AMENDING INDONESIA'S 2016 PATENT ACT WILL DRIVE BIOPHARMACEUTICAL INVESTMENT

Amending the 2016 Patent Act to bring Indonesia into line with international standards is key to becoming a regional biopharmaceutical manufacturing and innovation hub.

INTRODUCTION

The Indonesian government wishes to promote Foreign Direct Investment, economic growth, job creation and important sectors such as biopharmaceuticals. To support these objectives, the government has undertaken several important reforms, most notably the 2020 Omnibus Bill, which aims to improve the overall investment in the country. To support the Omnibus Bill, the government is amending the 2016 Patent Law, an unsatisfactory legislation that left Indonesia's patent standards beneath those of many countries, detracting from Indonesia's desirability as an investment destination and overall levels of international competitiveness.

Patent policy should work to promote national development priorities while benefitting citizens and consumers. In the case of biopharmaceuticals, patent law should work towards the government's goal of boosting Indonesia's biopharmaceutical manufacturing and innovative capacity, while making medicines readily available to patients.

The 2016 Patent Law, as originally conceived, worked against these ambitions. It created a great deal of uncertainty amongst international and local investors by casting doubt of the surety of patent rights, especially

in its wide-ranging provisions on compulsory licensing. Other problematic provision included a ban on patents for new uses of existing indications, an important patent right that is available in many jurisdictions.

It is therefore encouraging that the Indonesian Government is taking action to update and amend the 2016 Patent Law, and that the draft patent law amendments have been added to the docket of parliamentary priorities (Prolegnas) for 2023.

To assist the parliamentary debate of reform to the 2016 Patent Act, this brief identifies some pathways towards a patent system that can assist in building Indonesia's international competitiveness while addressing its domestic policy priorities.

COMPULSORY LICENSING

Compulsory licenses should only be issued in accordance with international rules and only in exceptional circumstances and as a last resort. The seriousness of overriding property rights means compulsory licensing should not be used to promote domestic industrial interests, nor as a lever to negotiate prices.

The 2016 Patent Act had several provisions around compulsory licensing that made the Indonesian patent system an international outlier. The original Act allows extremely broad legally permitted grounds for a compulsory license. Further, the 2016 Act's onerous local working requirement meant a compulsory license could be issued if a patented product was not manufactured in Indonesia. This provision was far outside internationally accepted patent norms and seems more directed at industrial policy than consumer interest, not least because it stood to significantly undermine the supply of innovative medicines.

The Omnibus Law took some positive steps to correct these flaws, removing the local working requirement from compulsory licenses and thereby aligning Indonesia's patent working requirements with international rules. However, the draft amendments to the 2016 Patent Act still contains numerous wrinkles which undermine the certainty of patent rights in Indonesia.

DRAFT AMENDMENTS TO THE 2016 PATENT ACT: COMPULSORY LICENSING

PUBLIC INTEREST

The original 2016 Act left the grounds for a compulsory license vague and broad. The draft Amendments have not entirely corrected this. Article 82 of the Amended 2016 Patent Act provides that anyone may petition the government for a compulsory license by claiming that the patent holder did not implement its patent in Indonesia as defined in Article 20 within 36 months of patent grant, or simply by asserting that a compulsory license is in the "public interest."

However, issuing compulsory licenses by simply declaring that it is in the "public interest" is not consistent with international norms, which make clear that compulsory licensing is only appropriate in exceptional circumstances. The "public interest" does not include any clear definitions, and widens the scope for a compulsory license to all kinds

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of circumstance, ranging from the cost of a medicine to lack of availability. These issues are best addressed by other mechanisms, as discussed later.

