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#### Biotech R&D is set for high growth and investment now

NASDAQ 8/9 [NASDAQ is a stock market index that includes almost all stocks listed on the Nasdaq stock exchange. Along with the Dow Jones Industrial Average and S&P 500, it is one of the three most-followed stock market indices in the United States. This article was written by NASDAQ contributors and published on CNBC. The editorial staff of CNBC did not contribute to the creation of this study.) “Why the Nasdaq Biotechnology Index is poised for a run of sustainable growth” CNBC, NASDAQ, 8/9/2021, <https://www.cnbc.com/advertorial/2021/08/09/why-the-nasdaq-biotechnology-index-is-poised-for-a-run-of-sustainable-growth-.html>] RM

Between the recent bio innovation success stories in the battle against Covid-19 and the technology-driven advances ushering in new efficiencies for research and development (R&D), **the biotech industry has never been more relevant**.

As home to more than 265 companies, the pioneering Nasdaq Biotechnology Index (NBI) has long been committed to providing healthcare’s innovators with access to the capital they need to keep moving forward. Now, investors have access to the Index’s companies through a new ETF, the Invesco Nasdaq Biotechnology ETF (IBBQ).

Launched in 1993, in the wake of the original “biotech revolution” led by the discovery of recombinant DNA, NBI® remains the most representative index in the space. In fact, 98% of all U.S. listed biotech companies are listed on Nasdaq. When considering the massive growth taking place in the sector, it’s no surprise that NBI has outperformed both the S&P 500 (SPX) and Health Care Select Sector Index (IXVTR) in certain market environments.

According to Mark Marex, Index R&D Senior Specialist for Nasdaq who recently compiled an in-depth report on the NBI, global events and digital acceleration have contributed to the Index’s recent strong performance; and Nasdaq’s dedication to maintaining a true benchmark for technology-driven healthcare innovation has provided a framework for growth.

Building the ideal benchmark

Given the existence of pureplay biotech firms, hybrid biopharmaceutical companies, and less R&D-intensive pharmaceutical manufacturers, creating a single benchmark that truly captures the biotech sector and the symbiotic relationships among its players is no easy task.

One of the unique aspects of NBI, versus biotech-focused indexes created by other index providers, is its subsector classifications split between Biotechnology and Pharmaceuticals. As of June 30, 2021, ICB (FTSE Russell’s Industry Classification Benchmark) classified 222 NBI companies as Biotechnology and 47 as Pharmaceuticals. The resulting split by index weight is approximately 65% and 35%, respectively, which illustrates the major difference between the two groups: Pharmaceutical companies tend to be much larger than Biotechnology firms.

This split within a single index provides advantages for investors: While offering some exposure to more established pharmaceutical companies, it also includes R&D-heavy biotech firms that over time may transition into biotech-driven pharma companies. That’s exactly what happened this year when NBI’s largest company, Amgen (AMGN / $144Bn), was reclassified by ICB from Biotechnology to Pharmaceuticals. By retaining firms as they straddle the two classifications over the course of their lifecycle, NBI presents potential growth advantages when compared with index providers that focus rigidly on one classification versus the other.

Home to world-changing breakthroughs

Nasdaq’s vision for the Index has served it well, **both in terms of its longevity and its current role as a champion of the companies paving the way for a post-pandemic world through their technological advances and life-saving treatments**. The broad reach of NBI constituents across multiple fronts in the fight against Covid-19, for example — from diagnosis to vaccines and treatment —demonstrates the strength of its core approach.

NBI companies including Gilead and Regeneron made headlines for their successes during the pandemic with antiviral therapeutics and antibody-based therapeutics for high-risk patients. But it’s the stunning success of m-RNA vaccine technology from Moderna and BioNTech, two NBI companies, that most clearly showcase the home run potential among the biotech entrepreneurs in the space.

And while NBI is currently up 8.2% YTD on a price-return basis (as of June 30) **versus a broader market gain of 14.4% by SPX**, the S&P Biotechnology Select Industry Index (SPSIBI) is down 3.7%.

It’s worth noting that in 2020, NBI outperformed SPX with a price gain of 25.7% versus 16.3%, respectively. This shows the resilience of the NBI and the inherent strength of its current mix of companies.

