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How IP Nitty-gritties Hinder Universal Immunisation?

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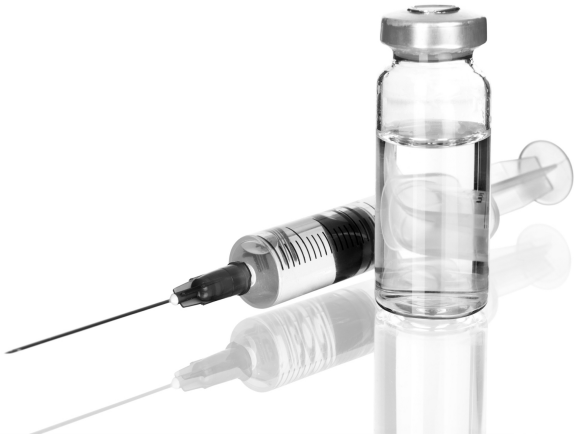
Since the COVID-19 immunisation started almost a year ago in January 2021, 60.2 per cent of the world population has received at least one dose of a COVID-19 vaccine and only 9.4 per cent of people in low-income countries have received at least one dose (source: our world in data). While there are many challenges to do so, the repeated argument being 'pharma companies should forego Intellectual Property (IP) to expedite universal immunisation'. Should pharma companies waive IP during the pandemic? Will this ensure universal immunisation and equal distribution of therapies? Let's find out.



The coronavirus crisis which has enraged the world has also opened up debates around IP and public health. The general debate is that waiving IP rights increases access to medicines and vaccines. The pharmaceutical industry, on the other hand, feels IP is not a hindrance but a help to contain and end COVID-19 and actually spurs innovation.

'Proposals to temporarily waive IP protections for COVID-19 vaccines and suspend IP enforcement have met with opposition at the World Trade Organisation (WTO) because such waivers could undermine the Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement, which requires WTO member countries to recognise basic protections for IP rights, and potentially return to a time when over 50 countries did not recognise patent protection for pharmaceutical products,' said **Delphine Knight Brown, Partner, Intellectual Property Practice Group, Freeborn & Peters LLP, USA.**

Should Biopharma firms waive IP?

There's a large persuasive literature regarding different licensing models, pricing, subsidisation of production/consumption, technology transfer or waiver of patents for essential medicines during pandemics.

'Waivers have attracted public attention but are not the only or necessarily best way of facilitating access. It is important to recognise that proposals deal with specific essential medicines, in particular vaccine patents, rather than patents and trademarks for all proprietary medicines. There's little discussion of waiving all IP. Waiving all IP – as distinct from patents for specific essential medicines – is not feasible under international law and won't be supported by countries such as India with a large generics sector,' said

Dr Bruce Baer Arnold, Associate Professor, CELTS Fellow , Canberra Law School, Australia.

Biopharma companies should not be mandated to waive IP for proprietary medicines during a pandemic, feels **Jaci McDole, Senior Policy Analyst, Information Technology and Innovation Foundation, USA.**

She said, 'Incentivising innovation is vital for ending current and future pandemics, eradicating diseases, and ensuring long and healthy lives for all people. IP protection provides incentives and the means for companies--including many startups helping to end this pandemic--to simply exist, much less produce the vaccines, treatments, PPD, and equipment we and those in the healthcare industry rely upon. Mandatorily waiving IP would kill many of these vital startups and discourage costly but necessary risk-taking (such as that which led to mRNA vaccines). It also opens the door for subpar or counterfeit products that could harm users and reduce confidence in legitimate products."

Protection of IP rights for the benefit of current and future innovation versus the potential of satisfying an unmet need in fighting a global pandemic seems the classic Hobson's Choice. One key factor in obtaining agreement beyond voluntarily sharing to actually waiving IP protection is whether biopharma companies can and should be required to disclose trade secrets.

'Trade secrets are considered highly confidential, proprietary information by biopharma companies and also often relate to ongoing research and development processes and pipelines, not merely single products. For example, the mRNA vaccines produced by Pfizer and Moderna employed technology that had been previously utilised in biomedical research but the specific manufacturing processes used to produce the COVID-19 vaccines likely could not be easily replicated. Therefore, in order for other companies to also produce the vaccines, biopharma companies might need to disclose know-how, including training, technical assistance, materials and company documents, all of which are typically considered protected trade secrets,' said Delphine**.**

Experts agree that the sharing of know-how is critical to scaling up COVID-19 vaccine production and developing second generation vaccines to address variants. However, there is no precedent for forcing biopharma companies to involuntarily disclose trade secrets. To date, no vaccine company has voluntarily shared its know-how through the World Health Organisation's COVID-19 Technology Access Pool (C-TAP).

'Compulsory licenses were issued in the past for patents to boost production of AIDS and HIV drugs, but even those licenses did not require disclosure of trade secrets. Similarly, IP waivers for production of Pfizer's recently approved antiviral drug product might not require the disclosure of trade secrets. However, IP waivers involving Merck's biologic product would likely include the sharing of know-how and related, protected trade secrets. In the absence of voluntary licensing, compulsory licenses authorised on public health grounds may be the solution again to avoid companies' reluctance to waive IP,' said Delphine**.**

IP waiver ensures universal immunisation?

When the IP waiver concept was first proposed, Moderna agreed not to enforce its COVID-19 vaccine related patents during the pandemic. But despite Moderna's voluntary waiver of its IP rights, no other company has stepped up to manufacture the Moderna COVID-19 vaccine. The most significant obstacle to COVID-19 vaccine supply is not just the IP rights that companies have obtained or are pursuing but rather the lack of raw materials and manufacturing facilities to produce the vaccines and biotherapeutics.

'The COVID-19 pandemic has proven IP, including patents, are not the primary barrier to access for most countries. Supply chain issues, shortages of raw materials, inadequate manufacturing facilities and know-how, and poor infrastructure and distribution systems are the primary causes of delayed universal immunisation,' said Jaci.

Technology transfer, scaling up manufacturing, government and private partnerships etc. could help in achieving vaccine equality.

IP rights have also facilitated a great deal of voluntary technology transfer, resulting in partnerships and bolstering the manufacturing of vaccines. For example, UK's Astra Zeneca's vaccine was developed in collaboration with Oxford University and is produced in India by the Serum Institute under a licensing agreement.

Government and private sector partnerships could be forged much more expeditiously and still result in the desired rapid ramp up of COVID-19 vaccine production. For example, Moderna and Samsung Biologics announced an agreement for fill-and-finish manufacturing of Moderna's COVID-19 vaccine.

Investment in manufacturing is an important piece of the solution. Whether existing companies can retool facilities and jump start manufacturing or facilities need to be created through investment will be an important factor in accomplishing the desired scale up of vaccine production.

'Scaling up COVID-19 vaccine production is clearly the first step to ensure universal immunisation. Ensuring equitable availability and delivery will also be necessary. Coordination and collaboration will be required within a complex network of investing in technology transfer, contracting existing and creating new manufacturing facilities, sourcing materials and pooling procurement facilities,' said Delphine**.**

'Patents are just one part of a complicated equation. We need universal access (i.e. supply), affordability and government action regarding vaccine hesitancy. In all countries we need strengthening of the public health system: the COVID variants are demonstrating that immunisation is a key part of the equation but not the only part,' said Dr Arnold.

This is a tricky situation to be in. It's unlikely that the pharma industry will change its IP regime overnight, and the onus to vaccinate the entire world is not on the pharma industry alone. Universal immunisation will require a coordinated approach in which the governments, pharma firms, and the entire ecosystem will need to come forward and do their part.

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