COMPULSORY LICENSES AND INDUSTRIAL POLICY

Criticisms that the Indonesian patent system is too slanted towards industrial policy have been addressed to an extent by the 2020 Omnibus Bill, which removed the local working requirement. Nevertheless, the draft Amendments to the Patent Act do not remove entirely the possibility that compulsory licenses could be used to facilitate industrial policy. Article 82A of the Amended 2016 Patent Act provides that a compulsory license may be issued where "a Patent resulting from the development of a previously granted Patent could not be implemented without using the Patent of another party that is still under protection," if doing so will "result in an increase in national economic growth". This is a clear statement that the draft patent law amendments should facilitate compulsory licensing for industrial policy purposes.

This provision should be addressed, not least because international evidence shows that medicines manufactured locally under compulsory licenses are often uncompetitive and unsustainable:

- In Zimbabwe the local supplier that was granted a compulsory license in 2003 was forced to exit the market altogether in 2012 due to competition from medicines from India. Local manufacturer Pharco NDA Mozambique was never able to start production of ARVs following compulsory license because the cost of imported APIs made it uncompetitive.

- Tanzania's attempts to promote its local industry failed largely because of its inability to compete with international generics producers, and the cost of imported APIs.

- Another cross-country study examining attempts to promote access to medicines via local production found supportive evidence to be "sparse at best".

- A review of thirty case studies found that compulsory license prices exceeded the median international procurement prices in nineteen of the thirty case studies, often with a price gap of more than 25 percent. The gap was most pronounced in low-income countries that manufacture medicines locally under compulsory licenses.

- In Ethiopia, one survey shows that locally-produced medicines are 45% more expensive than imported produced, with eight of nine medicines procured as both local and imported products cheaper when imported.

- In Tanzania, research shows locally-produced medicines are less available, with patients paying slightly more.

- In Vietnam, drug prices on the lowest-priced generics have been more than 10 times higher than that predicted by WHO modelling and have increased at an average rate of nearly 8% per year. Local bids winning government procurement tenders can be 150-250% higher than imported products.

Another problematic area within the Amended Act is that compulsory licenses may be issued to address healthcare cost concerns. But the WTO TRIPS Agreement contains no provisions that justify medicines price for the issuing of compulsory licenses. Nevertheless Articles 111 and 111A of the amended Patent Act contain several provisions that allow use of compulsory licensing where pharmaceutical

products are deemed “expensive”. It is inappropriate to use compulsory licenses in pricing negotiations between governments and right holders. Certainly, this is not in the spirit of the TRIPS Agreement. Furthermore, international evidence shows that compulsory licenses do not always lead to the best price:

- A 2015 study showed that countries that use compulsory licensing to manufacture or import generic antiretroviral medicines often pay more than those who negotiate for the best branded or generic deal through international procurement mechanisms such as the Global Fund for Aids, Tuberculosis and Malaria and UNICEF. Compulsory license prices exceed the median international procurement prices in nineteen of the thirty case studies, often with a price gap of more than 25 per cent.

- The study also found that countries that manufacture medicines locally under compulsory licenses typically pay 83 per cent more than similar peer countries.

- In Brazil, efavirenz manufactured under compulsory license by the local state-owned pharmaceutical company was uncompetitive compared to that sourced previously from an Indian supplier: 6.3 times more expensive by 2013. This suggests that local manufacture under compulsory license can be sub-optimal from a public health perspective.

COMPULSORY LICENSES OFTEN DO NOT TRANSLATE INTO WIDESPREAD ACCESS – MALAYSIA CASE STUDY.

Recent Malaysian experience gives some lessons for Indonesia around the limitations of compulsory licensing to achieve public health goals. In 2017, Malaysia issued a government use license (GUL), a form of compulsory license, for the production and distribution of the Hepatitis C drug, sofosbuvir. This move was made in response to cost of the drug, which was deemed by the Malaysian government to be unaffordable for public subsidisation. According to government modelling, around 500,000 patients in Malaysia needed access to the drug.

> In 2021, only 2% of Malaysian Hepatitis C patients had access to sofosbuvir, even though a compulsory license was issued in 2017.

