## DA

#### Biotech industry strong now

Cancherini et al. 4/30 [(Laura, Engagement Manager @ McKinsey & Company, Joseph Lydon, Associate Partner @ McKinsey & Company, Jorge Santos Da Silva, Senior Partner at McKinsey & Company, and Alexandra Zemp, Partner at McKinsey & Company), “What’s ahead for biotech: Another wave or low tide?“, McKinsey & Company, 4-30-2021, https://www.mckinsey.com/industries/pharmaceuticals-and-medical-products/our-insights/whats-ahead-for-biotech-another-wave-or-low-tide] TDI

Belying this downbeat mood, biotech has in fact had one of its best years so far. By January 2021, venture capitalists had invested some 60 percent more than they had in January 2020, with more than $3 billion invested worldwide in January 2021 alone.5 IPO activity grew strongly: there were 19 more closures than in the same period in 2020, with an average of $150 million per raise, 17 percent more than in 2020. Other deals have also had a bumper start to 2021, with the average deal size reaching more than $500 million, up by more than 66 percent on the 2020 average (Exhibit 3).6

What about SPACs?

The analysis above does not include special-purpose acquisition companies (SPACs), which have recently become significant in IPOs in several industries. Some biotech investors we interviewed believe that SPACs represent a route to an IPO. How SPACs will evolve remains to be seen, but biotechs may be part of their story.

Fundamentals continue strong

When we asked executives and investors why the biotech sector had stayed so resilient during the worst economic crisis in decades, they cited innovation as the main reason. The number of assets transitioning to clinical phases is still rising, and further waves of innovation are on the horizon, driven by the convergence of biological and technological advances.

In the present day, many biotechs, along with the wider pharmaceutical industry, are taking steps to address the COVID-19 pandemic. Together, biotechs and pharma companies have more than 250 vaccine candidates in their pipelines, along with a similar number of therapeutics. What’s more, the crisis has shone a spotlight on pharma as the public seeks to understand the roadblocks involved in delivering a vaccine at speed and the measures needed to maintain safety and efficacy standards. To that extent, the world has been living through a time of mass education in science research and development.

Biotech has also benefited from its innate financial resilience. Healthcare as a whole is less dependent on economic cycles than most other industries. Biotech is an innovator, actively identifying and addressing patients’ unmet needs. In addition, biotechs’ top-line revenues have been less affected by lockdowns than is the case in most other industries.

Another factor acting in the sector’s favor is that larger pharmaceutical companies still rely on biotechs as a source of innovation. With the top dozen pharma companies having more than $170 billion in excess reserves that could be available for spending on M&A, the prospects for further financing and deal making look promising.

For these and other reasons, many investors regard biotech as a safe haven. One interviewee felt it had benefited from a halo effect during the pandemic.

More innovation on the horizon

The investors and executives we interviewed agreed that biotech innovation continues to increase in quality and quantity despite the macroeconomic environment. Evidence can be seen in the accelerating pace of assets transitioning across the development lifecycle. When we tracked the number of assets transitioning to Phase I, Phase II, and Phase III clinical trials, we found that Phase I and Phase II assets have transitioned 50 percent faster since 2018 than between 2013 and 2018, whereas Phase III assets have maintained much the same pace. There could be many reasons for this, but it is worth noting that biotechs with Phase I and Phase II assets as their lead assets have accounted for more than half of biotech IPOs. Having an early IPO gives a biotech earlier access to capital and leaves it with more scope to concentrate on science.

#### Lack of IP protection makes medical innovation prohibitively risky and expensive

Grabowski et al 15 [(Henry, Professor of Economics, member of the faculty for the Health Sector Management Program, and Director of the Program in Pharmaceuticals and Health Economics at Duke University) “The Roles of Patents and Research And Development Incentives In Biopharmaceutical Innovation,” Health Affairs, 2/2015] JL

The essential rationale for patent protection for biopharmaceuticals is that long-term benefits in the form of continued future innovation by pioneer or brand-name drug manufacturers outweigh the relatively short-term restrictions on imitative cost competition associated with market exclusivity. Regardless, the entry of other branded agents remains an important source of therapeutic competition during the patent term.