The possibilities of accelerated R&D

As a whole, the life-changing work being done by NBI constituents requires enormous amounts of R&D. In 2020, R&D expenses for the entire group totaled $68.5Bn, nearly 31% of these companies’ revenue totals. Two-thirds of NBI’s firms reported R&D expenses that exceeded their revenues

For several NBI companies, however, these massive investments provided tangible benefits in the fight against Covid-19. Undoubtedly, years of back-end work and minimal profits ultimately helped deliver the very products that are now driving historic returns. Psychologically, their breakthroughs demonstrated the enormous potential of science and technology to serve humankind.

Looking ahead, **revolutions in Mapping and Engineering processes, boosted by rapid advancements in Machine Learning and Artificial Intelligence, are fostering a true fusion of Biology and Technology that could transform the traditionally costly and labor-intensive R&D function**. Some research estimates these advances could reduce the failure rate of drugs by up to 45% and shorten drug trials by up to 50%. The result could be even more breakthroughs, performed much more efficiently, greatly increasing the returns on biopharmaceutical R&D.

Even a conservative interpretation of the above numbers would significantly reduce R&D costs and boost the market capitalization of therapeutics companies from the current $2Tn up to $9Tn as soon as 2024, according to estimates from ARK Financial.

Meanwhile, increasingly cost-effective human genomics could revolutionize several other industries, from agriculture to biofuels.

By any measure, there is much to be excited about across the spectrum of biotech — especially coming out of a global pandemic. And while no person, nor index, can truly predict what the future holds, chances are strong that companies sitting within NBI will have a hand in leading the way.

“**For investors**, the Index already serves as a fascinating lens through which to view human society’s scientific and technological advancements,” says Mark Marex. “To me, it’s very exciting to ponder what the researchers, scientists, and business leaders in this space will accomplish next.”

#### IPR protections are key to sustain healthcare investments and manufacturing. Independently, it’s key to broader vaccine production.

Roberts 6/25/21 [James M. Roberts is a Research Fellow for Economic Freedom and Growth at the Heritage Foundation. Roberts' primary responsibility as one of The Heritage Foundation's lead experts in economic freedom and growth is to edit the Rule of Law and Monetary Freedom sections of [Index of Economic Freedom](https://www.heritage.org/index/). An influential annual analysis of the economic climate of countries throughout the world, the Index is co-published by Heritage and The Wall Street Journal.) “Biden’s OK of Global Theft of America’s Intellectual Property is Wrong, Dangerous.” 6/25/2021, The Heritage Foundation, Commentary—Public Health] RM

Last month, President Biden advocated removing international intellectual property rights (IPR) protections for American-made COVID-19 vaccines.

**Foreign companies may take the president’s policy as a green light to produce reverse-engineered, counterfeit substitutes**.

The best way to prevent and treat new diseases is to ensure that private American pharmaceutical companies continue their innovative research and vaccine production.

Three U.S. companies—Pfizer, Moderna, and Johnson & Johnson—created and manufactured the world’s most effective mRNA COVID vaccines in record time. An increasing majority of Americans have now been inoculated, but much of the developing world remains in desperate need of vaccines. Americans naturally want to help. The question is how.

Last month, President Biden advocated removing international intellectual property rights (IPR) protections for American-made COVID-19 vaccines. This, he said, would help make the vaccines more plentiful and available in needy countries. **It’s a short-sighted approach and doomed to fail.**

Mr. Biden wants to waive the World Trade Organization’s “Trade-Related Aspects of Intellectual Property Rights” (TRIPS) agreement for U.S. vaccines and let foreign countries issue “compulsory licenses“ allowing their domestic pharmaceutical companies to manufacture the medicines without adequately compensating the companies that invented them.

Practically speaking, countries such as India and South Africa are unlikely to manufacture the vaccines. They lack an advanced infrastructure for cold supply-chain distribution and many other crucial resources required by these products’ capital-intensive, state-of-the-art manufacturing process.

But the Biden policy is bad for many other reasons.

Developing breakthrough medications takes tremendous ingenuity and immense financial investments. **It’s an extraordinarily high-risk endeavor, and the prospect of making a profit is what convinces private companies to undertake those risks.**

Signaling that the United States will not fight to defend their intellectual property rights **actively undermines innovation and manufacturing** in American health care and medicines.

It also erodes patient protections by undermining quality control. Foreign companies may take the president’s policy as a green light to produce reverse-engineered, counterfeit substitutes. Already there are reports of ineffective and even dangerous counterfeit COVID-19 vaccines being sold around the world.