In November 2019, the Ministry of Health stated that only 4,500 patients had been treated with the compulsory licensed medicine, or 0.9% of the eligible patient population. By June 2021, that had increased to 10,000 Hepatitis C patients, only 2% of the estimated 500,000 Malaysians living with Hepatitis C.

Responding to the significant shortcomings in patient access, despite the existence of the generic medicine, Health Ministry National Head of Gastroenterology and Hepatology Dr Muhammad Radzi Abu Hassan told a press conference there were problems in getting lab support, coordinating with hospitals for the treatment of patients, and procurement that didn’t meet specifications..

This low uptake left the government with a surplus of medicine stocks, leading it to convert the CL to a voluntary license to sell the surplus medicines to medical tourists via the private sector. The pricing terms of the voluntary license were comparable to the original compulsory license.

This low uptake and usage of compulsory licensed HCV products suggests factors other than intellectual property rights are at play in

Voluntary licensing can help transfer technology to Indonesia, helping it develop ts technical skills base in advanced biopharmaceutical manufacturing.

determining access, even if treatment is free. For instance, Malaysia did not have a national hepatitis C programme until 2018, the creation of which required major capacity building, investment and training at the primary care level. Academic research has detailed a range of non-IP demand and supply barriers that have inhibited uptake of government-provided HCV care in Malaysia, in spite of free treatment.

THE IMPORTANCE OF VOLUNTARY COLLABORATION FOR TECH TRANSFER

Indonesia has an ambition to become a regional hub for vaccine and medicines manufacturing and R&D. Sustainable tech transfer in collaboration with rights holders under the IP framework is a much more effective way of achieving this than compulsory licensing.

The importance of technology transfer for modern biopharmaceuticals and vaccines cannot be overstated. Compulsory licensing enables generic competitors to override a patent. But when it comes to making a medicine, a patent by itself is generally insufficient. Modern vaccines and medicines are complex and cannot easily be copied or reverse-engineered with just a patent. Successful licensees require a bundle of technology including, but not limited to, patents – know-how, teaching, skills and other technical assistance, including to ensure product quality and safety.

Most vaccine and biologic medicine production technology is embodied in technical know-how specific to each product, which is not easily transferred. Such information is often known by few people within the innovator organization, protected by trade secrets.

For COVID vaccines, originators entered into voluntary licenses not only for wholesale manufacture but also for discrete parts of the manufacturing process. Both approaches helped drive rapid manufacture at a scale well beyond originators' capacities. This has continued with Covid therapeutics, via such mechanisms as the Medicines Patent Pool. Licensing within an agreed IP-protected framework is crucial to these deals given the amount of proprietary and commercially sensitive information shared.

Such close cooperation underdoes not occur under coercive interventions such as compulsory licensing, which leaves the would-be manufacturer to develop and devise its own manufacturing processes. This is a time consuming and costly exercise, making compulsory licensing especially ill-suited as a pandemic response measure.

Voluntary collaboration should always be preferable to promote rapid technology transfer, especially for developing countries like Indonesia that aspire to further develop its technical skills base in advanced biopharmaceutical manufacturing. Such collaboration will raise the level of skills within the country and result in more rapid access to quality medicines. Other advantages include:

- **Speed:** Voluntary licenses (VLs) are a faster way of making innovative Covid medicines available in LMICs. By signing a VL agreement, generic manufacturers do not have to wait for patent outcomes, pre-grant patent oppositions or apply for a compulsory license. This can save considerable time and money.

- **Quality assurance:** Another strength of the voluntary licensing approach is the emphasis on quality. This is a real issue considering the various scandals and quality issues that have arisen with certain substandard medicines marketed in low-income countries, including Indonesia. The Medicines Patent Pool for instance has strict safeguards to ensure medicine quality. Most bilateral voluntary licenses also include conditions requiring the licensee to follow certain quality standards.

DRAFT AMENDMENTS TO THE 2016 PATENT ACT: RESTRICTIVE PATENTABILITY CRITERIA

Countries that are successful in innovation allow patents for all forms of the invention that meet patentability criteria, without discrimination by sector or technology. It is particularly important to eliminate improper patentability restrictions in the biopharmaceutical sector given the importance of follow-on innovation.