Several economic characteristics make patents and intellectual property protection particularly important to innovation incentives for the biopharmaceutical industry. **5** The R&D process often takes more than a decade to complete, and according to a recent analysis by Joseph DiMasi and colleagues, per new drug approval (including failed attempts), it involves more than a billion dollars in out-of-pocket costs. **6** Only approximately one in eight drug candidates survive clinical testing. **6**

As a result of the high risks of failure and the high costs, research and development must be funded by the few successful, on-market products (the top quintile of marketed products provide the dominant share of R&D returns). **7**,**8** Once a new drug’s patent term and any regulatory exclusivity provisions have expired, competing manufacturers are allowed to sell generic equivalents that require the investment of only several million dollars and that have a high likelihood of commercial success. Absent intellectual property protections that allow marketing exclusivity, innovative firms would be unlikely to make the costly and risky investments needed to bring a new drug to market.

Patents confer the right to exclude competitors for a limited time within a given scope, as defined by patent claims. However, they do not guarantee demand, nor do they prevent competition from nonidentical drugs that treat the same diseases and fall outside the protection of the patents.

New products may enter the same therapeutic class with common mechanisms of action but different molecular structures (for example, different statins) or with differing mechanisms of action (such as calcium channel blockers and angiotensin receptor blockers). 9 Joseph DiMasi and Laura Faden have found that the time between a first-in-class new drug and subsequent new drugs in the same therapeutic class has been dramatically reduced, from a median of 10.2 years in the 1970s to 2.5 years in the early 2000s. 10 Drugs in the same class compete through quality and price for preferred placement on drug formularies and physicians’ choices for patient treatment.

Patents play an essential role in the economic “ecosystem” of discovery and investment that has developed since the 1980s. Hundreds of start-up firms, often backed by venture capital, have been launched, and a robust innovation market has emerged. **11** The value of these development-stage firms is largely determined by their proprietary technologies and the candidate drugs they have in development. As a result, the strength of intellectual property protection plays a key role in funding and partnership opportunities for such firms.

#### MRNA solves a litany of diseases, but continued innovation is key

Gupta 5/7 [(Swati, vice president and head of emerging infectious diseases and scientific strategy at IAVI, a nonprofit scientific research organization that develops vaccines and antibodies for HIV, tuberculosis, emerging infectious diseases (including COVID-19) and neglected diseases, PhD and MPH from Yale University) “The Application and Future Potential of mRNA Vaccines,” Yale School of Public Health, 5/7/2021] JL

The implications of mRNA technology are staggering. Several vaccine developers are studying this technology for deployment against rabies, influenza, Zika, HIV and cancer, as well as for veterinary purposes. Its potential utility is based upon its being a “platform technology” that can be developed and scaled rapidly. Given that only the genetic code for a protein of interest is needed, synthetically produced mRNA vaccines can be made rapidly, in days. Other vaccine approaches involve growing and/or producing proteins in cells, a process that can take months. Messenger RNA vaccines are generally regarded as safe, since they do not integrate into our cells’ DNA and naturally degrade in the body after injection. They also can be safely administered repeatedly, as we are seeing with the two-dose regimen for both the Pfizer-BioNTech and Moderna vaccines.

Despite the current success of mRNA vaccines for COVID-19, scientists continue to work on making the technology better. A number of laboratories are testing more thermostable formulations of mRNA vaccines, which currently must be kept at freezing or ultra-cold temperatures. Others are investigating second-generation vaccines that will only require a single shot, and “universal” coronavirus vaccines that could protect against future emerging coronaviruses. Messenger RNA vaccines that target a broad range of different diseases, all in one shot, are also in development; this approach has the potential to greatly simplify current vaccination schedules.

Taken together, these advantages and potential future developments position mRNA vaccines as an increasingly important technology in our arsenal of tools against infectious disease outbreaks, and are likely to be critical to fighting future epidemics and pandemics. Global partnerships like the Coalition for Epidemic Preparedness and Innovation (CEPI), tasked with facilitating the development of vaccines to stop future epidemics, have called for vaccines to be able to be tested in the clinic within months after a new pathogen is identified. With the latest discoveries in mRNA technology, we are well on our way to this goal; the ability of this platform technology to be transformative is no longer a hope, but more likely to be a reality in the very near future.

