Inclusive Biomedical Innovation during the COVID-19 Pandemic

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In the article *Is the Patent System a Barrier to Inclusive Prosperity? The Biomedical Perspective* author Helen Gubby makes a bold claim: that ‘the whole biomedical sector should be taken out of the ambit of the patent system’ (Gubby, 2020). In support, Gubby points out the manipulative strategies biomedical companies use to ‘evergreen’ their patents, and thus their high monopoly prices. The article addresses important questions of who should own new drugs, whether steep and exclusionary pricing is ever justified, and the role of the government in drug development. The COVID-19 pandemic has brought these questions to the fore of public discourse. It is likely that major legislative reforms will be made in its wake, but complete abolition of the patent system is doubtful.

What actions should governments take to ensure inclusive innovation in the present COVID-19 crisis? Some wealthy nations, including the United States, United Kingdom and Australia, have rushed to purchase vaccines exclusively for their own citizens, leading to ‘vaccine nationalism’. These deals do indeed spur the desired innovation in vaccine development, but do so at major ethical costs. (Bollyky and Bown, 2020). A sounder approach, that incorporates many aspects of Gubby’s vision while working within the existing patent system, is being enacted by the multilateral Coalition on Epidemic Preparedness Innovations (CEPI).

The unique case of pharmaceutical patents

Gubby’s flair for the historical shines in her description of how the patent system began, in the words of Adam Smith and Jeremy Bentham. But the portrayal of patents as a ‘harmless enough’ monopoly that allows individual inventors to profit from their ideas downplays the grander societal goal of patents: to incentivize innovation. Even this description is not sufficient, as innovation certainly occurred before the patent system and continues to flourish in fields without patents, such as fashion and the culinary arts (Tabarrok, 2011). Patents function to specifically incentivize innovation in situations where, without patents, innovation is much less likely to occur.

Classic teaching is that pharmaceuticals are a prime example of where patents are most useful. Therapeutics development is costly, and firms only embark on the long path of discovery, development and FDA review if they are able to turn a profit in the end. Production of generics, on the other hand, can be pennies per pill. Without patent protection, the incentive to imitate supersedes that to innovate, and new drugs are not produced (Cowen and Tabarrok, 2018). In other words, the price we pay for new drugs is a short-term monopoly that does exclude some patients (the deadweight loss). Once off-patent, these drugs become cheap and ubiquitous staples of medicine for future generations. At least, that is the hope.

The lack of new drugs developed specifically for nations with weak intellectual property enforcement is telling. Gubby correctly notes that ‘by the end of the twentieth century, only about one per cent of newly developed drugs were for tropical diseases’. Weak patent protection in these countries offers no way for pharmaceutical companies to recoup their R&D costs, and explains their disinterest to addition to the lower purchasing power of these countries. Economists have argued that all countries ought to take intellectual property rights seriously, in order to motivate private companies to make drugs for their populations. But often, the countries in question disagree.

H5N1, Indonesia, and the need for equitable access

During the 2005–2007 H5N1 avian influenza epidemic, a vaccine was purportedly developed using virus samples originally from Indonesia (Sedyaningrisih et al., 2008). Patent theory predicts this: private firms, in countries of strong intellectual property protection such as Australia, will be
incentivized to create the vaccine despite high R&D costs. In other words, the company aimed to patent the vaccine and sell it at a high price.

The fact that the vaccine was created could be considered a win for the patent system. However, Indonesia certainly did not see it this way, and quickly announced their withdrawal from the WHO virus sample sharing programme. In an article written by the Indonesian Ministry of Health, the inequity of the patent system in particular was called out: ‘pharmaceutical industries of developed countries . . . produce and patent the products . . . and sell them back to the developing countries at unaffordable prices’ (Sedyaningsih et al., 2008).

Indonesia’s stance was not entirely new; for example, India’s Patents Act of 1970 had allowed pharmaceuticals patented elsewhere to be freely copied for years. These types of legislation muddle the goals of ensuring access to new drugs, with that of incentivizing new drugs. As Nobel laureate Kremer and Glennerster state, ‘both goals are critical, and the world needs new institutions that will promote both’ (Kremer and Glennerster, 2004, p. 37). While patent enforcement is certainly flawed, blanket elimination of patents alone will neither increase the amount of new drugs we have, nor ensure their widespread access.

Balancing equity and innovation: the CEPI model

Of course, Gubby recognizes this. She ultimately advocates not simply for patent elimination, but rather for replacing biomedical patents with ‘robust public funding schemes’, including state funding, rewards and prizes. This imagines a distant future where governments both have the political will to eliminate patents, as well as the expertise to correctly set prizes in the highly technical field of biomedical innovation. Unfortunately, we are likely to face several global health threats before this future is realized. Readers should not, however, lose all hope for our current predicament. There are important short-term solutions that have already proven effective, and are currently being used to address the COVID-19 crisis.

In 1998, economist Michael Kremer suggested patent buyouts as a mechanism for governments to encourage pharmaceutical innovation for neglected diseases. The purchase of a patent would not hinder innovation, while still allowing governments to subsequently distribute the drugs at low cost (Kremer, 1998). The approach was inspired by the purchase of the Daguerreotype patent by the French government in 1839; the government then placed the patent in the public domain. Importantly, it works with existing patent structures to achieve equitable access, and is therefore more achievable in the short-term.

In 2010, this concept was piloted with a $1.5 billion dollar fund for pneumococcal vaccines (Kremer et al., 2020). The approach was rebranded an advance market commitment (AMC); fundamentally similar to a patent buy-out, but structured as a more palatable reward. The success of this pilot in collaboration with GAVI, the vaccine alliance, was estimated to have saved 700,000 lives, and led to the formation of the Coalition on Epidemic Preparedness Innovations (CEPI). CEPI was launched at Davos in 2017 with funding from sovereign investors and philanthropists, and is a fund explicitly meant to provide lower prices to novel vaccines for epidemic pathogens while still incentivizing their creation. CEPI provides funding and prizes for these vaccines in exchange for access and step-in rights to intellectual property (Huneycutt et al., 2020). CEPI is currently supporting several promising COVID-19 vaccines, and along with GAVI, the vaccine alliance, has recently created COVAX (Hachett, 2020).

COVAX is a collective action solution come to life: it proposes securing an AMC of $18.1 billion from nation-state participants to collectively purchase 2 billion doses of the first successful COVID-19 vaccine. These 2 billion doses would not be sufficient to vaccinate the entire population of participating nations. Rather, they would be distributed to healthcare workers and high-risk populations of all countries first, in order to more quickly mitigate COVID-19 spread.

Aside from fair allocation, CEPI also enforces many of the patent reforms Gubby covers, including that ‘IP should not be used in a way that impedes equitable access’ as well as not pursuing ‘additional, secondary patents to “evergreen” the relevant technology’ (Huneycutt et al., 2020), though enforcing this has not been without its challenges. In sum, inclusive biomedical innovation is currently being worked towards with the CEPI structure, and has achieved success in the past with pneumococcal vaccines. It may crucially achieve this while working with the existing incentive structure of patents, which are unlikely to be removed immi-
nently. CEPI represents the first step towards Joseph Stiglitz’s vision, cited by Gubby, of a fund which provides large rewards for cures to common diseases such as malaria, and smaller rewards for rarer diseases or less innovative ‘me-too’ drugs (Stiglitz, 2006). As a fledgling organization facing a Goliath, it deserves international support in its dual goals of incentivizing innovation and ensuring equitable access to biomedical advances.

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