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Don't worry about the drug industry's profits when considering a waiver on covid-19 intellectual property rights

Luke Hawksbee and colleagues argue that policy makers should prioritise public health over private monopolies in the debate around global access to covid-19 vaccines and treatments

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Most experts agree that we should vaccinate as many people on the planet against covid-19 as quickly as possible; where they disagree is how to do it. At the heart of many debates has been the issue of intellectual property rights: should companies that developed vaccines against covid-19 be required to make their knowledge available to others who can produce these vaccines? Or would a waiver of intellectual property rights or other reforms to the current intellectual property system jeopardise future innovation?

This debate rose high on the global policy agenda after President Joe Biden showed support for a temporary waiver on covid-19 vaccine intellectual property rights. He has now been backed by the US Senate and joined by others ranging from the World Health Organization to the UK's Independent Scientific Advisory Group for Emergencies, Médecins Sans Frontières, and even the pope. Yet, half a year later, some European countries remain obstinately opposed, and the head of the World Trade Organization has warned that negotiations were "stuck." This is despite interventions from organisations like Amnesty International and threats of legal challenges from patients' and health workers' representatives.[1] Meanwhile, the Covax scheme seems designed to preserve existing market mechanisms and power dynamics.[2]

The argument against reforming the intellectual property system is that intellectual property rights are necessary to compensate for the financial risks that the drug industry takes on when investing in the research and development needed to develop new products. In the case of covid-19 vaccines, the amount of risk facing drug companies is debatable because governments provided a substantial share of research and development funding and bought large quantities of the vaccines in advance.[3] Do those governments deserve a "return" on their investment in the form of lower prices or greater access to the vaccines for poor people worldwide to increase global immunity, for example? Or is waiving intellectual property rights a form of state theft that might imperil future research vital for public health?

Predictably, the drug industry has held that a waiver would reduce the profits that incentivise new drug development. Emergence of the omicron variant, however, shows the risks of the status quo: maximising vaccination is not only a moral necessity but also a potential bulwark against the evolution of other variants that might be even more contagious, virulent, or immune evasive. Moreover, we argue that a waiver would not threaten future drug development, primarily because the link between profits and innovation is tenuous, and public sector contributions are already a major driving factor in much of the innovation that most benefits public health.

The drug industry's consistently high profits

The industry's arguments would be stronger if there was evidence that they would be unable to attract investors—thus undermining their ability to fund research and development—if their profits were threatened. But this does not seem to be the case. The Fortune 500, a list of the largest corporations in the US (determined by revenue, that is total annual income) has been published annually since 1955. This allows us to calculate net profit margins: the percentage of the revenue a company receives that is surplus to covering their spending on items such as research and development or marketing, and is either paid out to shareholders, saved in company coffers, or used to buy back their own shares.

A calculation of average net profit margins shows that the drug industry has long been the most profitable sector, exceeding even the energy and financial industries (fig 1, fig 2). From 1954 to 1999, the drug industry's mean profit margin was already more than double the average of other sectors; since the turn of the century, this has ballooned to more than triple.

