

Discussion Monitoring Article

The Impact of Abolishing Article 20 of the Patent Law on Medicine Access

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In the course of the COVID-19 Pandemic, the Government remains unyielding on continuing the discussion of the Omnibus Law on Job Creation Bill even though it has been opposed by many elements of civil society, labor, and academics. The Omnibus Law on Job Creation Bill does not only contain issues on labor, environment, and food, but also other aspects such as patents.

The Government through the Omnibus Law on Job Creation Bill plans to abolish Article 20 of Law No. 13 of 2016 on Patents. The article states that every product to be registered for a patent must be produced in Indonesia by a process of technology transfer and employment. The Government's plan to abolish this article through the Omnibus Law has been rolling for a long time, the Government argues that this article is against the TRIPs regulations, and many countries, specifically European countries who object to this very article.

To answer the problems arising in this regard, Indonesia for Global Justice together alongside the Indonesia Aids Coalition held a Discussion Series on Omnibus Law and COVID-19: The Impact of Abolishing Article 20 of the Patent Law on

Access to Affordable Medicines. The discussion presented Prof. Agus Sardjono of the Faculty of Law of the University of Indonesia and Ms. Lutfiyah Hanim of the Third World Network as speakers. In their presentation, the two speakers conveyed several important points related to the Abolition of Article 20 of the Patent Law in the Omnibus Law, including the principle of local working in the article, the purpose of regulating article 20, how this article relates to TRIPs and its relation to our state constitution.

The principle of Local Working in Article 20 of the Patent Law

Prof. Agus Sardjono stated that Article 20 of the Patent Law is an article regarding the principle of Local Working. The principle of Local Working is the compensation requested by the state to the patent recipient to implement his invention inside the country which granted the patent. This principle is applied in many countries including America. Indonesia itself has implemented this principle since the first Patent Law in 1989, the Patent Law in 2001, to the 2016 Patent Law. The difference in the application of this principle existed in 2016 where there was a sanction if the

patent owner does not apply for the granted patent, then the patent can be revoked.

The purpose of local working in Indonesia is clearly stated in Article 20 of the Patent Law, namely for technology transfer, absorption of investment, and provision of employment. Whereas abroad, the aim is even broader, namely to prevent patent blocking, an action which is usually taken by patent holders who register their patents simply to prevent the technology from being implemented by other people in the patent granting country.

In addition, patents are expected to bring social impacts on education, the economy, and technology development as a form of reward for the monopoly granted.

The Abolishing of Article 20 of the Patent Law Will Deteriorate Medicine Access Condition in Indonesia

A researcher of Third World Network, Lutfiyah Hanim explained that the application of the Patent regulation is the implementation of our membership in the WTO where one of the agreements is TRIPs which sets standards on patents. TRIPs are the minimum standards implemented by developed countries when this regulation was passed. In addition to the minimum standard, the regulation also provides the flexibility of TRIPs to balance the rights of IPR holders and users and this is emphasized in the Doha agenda.

When a patent is related to medicine, the patent holder will get a monopoly. This means that the patent holder can fully authorize the product, starting from production, becoming a supplier, determining the price to determining which country they will market the product in. Meanwhile, if it is not patented or the patent has expired, there will be no monopoly; hence it can be produced by many parties and many suppliers and allows for competition. This matter will make access to affordable medicines more feasible.

Another challenge arising in medicine access, according to Lutfiyah Hanim, is *patent evergreening* or extension of the patent monopoly. She said that several cases of patent extension occurred on medicines whose patents should have expired.

Description	Status	Patent application number	Patent Number	Expired date
Ritonavir crystalline polymorph (Indonesia - Komposisi farmasi mengandung kristal ritonavir bentuk II dan pembuatannya)	Granted	W00200703601	IDP000030607	19/07/2019
Ritonavir crystalline polymorp	Granted	W0020010165	IDP000021288	19/07/2019
Ritonavir crystalline polymorph (bahasa Indonesia - Ritonavir amorf (pecahan W0020010165))	Granted	W0020080567	IDP000030609	19/07/2019
formulasi yang disempurnakan terdiri dari ritonavir	Granted	W0020010255	IDP00021296	25/05/2020
Ritonavir and LPV/r heat-stable formulations	Granted	W00200600560	IDP000023461	23/08/2024

Source: Lutfiyah Hanim's Presentation on Omnibus Law & COVID-19 Series of Discussion

As an example, in the case of Ritonavir, the patent should have expired since July 2019 yet the patent was extended to 2024. At that time generic versions of the drug should have entered. Another example is

the sofosbuvir patent, whose patent should expire in 2024, but there is an extension of the patent to 2032. Sofosbuvir itself applies for a voluntary license, therefore an affordable version of the medicine is available. Nevertheless, the price itself in Indonesia remains quite high, around USD 1,000 for a single treatment in 3-4 months.

