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## Patent Waiver for Covid-19 Vaccines – Necessary or Reckless?

The world is in an upheaval now with the pandemic raging for over a year. The discussions and decisions that probably would never have been made a few years ago are being made today in the interest of the greater good and the public at large. When Bill Gates expressed his reservations against lifting IP protection on vaccine patents, it left the world reeling and his comments understandably criticised by experts and laymen alike. Several developing nations, including India, approached the World Trade Organisation (WTO) last year for approvals for the vaccine formula to be released to other manufacturers. A few days ago, we received further news that the United States supports a temporary lift on patents related to the Covid-19 vaccines and the Gates Foundation itself in an about face statement mentioned that they now support the opening of patents for the vaccine. All of this relates to the now growing concept of a Patent Waiver or an Open Patent.

We know that under intellectual property law, a patent is granted for a limited period for an idea or process that is novel, non-obvious and has value to the public. It allows the manufacturer to monetise this novel idea or process and prevent anyone else from making, using, or selling this invention for a limited period. An open patent or patent waiver removes this monopoly and permits anyone to make, use or sell this idea or process without fear of patent infringement. Tesla's popularity increased in 2014 with Musk's announcement that the company was going to open source their patents and would not sue anyone who wanted to use their technology, albeit with some restrictions on such use.

A patent waiver is a tremendous opportunity for other manufacturers. If granted, it aims to advance human growth and technology, enhances competitiveness, and increases sustainability. But does this utopian forward thinking process apply pan industries, can this be applied to the pharmaceutical industry in the same spirit. The world undoubtedly needs to ramp up its Covid-19 vaccine production. It is literally a matter of life and death. However, are we looking at this with coloured glasses hoping for a miracle, to end the waves of the devastating virus?

Patents while expected to provide detail, only cover a skeleton of the idea or process. Patent applications are expected to include enough information for someone in the same industry with the same amount of experience to copy the idea or process. However, do the vaccine patents cover the entire production process in microscopic detail? We know that the vaccines of the Messenger RNA (mRNA) type are a new variety of vaccines, never used on the market before, but tested on humans for other infectious diseases.

Which brings us to the real issues, how many of us have perfected a new dish with simply the recipe, minus the technique and skill.... and succeeded in our first attempt? Will providing the recipe for a Covid-19 vaccine to other manufacturers also provide the background knowledge, the technique, methodology and adequate skill required to manufacture this vaccine to perfection? Will there be additional government approvals, licenses and mandatory trials or will such manufacturers be permitted to release their vaccines for public consumption without the mentioned required elements? In our panic, are we jumping the gun, and could this decision possibly leave us with new problems of disastrous after-effects to contend with?

Gates had reasoned that "every manufacturing process needs to be looked at in a very careful way". A patent waiver of the Covid-19 vaccines even if temporary must be accompanied with a

transfer of background knowledge, training, production detail, trial, and regulatory approval. We must consider the practicality of this. Is it even possible for these patent owners to facilitate this knowledge transfer to third parties amidst their own challenging responsibility to meet vaccine demand of the world?

Additionally, the cost of raw materials, skilled workforce and the required infrastructure needed to develop these vaccines would make it unlikely that manufacturers would simply jump on the vaccine production train without needing to make large investments of their own. People are forgetting that Moderna issued a patent waiver for its vaccine formula back in October 2020 and we have not heard of anyone who has taken up this opportunity. Another facet is that sadly we are also facing a raw material shortage, and if these materials are funneled to manufacturers without the requisite expertise to develop these vaccines, we should consider that our existing vaccine producers could run out of the needed stock to meet even current supply requirements.

A patent waiver for the Covid-19 vaccine is welcome news when the world is searching for some form of respite from the harshness of the pandemic, but the practical reality and hard truth is that it is not going to make that much of a difference to the current epidemic. Even if other manufacturers choose to make use of the waiver to ramp up vaccine production, precautions need to be put in place to ensure safety remains the highest priority. We need to ensure that in our hurry to protect ourselves we do not harm ourselves further.