Biopharmaceutical stakeholders indicate that the Indonesian government may be ready to address concerns related to patentability of new uses through the draft patent law amendments. This is a positive development, and the government should be congratulated on this new direction.

Patent protection for second uses of existing medicines is particularly important component to a functioning innovation ecosystem within a country. Drug repurposing offers significant benefits as an avenue for R&D, particularly in an urgent pandemic situation: the already known safety and efficacy profiles of studied drugs avoid exposing patients to drugs with unknown risks; and investigators can leverage the accelerated development timelines associated with drug repurposing, for example by starting at later stages of development or using smaller samples in clinical trials.

Many important existing drugs have been successfully repurposed. Research suggests that up to 15% of given indications for drugs on the WHO's Essential Drugs List were follow-on indications. According to some estimates, approximately 90% of medicines most used by patients are approved by the US Food & Drug Administration (FDA) for diseases other than their original approval (so-called "secondary indications"). Five of the most widely used Covid therapeutics are repurposed drugs.

Although cheaper than running clinical trials for *de novo* medicines, there are significant costs associated with gaining marketing authorisation for repurposed drugs. Thus far, governments and other public agencies have appeared to be largely unwilling or unable to finance drug repurposing R&D. As a result, this significant cost burden has very much fallen on the private sector.

Moreover, new indications tend not to be recognised until long after patent protection has been obtained on the original indication – and often, so long after, that the patent has expired and generic competitors have already entered the market. This means that innovators that have developed drugs for one indication will likely have lost much, if not all, of the market exclusivity offered by the patent on the first medical use by the time that potential second medical uses are revealed.

This effectively makes the development process around second indications even riskier, since the diminished patent exclusivity reduces the innovator's opportunity to recoup their R&D spend and secure returns on investment.

BENEFITS OF SECONDARY USE PATENTS FOR EMERGING MARKETS

However, jurisdictions that are home to successful innovative industries mitigate that risk by offering robust patent protection for new medical uses. This is also the reason why several patent offices around the world do grant patents for new medical uses.

The European Patent Office (EPO), for example, has since the 1980s made patent protection available for new uses, in addition to Australia, Canada, China, Japan, South Korea, Israel, Mexico, Nigeria, New Zealand, the Philippines, Russia, Singapore, South Africa, Taiwan, Thailand, Ukraine and the United States.

Providing patent protection to follow-on innovation is important for the growth of pharmaceutical companies in emerging markets like Indonesia. Follow-on innovation can act as an entry into fully-fledged *de novo* drug R&D: young Indonesian companies could undertake proof of concept studies on existing molecules and license them out to more established R&D companies, or alternatively in-license molecules from established pharma companies, screen and validate them, and license them back to the parent companies for development. The management of clinical trials is also an important growth area in Indonesia, important to complete drug repurposing studies.

Such business models can help the industry move up the value chain and in turn, generate high-quality jobs and sustainable economic growth. But they depend on appropriate patent protection. It is encouraging the amendments to the Patent Act are moving Indonesia in this direction.

CONCLUSION

Given its many strengths, Indonesia holds great potential to become a regional biopharmaceutical manufacturing and innovation hub. This ambition cannot be achieved through coercive measures such as compulsory licensing, however. No country has yet succeeded in building a viable local biopharmaceutical industry through the confiscation of patent rights.

The best way to encourage investment, technology and skills transfer is through collaboration between international and domestic partners. The correct framework for the protection of patents is essential, as it allows international partners to collaborate and share valuable proprietary information without the risk of sacrificing wider business objectives.

Indonesia is taking encouraging steps to improve the standards of its patent protection, bringing it more into line with international norms. Yet a few questions remain within the draft amendments to 2016 Patent Act, particularly around compulsory licensing. Address these, and Indonesia could become a regional biopharmaceutical investment magnet.

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