Paten Sofosbuvir di Indonesia, 2004 - 2032

Country	Product Name(s)	Disease Area(s)	Patent Description	Patent Status	Patent Application Number	Expected Expiry Date (dd/mm/yyyy)	Last Updated On (dd/mm/yyyy)
Licenses(s) and other Agreements(s):							
Bilateral licenses on sofosbuvir (SOF, SOF/ledipasvir, SOF/velpatasvir, SOF/NS5A/sofosbuvir)							
Indonesia	Sofosbuvir 400 mg P/B/B/E	Hepatitis C (HCV)	Sofosbuvir active metabolite	Granted	IN00020503201	21/04/2024	18/11/2019
			Sofosbuvir active metabolite	Granted	IN00021101421	21/04/2024	18/11/2019
			Sofosbuvir active metabolite	Filed	IN00021101419	21/04/2024	18/11/2019
			Sofosbuvir processes & intermediates	Granted	IN00021204454	21/03/2021	18/11/2019
			Compositions comprising crystalline Sofosbuvir	Granted	IN00021401478	27/11/2022	18/11/2019
			Sofosbuvir compound (prodrug)	Not Filed			

Prior to the discourse on abolishing Article 20 of the Patent Law, access to medicines in Indonesia had already had its issues. If Article 20 of the Patent Law is then abolished, the patent holder company does not need to invest anything; because there is no obligation for local production. This also opens up opportunities for patent blocking, thus worsening medicine access in Indonesia. For now, several medicines in Indonesia are patented until the patent expires, for instance, Didanosine and Abacavir.

The Abolishing Article 20 of the Patent Law Is Not a Solution

The Government's plan to abolish Article 20 of the Patent Law at the urging of developed countries and the argument that the Article is contrary to Article 27 of the TRIPs is clearly not a solution. The Government's opinion that this article is

contrary to Article 27 TRIPs which does not allow discriminatory regulations according to Prof. Agus Sardjono was involuntarily forced. The discrimination used as an excuse to demand the abolition of Article 20 of the Patent Law is a mistake. Discrimination is applied not to local products versus imported products, but discrimination against citizens of the WTO participating nations. The principle of the most favored nation and national treatment is about the nation, not about the product.

Prof. Agus Sardjono explained that the regulations in TRIPs allow the implementation of *local working* principles. TRIPs clearly states in several articles that require technology to develop with the provision of rewards to the inventors of new technology. This means that patents must have a social and economic impact on the citizens who participate in the TRIPs agreement, as stated in Article 7 TRIPs.

“The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations”

According to Prof. Agus Sardjono, Article 7 pointed out that patents are tools to disseminate technology and a means to transfer technology, therefore patents have a high social impact, both through learning

(education) and the economic progress of nations through technological development itself.

Therefore, the solution to this objection should be to regulate, thus *local work* can be implemented fairly and benefit all parties, including the patent owners themselves. According to Prof. Agus Sardjono, several steps can be taken, including:

1. Providing the patent owners, a sufficient period of time to choose to implement the technology themselves.
2. For certain products related to public health and urgent national interests, the implementation of local work can be conducted through a compulsory license with appropriate royalties.
3. If the patent owners have objections to making their product themselves or refuse to grant a license to a local partner, then the patent may be filed by the Prosecutor on behalf of the nation of Indonesia in order to enforce the national interest.
4. After the patent is terminated, anyone can use the invention freely,

because it is no longer protected by the patent. That is why abolition cannot be implemented arbitrarily but through a well and just trial process.

It is fundamental for all elements of the society to urge the Government and the House of Representatives to stop the plan to abolish Article 20 of the Patent Law in the Omnibus Law. Moreover, this article is a constitutional mandate to educate the nation's life and create job opportunities. Further, the elimination of this article will deteriorate the conditions for access to cheap and affordable medicines in Indonesia due to stronger patent regulations and the possibility of a loss of domestic production of these medicines. Especially in the course of the Pandemic, the health system in our country was still far from ideal conditions to ensure public health.