#### Disease causes extinction – defense is wrong

Piers Millett 17, Consultant for the World Health Organization, PhD in International Relations and Affairs, University of Bradford, Andrew Snyder-Beattie, “Existential Risk and Cost-Effective Biosecurity”, Health Security, Vol 15(4), http://online.liebertpub.com/doi/pdfplus/10.1089/hs.2017.0028

Historically, disease events have been responsible for the greatest death tolls on humanity. The 1918 flu was responsible for more than 50 million deaths,1 while smallpox killed perhaps 10 times that many in the 20th century alone.2 The Black Death was responsible for killing over 25% of the European population,3 while other pandemics, such as the plague of Justinian, are thought to have killed 25 million in the 6th century—constituting over 10% of the world’s population at the time.4 It is an open question whether a future pandemic could result in outright human extinction or the irreversible collapse of civilization.

A skeptic would have many good reasons to think that existential risk from disease is unlikely. Such a disease would need to spread worldwide to remote populations, overcome rare genetic resistances, and evade detection, cures, and countermeasures. Even evolution itself may work in humanity’s favor: Virulence and transmission is often a trade-off, and so evolutionary pressures could push against maximally lethal wild-type pathogens.5,6

While these arguments point to a very small risk of human extinction, they do not rule the possibility out entirely. Although rare, there are recorded instances of species going extinct due to disease—primarily in amphibians, but also in 1 mammalian species of rat on Christmas Island.7,8 There are also historical examples of large human populations being almost entirely wiped out by disease, especially when multiple diseases were simultaneously introduced into a population without immunity. The most striking examples of total population collapse include native American tribes exposed to European diseases, such as the Massachusett (86% loss of population), Quiripi-Unquachog (95% loss of population), and theWestern Abenaki (which suffered a staggering 98% loss of population).

In the modern context, no single disease currently exists that combines the worst-case levels of transmissibility, lethality, resistance to countermeasures, and global reach. But many diseases are proof of principle that each worst-case attribute can be realized independently. For example, some diseases exhibit nearly a 100% case fatality ratio in the absence of treatment, such as rabies or septicemic plague. Other diseases have a track record of spreading to virtually every human community worldwide, such as the 1918 flu,10 and seroprevalence studies indicate that other pathogens, such as chickenpox and HSV-1, can successfully reach over 95% of a population.11,12 Under optimal virulence theory, natural evolution would be an unlikely source for pathogens with the highest possible levels of transmissibility, virulence, and global reach. But advances in biotechnology might allow the creation of diseases that combine such traits. Recent controversy has already emerged over a number of scientific experiments that resulted in viruses with enhanced transmissibility, lethality, and/or the ability to overcome therapeutics.13-17 Other experiments demonstrated that mousepox could be modified to have a 100% case fatality rate and render a vaccine ineffective.18 In addition to transmissibility and lethality, studies have shown that other disease traits, such as incubation time, environmental survival, and available vectors, could be modified as well.19-2

## Case

### Advantage

#### Waivers don’t improve vaccine supply or distribution, but do allow for poorly made vaccines that undermine vaccine confidence

Delgado 5/25 [(Carla, health & culture journalist who’s written for Insider, Architectural Digest, Elemental, Observer, and Mental Floss) “Experts Say Patent Waivers Aren't Enough To Increase Global Vaccination,” Verywell Health, 5/25/2021] JL

“Waiving intellectual property rights for COVID-19 vaccines is likely to only have a modest impact on global vaccine supply,” William Moss, MD, executive director of the International Vaccine Access Center at the Johns Hopkins Bloomberg School of Public Health, tells Verywell. “A vaccine IP waiver is not in itself likely to lead to increased vaccine production in less developed countries because much more needs to be in place to increase the global vaccine supply.”

For several countries outside of the U.S. that have the necessary equipment to produce mRNA vaccines effectively and safely, the IP waiver can be of great help. However, many more countries lack this capacity, and this move still leaves them behind.