Those pushing to break U.S. pharmaceutical patents say they want to do so for altruistic reasons. Consequently, they also insist that the prices for the medications be set far below their actual value.

But history shows us that forcing private companies to provide vaccines at an “affordable price,” regardless of the cost to the companies, actually impedes the manufacture of high-quality vaccines. Moreover, it inhibits the **future development of vaccines** needed to meet as-yet-unknown diseases.

Washington first imposed vaccine price controls as part of Hillary Clinton’s 1993 healthcare-for-all crusade. As the Wall Street Journal later noted, it was a body blow to the U.S. vaccine industry. Ironically, government-decreed prices left the companies unable to produce enough vaccines to meet Mrs. Clinton’s admittedly admirable goal of universal immunization of children. Since then, U.S. firms have largely eschewed the vaccine market because they could not recoup their R&D and manufacturing costs and earn enough profit to fund future innovation.

Ultimately, **compulsory licensing legalizes the theft of intellectual property**. Recognizing this, senators from both sides of the aisle have joined with other government officials and industry leaders to call on the administration to reverse this bad decision.

The U.S. patent protection system has served the nation well since its founding.  **It is and has been a bulwark of American prosperity**, but the strength of that protection has been weakening in the past few decades. **Compulsory licensing contributes to the erosion** of that protection.

As the U.S. and the rest of the world emerge from the pandemic, it is clear that more innovative medicines and vaccines will be needed for future protection from viruses and other emerging biological threats.

**The best way to prevent and treat those new diseases is to ensure that private American pharmaceutical companies continue their innovative research and vaccine production**.

That way, U.S.-manufactured vaccines can be made available to all Americans quickly. And governments can subsidize their export and sale to other countries far more effectively and less expensively than through compulsory licensing schemes.

Meanwhile, let’s hope Mr. Biden listens to the more reasonable and less-agenda driven voices in this debate and reverses course on the TRIPS waiver.

#### COVID was a precursor to deadlier pandemics—vaccine production will determine everything.

Lander 8/4/21 [Eric Lander, President Biden’s Science Advisory and Director of the White House Office of Science and Technology Policy) “Opinion: As bad as Covid-19 has been, a future pandemic could be even worse—unless we act now” 8/4/21, The Washington Post] RM

[Coronavirus](https://www.washingtonpost.com/coronavirus/?itid=lk_inline_manual_3) vaccines can end the current pandemic if enough people choose to protect themselves and their loved ones by getting vaccinated. But in the years to come, we will still need to defend against a pandemic side effect: collective amnesia.

As public health emergencies recede, societies often quickly forget their experiences — and **fail to prepare for future challenges**. For pandemics, such a course would be disastrous.

**New infectious diseases have been emerging at an accelerating pace,** and they are spreading faster.

Our federal government is responsible for defending the United States against future threats. That’s why President Biden has asked Congress to fund his plan to build on current scientific progress to keep new infectious-disease threats from turning into pandemics like covid-19.

As the president’s science adviser, I know what’s becoming possible. For the first time in our history, we have an opportunity not just to refill our stockpiles but also to transform our capabilities. However, **if we don’t start preparing now for future pandemics, the window for action will close.**

Covid-19 has been a catastrophe: The toll in the United States alone is [more than 614,000 lives](https://www.washingtonpost.com/graphics/2020/national/coronavirus-us-cases-deaths/?itid=lk_inline_manual_11) and has been estimated to exceed [$16 trillion](https://jamanetwork.com/journals/jama/fullarticle/2771764), with disproportionate impact on vulnerable and marginalized communities.

But a future pandemic could be even worse — unless we take steps now.

It’s important to remember that the virus behind covid-19 is far less deadly than the 1918 influenza. The virus also belongs to a well-understood family, coronaviruses. It was possible to design vaccines within days of knowing the virus’s genetic code because 20 years of [basic scientific research](https://science.sciencemag.org/content/372/6538/109.full) had revealed which protein to target and how to stabilize it. And while the current virus spins off variants, its mutation rate is slower than that of most viruses.

**Unfortunately, most of the 26 families of viruses that infect humans are less well understood or harder to control**. We have a great deal of work still ahead.

The development of [mRNA vaccine technology](https://www.washingtonpost.com/health/2020/12/06/covid-vaccine-messenger-rna/?itid=lk_inline_manual_17) — thanks to more than a decade of foresighted basic research — was a game-changer. It shortened the time needed to design and test vaccines to less than a year — far faster than for any previous vaccine. And it’s been surprisingly effective against covid-19.