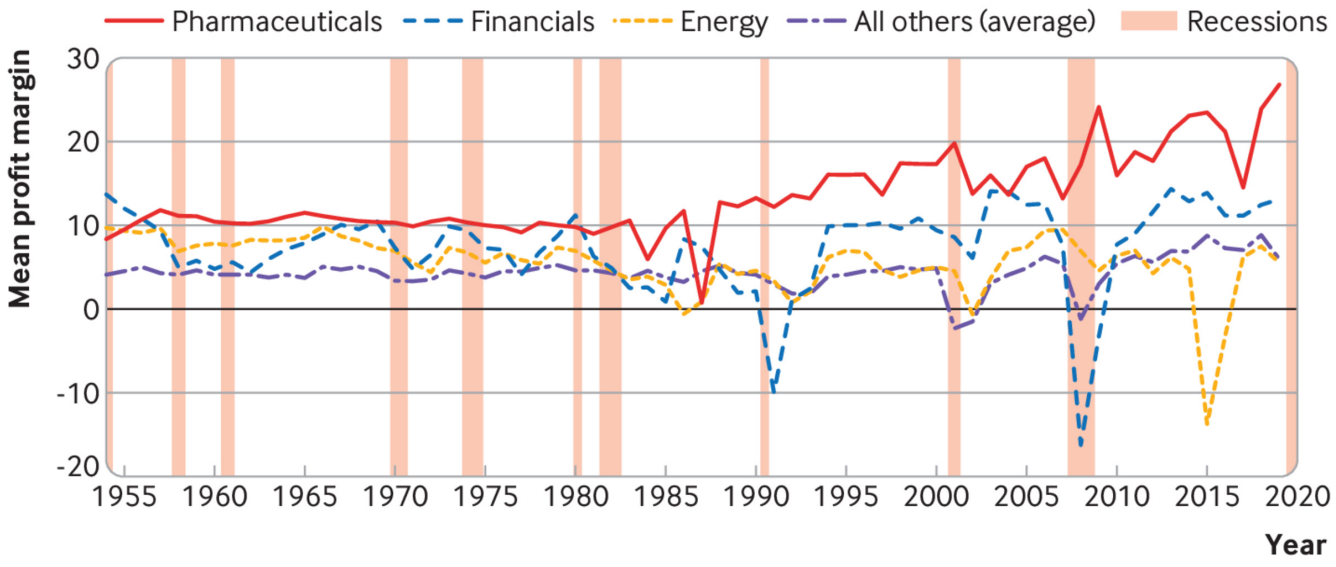

Fig 1 | Fortune 500 sectoral profit margins by year

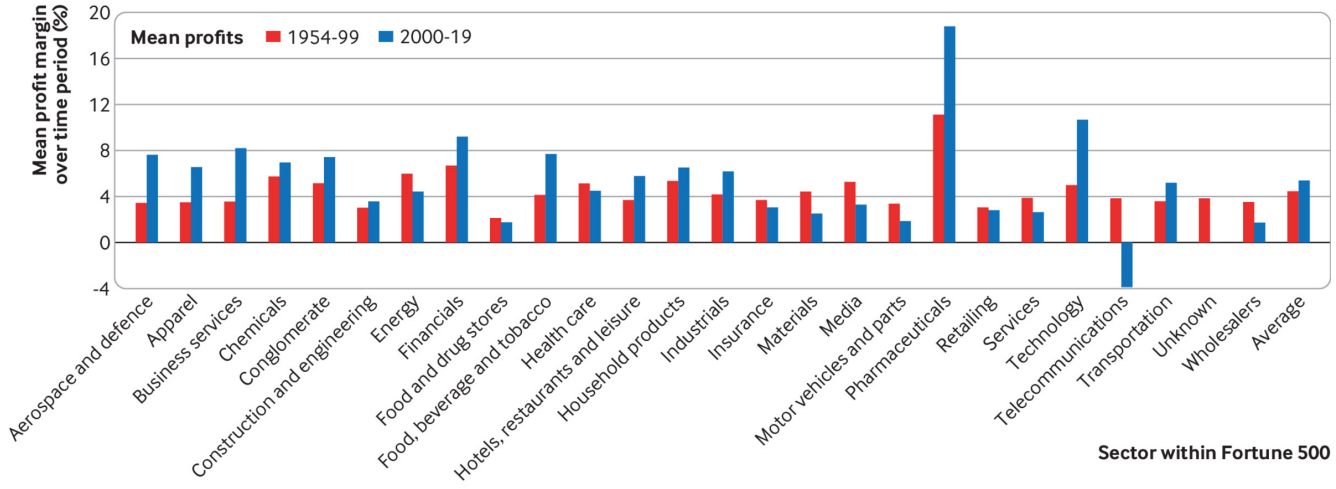

Fig 2 | Fortune 500 sectoral profit margins before and after 2000

These data mirror previous research. Between 2000 and 2018, a sample of leading drug companies achieved about 1.8 times the profit of non-drug companies in the Standard and Poor's 500 stock market index, a long running list of 500 of the largest companies traded on US stock markets.[4] The global drug industry's share of total net profits made by all companies listed on the stock market rose from around 3% in the mid-1970s to a staggering 10% at its peak in the early 2020s. Since then, it has fallen back a bit, but drug companies still account for over 5% of all stock market value in the 2020s to date.[5]

The fact that returns on invested capital to drug companies are less volatile than most other sectors[6] further challenges the claim that high profits are necessary to compensate for a "uniquely high risk gamble" for investors. Comparing profits to investments rather than looking at sales alone corroborates our data using a different measure of profitability: the return on invested capital is the highest of all sectors.[6]

In short, even if drug companies lost a fifth of their profits they would still outperform 75% of other sectors, and losing nearly a third of their profits would leave them earning no less than the average industry.[6] Remember: these profits are, by definition, left over after paying for research and development.

