase by the patient. Therefore, a rigorous analysis of patent applications is essential to prevent the granting of undeserved patents. The participation of people, companies and civil society organizations interested in this process is important. By bringing elements that may have gone unnoticed by the examiner, the participation of third parties may raise the quality of patents granted and avoid the granting of undeserved patents that could negatively impact access to the good. Thanks to patent oppositions in India, for example, it was possible to reduce the price by 99% of first-line treatment combinations for HIV/AIDS, as new producers started to produce the medicines because there were no patents that prevented them.

What is at stake in the National Congress of Brazil?

Among the bills that aim to reform the patent law currently underway in the National Congress, bill 5.402/2013 proposes changes related to participation of third parties in patent application examination.

Bill / Authoring	Summary
PL 5.402/2013 Newton Lima Neto (PT/SP) Dr. Rosinha (PT/PR)	Modifies article 31 of LPI. Aims to establish the procedure for opposition to patent applications before the grant of the patent at the administrative level.
	Includes article 31-A in the LPI. Aims to create a facilitated procedure for sending information regarding patent applications, besides initiating an opposition or administrative annulment procedure.

Caption: favorable to the right to health, contrary to the right to health

What GTPI thinks about it?

The participation of third parties in the analysis of a patent application can help to prevent the granting of a undeserved patent or even increase the quality of granted patents, making more clear the object and scope of protection. Therefore, all forms of participation or challenging should be widely provided in the laws. However, judicial procedures are expensive and slow and until a final decision is reached, the patent owner, in practice, continues to enjoy the rights conferred by the patent. Therefore, measures that can be taken at the administrative level must be strengthened. Also, the priority should be given to measures that can be taken **before the grant** of the patent in order to reduce the risk of granting an undeserved patent that may have a negative impact on access to the protected product.

We understand that the Brazilian law makes third parties participation before the grant of the patent very fragile, especially because the patent examiner or the applicant are not obliged to respond to the information presented in the "Assistance to examination". Therefore, the replacement of the model "Assistance to examination" by the "opposition to the patent application" can strengthen the participation of individuals, laboratories and civil society organizations in this process **by imposing to the patent examiner the obligation to respond to the information presented**. Moreover, the possibility to send information in a simple way without the need to initiate an administrative or judicial proceeding expands the possibilities of participation to a greater number of stakeholders and must be supported. Therefore, we believe that the proposals presented by bill 5.402/13 should be approved.

ASSISTANCE TO EXAMINATION PRESENTED BY GTPI/REBRIP			
cine / patent	mation about the case	Year	Result
Lopinavir/ritonavir PP1101190-4	A divisional patent was requested in a manner not provided for by Brazilian patent law. GTPI pointed out that illegality.	2006	PATENT DENIED
Tenofovir (TDF) PI9811045-4	When the patent application was filled, disoproxila tenofovir fumarate (TDF) was already in the public domain in Brazil. GTPI presented evidence about the lack of novelty of the application.	2006	PATENT DENIED
Tenofovir (TDF) PI 9816239-0	After TDF's patent was challenged, the company requested a divisional patent. GTPI presented information showing that this divisional patent did not meet the patentability requirements, such as novelty and inventive step.	2009	PATENT DENIED
Tenofovir/Emtricitabina PI0406760-6	The application is for a combination of two drugs already known and in the public domain in Brazil. GTPI presented arguments demonstrating the lack of novelty and inventive step.	2010	PENDING DECISION
Lopinavir/ritonavir PI0413882-1	The application is for a new formulation of a drug already known. GTPI presented arguments showing the lack of novelty and inventive step.	2012	PENDING DECISION

About us

The Working Group on Intellectual Property of the Brazilian Network for the Integration of Peoples (GTPI/Rebrip) is a group made up of civil society organizations, researchers and activists. Since 2003, we develop activities aimed at reducing the negative impacts of patents on public health policies in Brazil and in the Global South. One of GTPI's lines of work is monitoring bills that may positively or negatively affect access to health goods. Learn more about what GTPI thinks about bills amending the patent law at: www.deolhonaspatentes.org.br.

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