Still, there’s much more to do. We don’t yet know how mRNA vaccines will perform against other viruses down the road. And **when the next pandemic breaks out, we’ll want to be able to respond even faster.**

Fortunately, the scientific community has been developing a bold plan to keep future viruses from becoming pandemics.

Here are a few of the goals we should shoot for:

The capability to design, test and approve safe and effective vaccines within 100 days of detecting a pandemic threat (for covid-19, that would have meant May 2020); manufacture enough doses to supply the world within 200 days; and speed vaccination campaigns by replacing sterile injections with skin patches.

Diagnostics simple and cheap enough for daily home testing to limit spread and target medical care.

Early-warning systems to spot new biological threats anywhere in the world soon after they emerge and monitor them thereafter.

We desperately need to strengthen our public health system — from expanding the workforce to modernizing labs and data systems — including to ensure that vulnerable populations are protected.

And we need to coordinate actions with our international partners, because pandemics know no borders.

These goals are ambitious, but they’re feasible — provided the work is managed with the seriousness, focus and accountability of NASA’s Apollo Program, which sent humans to the moon.

Importantly, these capabilities won’t just prepare us for future pandemics; they’ll also improve public health and medical care for infectious diseases today.

Preparing for threats is a core national responsibility. That’s why our government invests heavily in missile defense and counterterrorism. We need to similarly protect the nation against biological threats, which range from the ongoing risk of pandemics to the possibility of deliberate use of bioweapons.

Pandemics cause massive death and disruption. From a financial standpoint, they’re also astronomically expensive. If, as might be expected from [history](https://www.cfr.org/timeline/major-epidemics-modern-era) and current trends, we suffered a pandemic of the current scale every two decades, the annualized cost would exceed $500 billion per year. Investing a much smaller amount to avert this toll is an economic and moral imperative.

The White House will put forward a detailed plan this month to ensure that the United States can fully prepare before the next outbreak. It’s hard to imagine a higher economic or human return on national investment.

#### Ecosystem sensitivity from climate change means future pandemics will cause extinction—assumes COVID

Supriya 4/19 [Lakshmi Supriya got her BSc in Industrial Chemistry from IIT Kharagpur (India) and a Ph.D. in Polymer Science and Engineering from Virginia Tech (USA). She has more than a decade of global industry experience working in the USA, Europe, and India. After her Ph.D., she worked as part of the R&D group in diverse industries starting with semiconductor packaging at Intel, Arizona, where she developed a new elastomeric thermal solution, which has now been commercialized and is used in the core i3 and i5 processors. From there she went on to work at two startups, one managing the microfluidics chip manufacturing lab at a biotechnology company and the other developing polymer formulations for oil extraction from oil sands. She also worked at Saint Gobain North America, developing various material solutions for photovoltaics and processing techniques and new applications for fluoropolymers. Most recently, she managed the Indian R&D team of Enthone (now part of MacDermid) developing electroplating technologies for precious metals.) “Humans versus viruses - Can we avoid extinction in near future?” News Medical Life Sciences, 4/19/21, https://www.news-medical.net/news/20210419/Humans-versus-viruses-Can-we-avoid-extinction-in-near-future.aspx] RM

Expert argues that human-caused changes to the environment can lead to the emergence of pathogens, not only from outside but also from our own microbiome, which can pave the way for large-scale destruction of humans and **even our extinction**.

Whenever there is a change in any system, it will cause other changes to reach a balance or equilibrium, generally at a point different from the original balance. Although this principle was originally posited by the French chemist Henry Le Chatelier for chemical reactions, this theory can be applied to almost anything else.

In an essay published on the online server Preprints\*, Eleftherios P. Diamandis of the University of Toronto and the Mount Sinai Hospital, Toronto, argues that changes caused by humans, to the climate, and everything around us will lead to changes that may have a dramatic impact on human life. Because our ecosystems are so complex, we don’t know how our actions will affect us in the long run, so humans generally disregard them.

Changing our environment

Everything around us is changing, from living organisms to the climate, water, and soil. Some estimates say about half the organisms that existed 50 years ago have already become extinct, and about 80% of the species may become extinct in the future.

As the debate on global warming continues, according to data, the last six years have been the warmest on record. Global warming is melting ice, and sea levels have been increasing. The changing climate is causing more and more wildfires, which are leading to other related damage. At the same time, increased flooding is causing large-scale devastation.