“The majority of the world’s countries lack the capacity to produce and distribute COVID-19 vaccines, and especially at the scale required to get this pandemic under control,” Richard Marlink, MD, director of the Rutgers Global Health Institute, tells Verywell. “They need funding, manufacturing facilities, raw materials, and laboratory staff with the technological expertise required.”

We've already seen what can go wrong with substandard vaccine manufacturing. In April, the Food and Drug Administration (FDA) inspected the Emergent BioSolutions factory in Baltimore and consequently shut down their production after concerning observations, which include:3

The factory was not maintained in a clean and sanitary condition.

Waste handling was found to be inadequate because generated waste was transported through the warehouse before disposal, which can potentially contaminate other areas.

Employees were seen dragging unsealed bags of medical waste from the manufacturing area across the warehouse.

Peeling paint, paint flecks, loose particles/debris were observed. There were also damaged floors and rough surfaces that cannot be properly cleaned and sanitized.

Employees were seen removing their protective garments where raw materials were staged for manufacturing.

They reportedly spoiled about 15 million doses of the Johnson and Johnson COVID-19 vaccine, and more than 100 million doses are on hold as regulators inspect them for possible contamination.4

“Vaccines are complex biological products, much more complex than drugs, and need to be produced by manufacturers and in facilities with the highest quality control standards,” Moss says. “Adverse events associated with a poorly made or contaminated batch of vaccines would have a devastating impact on vaccine confidence.”

In a statement last October, Moderna announced that they will not enforce their COVID-19-related patents against those who will make vaccines during this pandemic.5 While waiving some vaccine patents may allow third-party manufacturers to make and sell COVID-19 vaccines, the transfer of skills and technology that will allow them to manage production isn't very simple.

For instance, a spokesperson for Pfizer said that the Pfizer-BioNTech vaccine required 280 different components sourced from 86 suppliers across various countries. Manufacturing the vaccine would require highly specialized equipment and complex technology transfers.6

“Technology transfer also would need to be a critical component to expand vaccine manufacturing by other companies as an IP waiver is insufficient to provide the ‘know how’ needed to manufacture mRNA or adenovirus-vectored COVID-19 vaccines,” Moss says. “And supply chains for the reagents, supplies, and equipment would be needed.”

Interested manufacturers would need to have the proper equipment to test the quality and consistency of their manufacturing. At present, the World Health Organization (WHO) has plans to facilitate the establishment of technology hubs to transfer "a comprehensive technology package and provide appropriate training" to manufacturers from lower- and middle-income countries.7

While waiving vaccine patents is necessary, it's likely not enough. Additionally, negotiations about it are still ongoing. Even though the U.S. supports the waiver of COVID-19 vaccine patents, other countries like the United Kingdom, Japan, and Germany oppose it.8

It's also important to remember that manufacturing vaccines is only one step of the process of vaccinating the global population—distributing it is yet another hurdle.

“Many countries are counting on COVAX, a global collaboration to distribute COVID-19 vaccines more equitably around the world,” Marlink says. “The single largest supplier to COVAX is in India, where exports have been suspended since March due to the country’s COVID-19 crisis.”

#### TRIPs waiver is a symbolic gesture that prevents vaccine production and distribution

Ikenson 6/25 [(Dan, former director of the Cato Institute's Herbert A. Stiefel Center for Trade Policy Studies, MA in economics from George Washington University) “Stop Blaming Patents For The World’s Low Vaccination Rates,” Forbes, 6/25/2021] JL

The premise of the need for a TRIPS waiver is simply absurd. It serves to divert attention from the failures of governments to protect their citizens with smart public health policies and, importantly, to demonize intellectual property protections more broadly. Governments are already free to waive IP protections and to engage in compulsory licensing in times of health crises but have not done so because patents are not the bottleneck. The bottlenecks result from limited global expertise in the highly technical process of producing the vaccine, the dearth of production facilities and capacity to ramp up production at existing facilities, the tight supply of crucial pharmaceutical ingredients (including vials, bags, and other components), and the limited distribution channels through which the proper handling of vaccines at proper temperatures can be assured.

