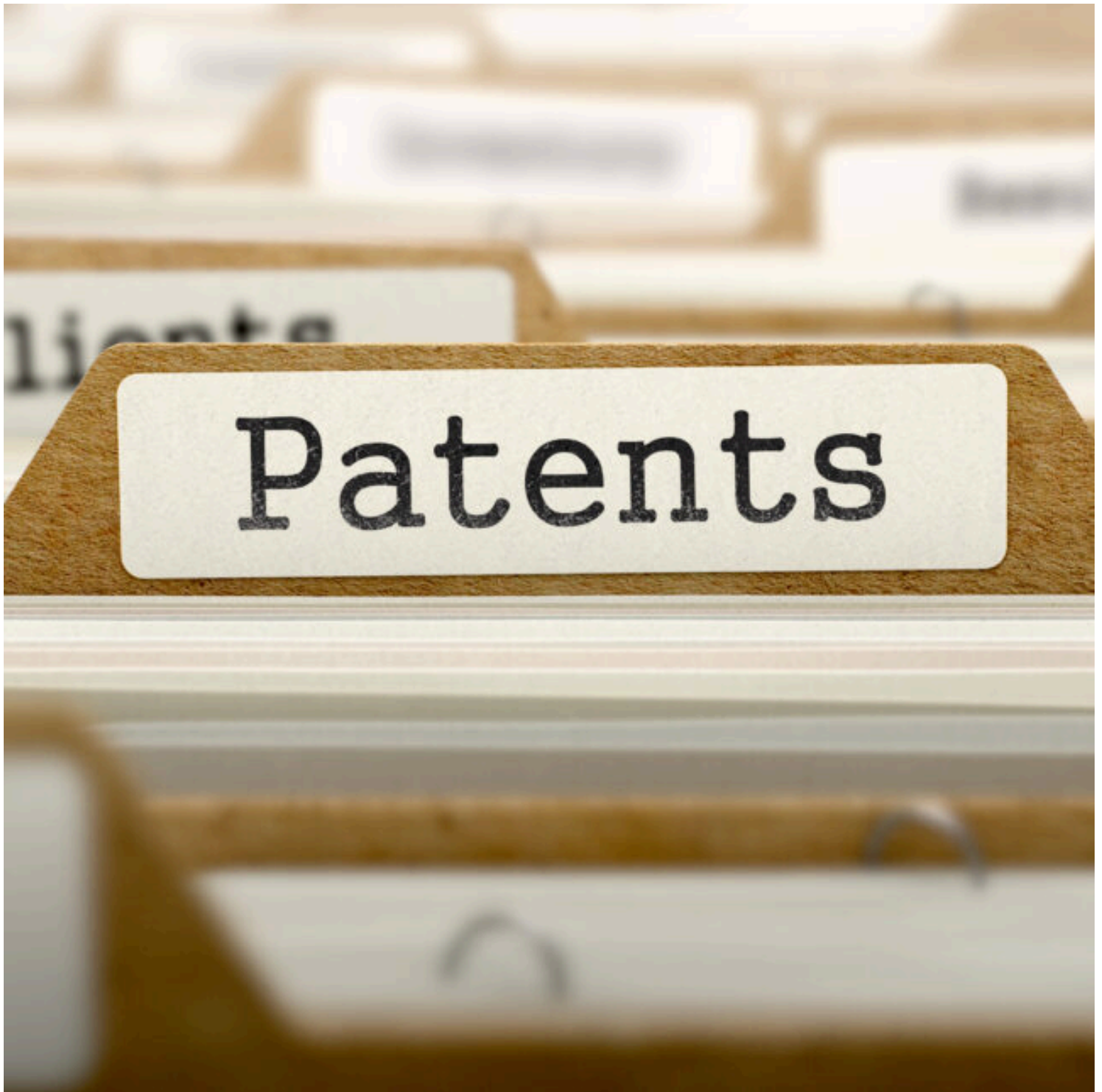


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PHARMALOT

Indonesian ruling against 'patent evergreening' by pharma industry sends critical message, patient advocates say

Critics say drugmakers uses the tactic to file patents with minor tweaks, keeping prices high



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In the latest battle over access to medicines, an Indonesian court recently struck down a provision in a law that allowed “patent evergreening,” a tactic used by drugmakers to file additional patents containing minor tweaks to existing medicines and, ultimately, forestall competition.