One question that arises is how much environmental damage have humans already done? A recent study compared the natural biomass on Earth to the mass produced by humans and found humans produce a mass equal to their weight every week. This human-made mass is mainly for buildings, roads, and plastic products.

In the early 1900s, human-made mass was about 3% of the global biomass. Today both are about equal. Projections say by 2040, the human-made mass will be triple that of Earth’s biomass. But, slowing down human activity that causes such production may be difficult, given it is considered part of our growth as a civilization.

Emerging pathogens

Although we are made up of human cells, we have almost ten times that of bacteria just in our guts and more on our skin. These microbes not only affect locally but also affect the entire body. There is a balance between the good and bad bacteria, and any change in the environment may cause this balance to shift, especially on the skin, the consequences of which are unknown.

Although most bacteria on and inside of us are harmless, gut bacteria can also have viruses. If viruses don’t kill the bacteria immediately, they can incorporate into the bacterial genome and stay latent for a long time until reactivation by environmental factors, when they can become pathogenic. They can also escape from the gut and enter other organs or the bloodstream. Bacteria can then use these viruses to kill other bacteria or help them evolve to more virulent strains.

An example of the evolution of pathogens is the cause of the current pandemic, the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). Several mutations are now known that make the virus more infectious and resistant to immune responses, and strengthening its to enter cells via surface receptors.

The brain

There is evidence that the SARS-CoV-2 can also affect the brain. The virus may enter the brain via the olfactory tract or through the angiotensin-converting enzyme 2 (ACE2) pathway. Viruses can also affect our senses, such as a loss of smell and taste, and there could be other so far unkown neurological effects. The loss of smell seen in COVID-19 could be a new viral syndrome specific to this disease.

Many books and movies have described pandemics caused by pathogens that wipe out large populations and cause severe diseases. In the essay, the author provides a hypothetical scenario where a gut bacteria suddenly starts producing viral proteins. Some virions spread through the body and get transmitted through the human population. After a few months, the virus started causing blindness, and within a year, large populations lost their vision.

Pandemics can cause other diseases that can threaten humanity’s entire existence. **The COVID-19 pandemic brought this possibility to the forefront**. If we continue disturbing the equilibrium between us and the environment, we don’t know what the consequences may be and **the next pandemic could lead us to extinction.**

### 1NC – WTO Credibility

#### Squo disproves – Moderna, J&J, AstroZeneca already in compulsory licensing agreements with South Africa, Brazil, Argentina, etc…

#### Waiving IP enforcement results in rampant increase in counterfeit vaccines – turns case.

Mercurio 21 (Bryan Mercurio is a Professor and Vice-Chancellor's Outstanding Fellow of the Faculty of Law at the Chinese University of Hong Kong, February 21, 2021, <https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3789820&download=yes>) CS

6. IP enforcement is of vital importance to maintaining safety standards.

The protection of IP not only provides incentives to innovators to create, but also plays a crucial role in ensuring the safety of vaccines and helping to prevent the importation **of fraudulent and dangerous goods**. Unlike the typical pharmaceutical industry, the vaccine market is not a free and open market.69 Vaccines contain biological products made from living organisms and the risk of failure in vaccine development and production is high. 70 Moreover, the manufacturing process for vaccines is much more complex as it requires the use of facilities and equipment with a high degree of specialization.71 The complexity of vaccine products implies that more time and regulatory requirements are needed in order to make or “copy” the vaccine production process. Therefore, the innovator should be expected to make conscious and meticulous decisions as to when and to whom to issue licences, as this is the most responsible way to bring their technologies to the world and safeguard global health.

In addition, as the COVID-19 pandemic continues there has been a **noticeable increase in the circulation of fake medicines** around the world. According to the International Criminal Police Organization (Interpol), **organized crime groups** have been producing fake drugs and medical products and selling them for **lucrative profits in developing countries**.72 With the development of COVID-19 vaccines on the market, a rapid rise in the illegal sale of fake items is expected, according to the United Nations Office on Drugs and Crime (UNODC).73 Counterfeits of the legitimate products provide false promises of protection and could lead to **disastrous consequences**, including **worsened illness and** **death** for the individual and the retardation of herd immunity for the population at large. Effective and proactive **IP** procurement is **essential** and useful in mitigating the risks of counterfeit and substandard medicines. IP enforcement measures play a significant role in preventing these fake and illicit medicines from circulating in the market. While important during normal times, IP enforcement can take on an enhanced role of safeguarding the public during this critical period of time. Waiving all COVID-19 related IPRs raises the risk of unsafe or fake vaccines circulating in supply channels and being sold to unsuspecting governments, **putting millions of human lives at risk** and reducing trust in vaccines.