To be sure, global health officials and biopharmaceutical companies have been working to resolve these real bottlenecks—a process that has benefited significantly from the fact that U.S. officials have more bandwidth to devote more attention and other resources to these matters precisely because U.S. vaccination efforts have been successful. And why have they been successful? In large measure, they have been successful because intellectual property protections have bred expectations of future intellectual property protections, which has invited and enabled an accumulation of R&D investment, infrastructure, and expertise in the United States.

The effort to surmount these real impediments to producing, distributing, and injecting vaccines is not made any easier by a symbolic waiver of IP protections—and may be made more difficult. The volume of vaccines necessary to ending the pandemic requires governments and public health officials to coordinate and focus on ramping up the capacity to produce and distribute, and to safeguard against the squandering of pharmaceutical ingredients by ensuring those inputs are channeled to producers with expertise in manufacturing and distribution. On the contrary, suspending IP protection might encourage novice firms with no expertise to end up wasting limited, essential ingredients.

#### Waivers antagonize drug-makers and manufacturers which reduces vaccine production

Furlong 4/21 [(Ashleigh, health care reporter for POLITICO, based in London, former reporter at the science policy publication Research Fortnight who covered biomedical research policy) “Why waiving patents might not boost global access to coronavirus vaccines,” Politico EU, 4/21/2021] JL

Lifting IP rules may make it pretty straightforward to make some types of drugs where technology transfer isn’t important, said ‘t Hoen. For example, during the pandemic, both Hungary and Russia have issued compulsory licenses for remdesivir, with both countries then producing the drug. But that’s not true for vaccines.

A vaccine patent prevents another company from producing the same product. But even without a patent in the way, the company that produced the vaccine holds an enormous amount of relevant know-how that it's not going to turn over for free. So when drugmakers make deals with other manufacturers to produce their vaccine, they transfer this knowledge along under strict agreements. For example, AstraZeneca reached a licensing agreement with the Serum Institute of India last June that ensured that SII treats AstraZeneca as a priority customer in return for access to the technology behind the Oxford/AstraZeneca vaccine.

Compulsory licensing may also be an over-hyped solution, aside from removing the possibility of being sued for patent infringement, says Guilherme Cintra, director of innovation policy at the International Federation of Pharmaceutical Manufacturers and Associations, a pharma lobby. It could actually be "an antagonistic move," he added. "In a way it removes trust, and undermines the possibility of engaging in good faith to build up manufacturing."

#### The plan alienates pharma companies and doesn’t solve lack of vaccine purchasing

Glassman 5/6 [(Amanda, executive vice president and senior fellow at the Center for Global Development, research focuses on priority-setting, resource allocation and value for money in global health, former director for global health policy at the Center from 2010 to 2016, former deputy director of the Global Health Financing Initiative at Brookings and carried out policy research on aid effectiveness and domestic financing issues in the health sector in low-income countries, MSc from the Harvard School of Public Health) “Big Pharma Is Not the Tobacco Industry,” Barrons, 5/6/2021] JL

In fact, several of them did just that in the pandemic: invested their own money to develop patented manufacturing technologies in record time. Those technologies are literally saving the world right now. Public funding supported research and development, but companies also brought their own proprietary ingenuity and private investments to bear toward solving the world’s singular, collective challenge. Their reward should be astronomical given the insane scale of the health and economic benefits these highly efficacious vaccines produce every day. Market incentives sent a clear signal that further needed innovation—greater efficacy, single doses, more-rapid manufacturing, updated formulations, fast boosters, and others—would be richly rewarded. Market incentives could also have been used to lubricate supply lines and buy vaccines on behalf of the entire world; with enough money, incredible things can happen.

But activist lobbying to waive patents—a move the Biden administration endorsed yesterday—sends exactly the opposite signal. It says that the most important, valuable innovations will be penalized, not rewarded. It tells innovators, don’t bother attacking the most important global problems; instead, throw your investment dollars at the next treatment for erectile disfunction, which will surely earn you a steady return with far less agita.