The decision, patient advocates say, sends an important message to other countries to challenge the industry practice.

Indonesia’s Constitutional Court ruled that a two-year-old amendment to a law, which had removed a prohibition on evergreening, was unconstitutional after deciding the original restriction is needed to balance the rights of patent holders with the broader public interest, particularly public health. The case had been brought by several patients and advocacy groups.

To underscore the issue, the patient groups noted that a study of 20 medicines used to treat highly prevalent or catastrophic diseases in Indonesia identified 68 patent applications, with some secondary patents extending the period of protection by five to 10 years beyond the expiration date of the primary patent. (The study was conducted by a lecturer at the School of Pharmacy at the Institut Teknologi Bandung and was submitted as evidence, but has not yet been published.)

“Patent rights should not be understood merely as an economic privilege, but also as rights carrying a dimension of social responsibility,” the court wrote. “Protection of inventors is necessary to sustain innovation, but at the same time, the benefits and impacts of innovation are intertwined with the interests of society.”

The court also broadened the interpretation of an “interested party” that can oppose a patent granted under Indonesia’s patent law. In doing so, the court recognized the legal standing of patient and consumer groups, nongovernmental organizations, and independent researchers to challenge a patent.

The decision was hailed by consumer advocates, who noted that when a generic version of an HIV combination medicine known as TLE became available in the country, the price dropped by 48%. They maintained this generated annual savings of \$8 million and allowed more than 45,000 additional people living with HIV to access treatment.

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The ruling is “an important step towards ensuring that the patent protection system maintains a proper balance between innovation and people’s right to access affordable treatment,” said Arni Rismayanti, who heads the Indonesian Pulmonary Hypertension Foundation, one of the groups that petitioned the court to overturn the provision.

It is not yet clear which medicines may now be targeted for patent challenges, according to Aditya Wardhana, the executive director of the Indonesia AIDS Coalition. But he believes the ruling offers a “stronger foundation” to challenge the patent that Gilead Sciences holds on its groundbreaking HIV prevention drug, lenacapavir.

The injectable medicine is widely seen as a key step toward eradicating the infectious disease and the company reached voluntary licensing deals with several generic makers to boost supplies of lower-cost versions. But the agreements have been criticized over provisions that box out some countries, among other things.

Evergreening has regularly caused controversy. The tactic can involve altering ingredients in the formulation of a drug, for example, or switching from a pill to capsule. Doing so extends the patent life of a medicine by adding a new patent that expires later than a previous patent.

Drugmakers have argued such moves are legitimate efforts that reflect genuine improvements to medicines. But consumer advocates, patient groups, and academics complain such changes are unjustified tweaks that unfairly delay availability of lower-cost generic drugs, contributing to rising health care costs and strained government budgets.

The issue gained notoriety in 2013 when India's Supreme Court rejected a bid by Novartis to patent an updated version of a pricey, best-selling cancer treatment on the grounds that the new version was only slightly different from the older one. The closely watched decision put the pharmaceutical industry on notice that evergreening would face increased resistance.

The episode emboldened advocates — and also lawmakers, in some countries — to increasingly challenge the pharmaceutical industry over its patent practices as the cost of prescription medicines continues to rise. In the decade since then, companies have come under increased scrutiny.

For instance, a study published in 2018 found that most secondary patents — 72%, to be precise — were granted by the Indian Patent Office for only marginal improvements. And only 15% of the secondary patents that were granted were properly scrutinized and cited in final written orders, as required. This was five years after the Novartis case was decided.

The issue has resonated widely. A growing number of governments are being pushed by patient advocates to sidestep patents and issue compulsory licenses. These would allow a country to grant a license to a public agency or a generic drugmaker to copy a patented medicine without the consent of the brand-name company that owns the patent.

For this reason, the court decision is “like a message that other countries can use to improve their patent regimes, which makes it a very important case,” said Sergiy Kondratyuk, a senior project manager at the International Treatment Preparedness Coalition, a nongovernmental organization that focuses on health issues.

In the U.S., concerns that drugmakers game the patent system have prompted various bills in Congress. And the Biden administration prompted the Food and Drug Administration and the Patent and Trademark Office to form a working group to improve communication about patent applications and reviews.