Profits do not safeguard global public health

Perhaps high profits could be justified on the grounds that drugs companies provide the innovations most needed to improve and protect public health. But it is far from clear that the drug industry is focused on the most needed new products. Only around 2–3% of new drugs represent important breakthroughs and around 9–11% offer a modest advantage over existing treatments.[7 8] Conversely, while many products offer little benefit, other crucial research is neglected by the industry: for instance, despite the urgent need for new products to counter the threat of antimicrobial resistance, development pipelines are largely empty and the few new products have relied on public sector support rather than pure market forces.[9]

But hasn't the drug industry been critical for rapid vaccine development in the ongoing covid-19 pandemic?

Over the past two decades, viral outbreaks including SARS-CoV-1 in 2002 and MERS-CoV in 2012 raised fears of a global pandemic—in retrospect they could be considered "dry runs" for the emergence of SARS-CoV-2 in 2019. Although effective covid-19 vaccines were developed at record speeds, and might have benefited from some of the scientific work in the wake of these previous viral outbreaks, vaccine development scientists have described how they struggled to obtain support for their earlier work against betacoronaviruses.[10] To a large extent, even the current vaccine rollout was dependent on public sector and third sector support (though exact figures are disputed).

Some experts have suggested that a single vaccine could protect against future variants of SARS-CoV-2 and many or all other betacoronaviruses—including ones we have not encountered yet.[11-14] Groups like the Coalition for Epidemic Preparedness Innovations are now promoting such "broadly protective" vaccines for two major reasons.[11] Firstly, they would reduce the chances of vaccine escaping variants evolving; secondly, they might even prevent future betacoronavirus pandemics altogether.[11-13] This idea had been proposed well before 2019. But the drug industry was reluctant to dedicate sufficient resources to combatting the coronavirus threats with new drugs or vaccines until a new virus was on our doorstep.

This should come as no surprise, given that the industry's dominant business model in the current intellectual property rights system is to develop patented drugs and generate the highest sales possible before the patent runs out, not necessarily to meet the greatest medical or public health need. There is no financial justification for a private company to invest in products for which there is no apparent market, including new antibiotics (which cannot be sold in vast numbers without provoking bacterial resistance) and drugs for neglected tropical diseases (which generally affect poor people in poor countries). Even with increasing profitability, additional profits are most likely spent on developing or marketing more profitable product lines, or else simply disbursed to shareholders, through dividends or share buybacks. A basic conflict exists between seeking profit for shareholders on the one hand and investing in medicines for underserved communities or getting ahead of the epidemiological curve on the other. The same incentive structure also explains why the industry has arguably adopted a "wait and see" approach to pandemic threats,[15] why companies have often shown unwillingness to donate vaccines, cut prices, or waive intellectual property rights, and why they have prioritised the highest bidders when allocating scarce vaccines.[16]

Industry fears reduced future profits

The pandemic is characterised by our inability to roll out products fast enough—under such circumstances an intellectual property rights waiver should not materially harm profits, as any vaccine or treatment produced by competitors would most likely be sold in addition to the originating company's sales rather than replacing them. The main problem is not minimising price (as it might be under more normal circumstances) but rather maximising supply: there is enough of a market for all current producers and more. We would therefore expect no material fall in covid-19 related profits for companies whose intellectual property rights are waived. Moreover, given 65 years of consistently high profits (and increasingly more so in recent decades), investors are unlikely to abandon pharmaceutical innovation because of loss of intellectual property rights in the exceptional circumstances related to covid-19, so nor would we anticipate substantial loss of investment funds for research and development.

So why are companies insistent that strong intellectual property rights must remain in place even for vital vaccines they cannot produce enough of during a global public health crisis? One reason is that many of the covid-19 vaccines currently on the market or in development incorporate new generic vaccine platforms that—with relatively simple changes—could yield not only further vaccines but treatments for other diseases.[17-21] A letter being circulated among US legislators warns that a waiver would allow China to "profit from our innovation," beating the US to develop products based on the new platforms.[22]

This might explain why certain leading companies are so keen to monopolise not only intellectual property rights, but also the productive capacity and, perhaps even more importantly, the knowledge, or "trade secrets," needed to produce the vaccines. Pfizer's chief executive officer noted the "dramatic potential" of the mRNA technology and stated, "We are now ahead and we plan to maintain the gap" in future development.[20] By collaborating with BioNTech, Pfizer can say that now "we have our own expertise developed." Little wonder that Pfizer are so reluctant to help competitors obtain for free the same knowledge.

