



Getting Behind COVID-19 Vaccine Innovators - Part I – Scaling Up Production Fast

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There is an ongoing need to rapidly increase vaccine supply to defeat the global pandemic. Some politicians and non-governmental organizations have claimed that vaccine patents are affecting supply and they have demanded legislation to override the patents. [Petitions](#) of support for overrides are circulating.

It is understandable that people want to pull every lever that may alleviate a public health emergency. Patent overrides would miss the mark. It is an oversimplification to suggest that getting rid of patents would increase vaccination. This article explains why innovator companies should be considered as partners, not adversaries, in order to increase vaccine access. Part I of this article addresses rapid scale-up and [Part II](#) addresses safety factors. [Part III](#) addresses vaccine equity.

Rapid Tech Transfer

Initial patents are filed at a very early stage of development, and do not include the necessary know how to commercially scale up and produce vaccines. Patents also do not provide guidance on quality assurance steps to ensure that a copy of a vaccine is safe and effective. Much of the knowledge to make safe and effective vaccines is in the unpublished know how of the experienced companies that originated them. It is not possible to turn off the patent taps one day and turn on the taps for vaccine copies the next. Creating your own 'unauthorized' version of an off-patent vaccine takes substantial time, experimentation, money, as well as significant regulatory scrutiny.

The most efficient route to increased vaccine supply is for innovator companies to license and engage other experienced vaccine manufacturers, and transfer their knowledge to those manufacturers. This is shown by [GSK and Novavax](#) entering into an agreement for GSK to provide fill and finish services for the COVID-19 vaccine developed by Novavax. GSK described the collaboration as a, "rapid technology transfer between the two companies beginning immediately." This is a more productive and certain way to increase vaccine supply than by overriding Novavax IP and waiting to see if other companies develop their own copy of the Novavax vaccine and get approval from regulators.

Innovator Vaccine Companies are Already Cooperating

There have been assertions that vaccine companies are restricting access to vaccines. These assertions are not accurate, because there have been many cooperative arrangements put in place to increase vaccine supply. Vaccine supply has increased so quickly that the [rate limiting step](#) has sometimes been supply of [raw materials](#).

In some cases, private companies have struck deals between themselves. Moderna, J&J and BioNTech have all licensed a leading multinational vaccine company, [Sanofi](#), that will produce hundreds of millions of COVID-19 vaccine doses. AstraZeneca has licensed the Serum Institute of India, which is one of the largest vaccine manufacturers in the world.

Innovator companies have also contracted out pieces of manufacturing to ramp up capacity, as in the GSK – Novavax example above.

Governments have facilitated COVID-19 vaccine partnerships. [US government funding](#) will allow Merck to use its facilities in the United States to produce [vaccine drug substance, formulate and fill](#) vials of Johnson & Johnson's vaccine.

These partnerships are not limited to first-world countries. AstraZeneca has [partnerships](#) with non-governmental organizations, such as the Coalition for Epidemic Preparedness Innovations (CEPI) and a vaccine organization, Gavi,



backed by the Gates Foundation. AstraZeneca started this process in 2020 for its vaccine as part of a [plan](#) to be able to produce up to 2 billion vaccine doses, with up to 1 billion of those doses allocated to [low- and middle-income countries](#).

AstraZeneca and its licensees are also supporting the WHO [COVAX](#) COVID-19 vaccine program. AstraZeneca plans additional licenses with manufacturers in developing nations such as [Brazil](#) and [Ghana](#).

Holding Innovator Companies' Feet to the Fire

It is clear that both government and non-governmental organizations on the front lines of the pandemic recognize that a rapid and massive scale up in vaccine production should primarily rely on covid vaccine originators as partners, as well as leveraging other experienced vaccine makers. The job of building manufacturing capacity is getting done - for example, AstraZeneca recently announced that it is on track to deliver [200 million doses a month](#). Moderna is going to provide [500 million low cost doses](#) to COVAX. Other companies are also scaling, licensing and increasing production. As well, AstraZeneca, Pfizer, and [Moderna](#) have provided [reduced pricing](#) for low income countries. Keep building on these efforts that are working.

[Part II of this article](#) will address how supporting innovator companies will increase vaccine acceptance.

¹ Some vaccine manufacturers have stated that they will not enforce COVID-19 related patents during the pandemic. There is debate, beyond the scope of this article, as to whether these assurances have been sufficient to address alleged patent risks.

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