#### IPR hasn’t harmed access – manufacturing capacity alt cause

Mercurio 2/12 (Bryan Mercurio, [Simon F.S. Li Professor of Law at the Chinese University of Hong Kong (CUHK), having served as Associate Dean (Research) from 2010-14 and again from 2017-19. Professor Mercurio specialises in international economic law (IEL), with particular expertise in the intersection between trade law and intellectual property rights, free trade agreements, trade in services, dispute settlement and increasingly international investment law.], 2-12-2021, “WTO Waiver from Intellectual Property Protection for COVID-19 Vaccines and Treatments: A Critical Review“, No Publication, accessed: 8-8-2021, https://papers.ssrn.com/sol3/papers.cfm?abstract\_id=3789820) ajs

2. Intellectual property rights have not hampered access to COVID-19 vaccines

A WTO waiver is an extreme measure which should only be used when existing WTO obligations prove inadequate. This was the case in relation to the compulsory licencing provisions under Article 31 of the TRIPS Agreement, which essentially precluded Members with no or inadequate manufacturing capabilities from making use of the flexibility granted in the TRIPS Agreement. 25 This was also the case with the Kimberley Process, which attempts to eliminate trade in “conflict diamonds”. 26

Although the IP waiver proposal states that “there are several reports about intellectual property rights hindering or potentially hindering timely provisioning of affordable medical products to the patients”, 27 the sponsors did not provide further elaboration or evidence to support their declaration that “many countries especially developing countries may face institutional and legal difficulties when using flexibilities available [under the TRIPS Agreement]”. 28 Instead, many of the examples used by India and South Africa point to problems not with the TRIPS Agreement but rather to failures at the domestic level. As mentioned above, the WTO allowed for the importation of medicines under a compulsory licence in 2003, and yet many developing countries have yet to put in place any framework to allow their country to make use of the flexibility. 29 This is not an institutional problem of the international system but rather a problem at the country level.

Two additional factors which make the proposed waiver unnecessary and potentially harmful. First, pharmaceutical companies are selling the vaccine at extremely reasonable rates and several announced plans for extensive not-for-profit sales.30 Although agreements between the pharmaceutical companies and governments are not publicly disclosed, the Belgian Secretary of State Eva De Bleeker temporarily made publicly available in a tweet the prices the EU is being charged by each manufacturer. The De Bleeker tweet indicated the European Commission negotiated price arrangements with six companies, with the range of spending between €1.78 and €18 per coronavirus vaccine dosage. Specific price per dose listed for each of the six vaccines was as follows: Oxford/AstraZeneca: (€1.78), Johnson & Johnson (€8.50), Sanofi/GSK (€7.56), CureVac (€10), BioNTech/Pfizer (€12) and Moderna (€18).31

While much as been made of the fact that South Africa agreed to purchase 1.5 million doses of the Oxford/AstraZeneca from the Serum Institute of India (SII) at a cost of €4.321 per dose,32 these criticisms are directed at the lack of transparency in pharmaceutical licenses and production contracts – an issue which would be wholly unaddressed by a waiver of IPRs.

Moreover, while the disparity in pricing is concerning the overall per dosage rate South Africa is paying nevertheless represents value for money given the expected health and economic returns on investment. Despite the disparity in pricing between nations, the larger point remains that the industry has not only rapidly produced vaccines for the novel coronavirus but is making them available at unquestionably reasonable prices.

Second, the proposed waiver will do nothing to address the problem of lack of capacity or the transfer of technology and goodwill. Pharmaceutical companies have not applied for patents in the majority of developing countries – in such countries, any manufacturer is free to produce and market the vaccine inside the territory of that country or to export the vaccine to other countries where patents have not been filed.33 Patents cannot be the problem in the countries where no patent applications have been filed, but the lack of production in such countries points to the real problem – these countries lack manufacturing capacity and capability.