We also think the industry fears that a waiver would change the nature of the discourse of pharmaceutical policy, potentially leading to price controls or reduced intellectual property rights in key markets such as North America, which accounted for 49% of global pharmaceutical sales in 2018.[23]

This is not the first time that drug companies have prioritised intellectual property rights in the face of a public health crisis endangering the lives of millions. Drugs effective against HIV were identified by 1996, yet poorer countries were priced out of the market for years. At that time, roughly 4.5 million South Africans (20% of the population) had HIV, but only 90 people were receiving antiretroviral therapy (ART).[24] In 1997, South Africa passed a law to import generic ART drugs that are vastly more affordable from neighbouring countries to enhance access to treatment. In response, 39 drug companies collectively sued South Africa.[25] Eventually the companies conceded, and with the help of additional international funding, huge progress has been made in rolling out affordable ART drugs: four million South Africans were receiving ART by the end of 2017. This flexibility around patent rights for ART did not cause a collapse in drug company profits, and research and development spending rose steadily across this period.

Roles for public and non-profit institutions

The idea that society can only reap the benefits of medical innovation if intellectual property monopolies provide the drug industry with extraordinary profits is no longer plausible. Record profits did not lead to the research we needed after SARS or MERS nor to solutions to antimicrobial resistance or neglected tropical diseases, and they have never guaranteed access to drugs or vaccines for the many millions of poor people around the world. There is no reason to think that profit seeking will provide the proper incentives to safeguard global health in the future, either. Rather, the incentive structure underlying research and development needs to be reformed through more public led and mission oriented research, where rewards are disconnected from the current size and affluence of the market served.[26]

Thankfully, there are existing models of medical research that prioritise public health over private profit, on which we could base future innovation. The Drugs for Neglected Diseases Initiative has

shown that non-profit organisations can bring new products to market at relatively low cost: from its creation in 2003 to the release of its current strategic plan in early 2021, well under a billion dollars was sufficient to develop eight new treatments for neglected diseases.[27] This stands in marked contrast to the drug industry's frequent—but controversial—claims that it costs upwards of $2bn to bring a single new product to market.[23 28] The Drugs for Neglected Diseases Initiative also negotiated liberal intellectual property agreements designed to maximise access to these drugs, working with partners in both industry and academia.[27]

State funded and managed organisations like the US National Institutes of Health or, in future, the EU's Health Emergency preparedness and Response Authority, could have a greater role in drug development. This aligns with proposals for a new European pharmaceutical strategy.[29] Governments could acquire promising early stage drugs and biologics (or the companies developing them) or could commission trials of promising but otherwise neglected therapeutics. Such activities could form part of innovative hybrid and network based initiatives that contribute vital research outside the traditional model of monopolising intellectual property rights and are not driven by anticipated profits but by public health priorities. Examples of such groups include Open Source Malaria—established by a non-profit private-public partnership—and the World Health Organization's Global Influenza Surveillance and Response System, which shares data and advice that contribute to effective flu vaccines.[30 31] Other alternatives that rebalance the risks and benefits to public and private actors, such as prizes for successful innovations and sharing of profits with governments providing research and development funding for successful products, have also been proposed.[32 33]

Although there is growing acceptance that private, profit driven, intellectual property protected approaches to drug discovery, development, and marketing are not working for people, change will only come about with political will that can overcome the combination of lobbying and inertia that maintains the status quo. As a first step, intellectual property rights for covid-19 vaccines should be waived, and necessary knowledge and technology should be transferred. This should be expanded to cover other covid-19 products such as therapeutics and should also be part of a wider programme including pricing policies, tackling bottlenecks of raw materials, dealing with unequal distribution of doses between countries, accelerating research into broadly protective coronavirus vaccines, and strengthening delivery systems, drawing on, for example, the experience of the Global Fund.

Even if leading companies do see their profits drop as a result of these measures (which they likely wouldn't, owing to the large surplus of demand over supply for most covid-19 products), we cannot place profits before human health and life, especially as profits would have to collapse catastrophically to jeopardise future innovation and drug discovery. This is not solely an ethical issue but also a question of risk management, as suggested by the emergence of the omicron variant. We urge an intensive effort to waive intellectual property rights on covid-19 vaccines, vaccinate the entire world, end the pandemic, and prepare for the next one. We are not in the business of hiring foxes to guard the henhouse: we should not worry about the drug industry's outsized profits if they are not in the interest of public health.

Key messages

- The largest drug companies make higher profits than the largest companies of any other sector, but this is no guarantee that they will provide the kinds of medical innovation that would most benefit public health
- The incentive structure of for-profit pharmaceutical research results in major threats to global public health being neglected
- The industry fears that a waiver on intellectual property rights would harm future profits by undermining the monopoly power on which they rest
- Intellectual property rights for covid-19 products should be suspended as part of an intensive effort to reduce variant emergence and end the pandemic

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