It is worth going back to first principles. What problem are we trying to solve? We have highly efficacious vaccines that we would like to get out to the entire world as quickly as possible to minimize preventable disease and deaths, address atrocious inequities, and enable the reopening of society, trade, and commerce. Hundreds of millions of people have been plunged into poverty over the past year; in the developing world, the pandemic is just getting started.

What is the quickest way to get this done? Vaccine manufacturing is not just a recipe; if you attack and undermine the companies that have the know-how, do you really expect they’ll be eager to help you set up manufacturing elsewhere? Is the plan to march into Pfizer and force its staff to redeploy to Costa Rica to build a new factory? Do the U.S. administration or activists care that this decision could take years to negotiate at the World Trade Organization, and will likely be litigated for years thereafter? Does it make sense to eliminate the incentive for private companies to invest in vaccine R&D or in the response to the next health emergency? And if the patent waiver is only temporary and building a factory takes months or years, will anyone bother to do so, even if they could?

No, none of it makes sense. Worse still, we could solve the policy problem more easily by harnessing market incentives for the global good by ponying up cash to vaccinate the entire world. No confiscation necessary.

The big problem is that countries have not bought enough vaccine to inoculate most of their populations. Covax, buying on behalf of 91 lower-income countries, is only collecting enough funding to cover 20% of their population. In many parts of the world, such as the Middle East, sub-Saharan Africa and some countries in Latin America, we see very low levels of vaccine prepurchasing. We have seen this week that the government of India had not ordered enough vaccine to cover its own population, for example, resulting in export bans on its domestic vaccine manufacturers; nor has it approved the Pfizer vaccine. Our collective focus instead must be to make the market: to set up advance purchase agreements to establish demand via country cooperation, Covax, and the multilateral development banks.

### Framing

**Moral uncertainty means preventing extinction should be our highest priority.  
Bostrom 12** [Nick Bostrom. Faculty of Philosophy & Oxford Martin School University of Oxford. “Existential Risk Prevention as Global Priority.” Global Policy (2012)]  
These reflections on **moral uncertainty suggest** an alternative, complementary way of looking at existential risk; they also suggest a new way of thinking about the ideal of sustainability. Let me elaborate.¶ **Our present understanding of axiology might** well **be confused. We may not** nowknow — at least not in concrete detail — what outcomes would count as a big win for humanity; we might not even yet **be able to imagine the best ends** of our journey. **If we are** indeedprofoundly **uncertain** about our ultimate aims,then we should recognize that **there is a great** option **value in preserving** — and ideally improving — **our ability to recognize value and** to **steer the future accordingly. Ensuring** that **there will be a future** version of **humanity** with great powers and a propensity to use them wisely **is** plausibly **the best way** available to us **to increase the probability that the future will contain** a lot of **value.** To do this, we must prevent any existential catastrophe.

**Reducing the risk of extinction is always priority number one.   
Bostrom 12** [Faculty of Philosophy and Oxford Martin School, University of Oxford.], Existential Risk Prevention as Global Priority.  Forthcoming book (Global Policy). MP. [http://www.existenti...org/concept.pdf](http://www.existential-risk.org/concept.pdf)Even if we use the most conservative of these estimates, which entirely ignores the   possibility of space colonization and software minds, **we find that the expected loss of an existential   catastrophe is greater than the value of 10^16 human lives**.  **This implies that the expected value of   reducing existential risk by a mere one millionth of one percentage point is at least a hundred times the   value of a million human lives.**  The more technologically comprehensive estimate of 10  54 humanbrain-emulation subjective life-years (or 10  52  lives of ordinary length) makes the same point even   more starkly.  Even if we give this allegedly lower bound on the cumulative output potential of a   technologically mature civilization a mere 1% chance of being correct, we find that the expected   value of reducing existential risk by a mere one billionth of one billionth of one percentage point is worth   a hundred billion times as much as a billion human lives. **One might consequently argue that even the tiniest reduction of existential risk has an   expected value greater than that of the definite provision of any ordinary good, such as the direct   benefit of saving 1 billion lives.**  And, further, that the absolute value of the indirect effect of saving 1  billion lives on the total cumulative amount of existential riskâ€”positive or negativeâ€”is almost   certainly larger than the positive value of the direct benefit of such an action.