While advanced pharmaceutical companies will have the technology, know-how and readiness to manufacture, store and transport complex vaccine formulations, such factories and logistics exist in only a handful of countries.34 Regardless of whether an IP waiver is granted, the remaining countries will be left without enhanced vaccine access and still reliant on imported supplies. With prices for the vaccine already very low, it is doubtful that generic suppliers will be able to provide the vaccine at significantly lower prices. Under such a scenario, the benefit of the waiver would go not to the countries in need but to the generic supplier who would not need to pay the licence fee or royalty to the innovator. Thus, the waiver would simply serve to benefit advanced generic manufacturers, most of which are located in a handful of countries, including China and Brazil as well as (unsurprisingly) India and South Africa. Countries would perhaps be better off obtaining the vaccine from suppliers that have negotiated a voluntary licence from the patent holder, as such licences include provisions for the transfer of technology, know-how and ongoing quality assurance support.

#### Waivers fail – license agreements are key to access and scaling up vaccines

Crosby et al 21 [[Daniel Crosby](https://www.jdsupra.com/authors/daniel-crosby/), [Evan Diamond](https://www.jdsupra.com/authors/evan-diamond/), [Isabel Fernandez de la Cuesta](https://www.jdsupra.com/authors/isabel-fernandez-de-la-cuesta/), [Jamieson Greer](https://www.jdsupra.com/authors/jamieson-greer/), [Jeffrey Telep](https://www.jdsupra.com/authors/jeffrey-telep/), [Brian White](https://www.jdsupra.com/authors/brian-white/)] “Group of Nearly 60 WTO Members Seek Unprecedented Waiver from WTO Intellectual Property Protection for COVID-related Medical Products,” JD Supra, March 5, 2021, <https://www.jdsupra.com/legalnews/group-of-nearly-60-wto-members-seek-2523821/> TG

Waiver risks uncontrolled use of patented technologies, without improving vaccine access. Pharmaceutical companies can provide, and have provided, licenses to distribute or scale-up production of COVID-19 vaccines and therapies at reduced cost. Such license agreements allow for expanded access in low- and middle-income countries, while also setting reasonable parameters so that patents and other IP rights are used to address the specific medical needs of the COVID-19 pandemic at hand, and not for other purposes. License agreements also allow for orderly technology transfer, including of unpatented “trade secret” information and other critical “know-how,” that may be essential to efficiently producing and scaling-up safe and effective versions of technologically complex vaccines and biologic drug products.

Under the present TRIPS waiver proposal, however, member countries could try to exploit an extraordinarily broad scope of IP and copy patented technologies so long as they are “in relation to prevention, containment or treatment of COVID-19.” For example, under an expansive reading of the proposed waiver language, a member country could try to produce patented pharmaceutical compounds that have other indicated uses predating COVID-19, if such compounds had later been studied or experimentally used for potential symptomatic relief or antiviral activity in COVID-19 patients. The same risks may be faced by manufacturers of patented materials or devices that have multiple uses predating COVID-19, but also may be used as “personal protective equipment” or components thereof, or in other measures arguably relating to COVID-19 “prevention” or “containment.”

At the same time, it is unclear how the proposed TRIPS waiver could provide the technology transfer and know-how critical for making the complex molecules and formulations constituting the various COVID-19 vaccines. Vaccine manufacture undertaken by an unauthorized party without the proper processes and controls could result in a different product that is potentially ineffective or results in unwanted health consequences. And even if an unauthorized manufacturer could overcome those substantial hurdles to reverse-engineer and scale up a safe and effective vaccine copy, it would likely take substantial time and a series of failures to do so. Notably, several of the original COVID-19 vaccine developers have recently faced low product yield and other manufacturing challenges during pre-commercial scale-up efforts and the initial months of commercial production.

#### China will never comply in any case that violates its interests, which is all of them

Dickinson 2012

Steve, China based corporate law attorney, former lecturer at Beijing School of Law, Another China WTO Loss. Another Nail In The Coffin Of World Trade, 2/6/2012 http://www.chinalawblog.com/2012/02/another\_china\_wto\_loss\_another\_nail\_in\_the\_coffin\_of\_world\_trade.html

Preserving its track record of major defeats before the WTO, China recently lost its appeal of the WTO panel decision in the minerals export case. The appeal decision was issued on January 30 and can be found here. Briefly stated, the original panel report held that Chinese export duties and export quotas for certain industrial minerals violate WTO requirements. China was ordered to reduce its duties and dismantle its export quota system. China appealed and lost on all important issues. This decision has important implications. As most observers have noted, the real issue is export quotas and the real target is China’s export quota system for rare earths. Under the terms of this decision, China’s rare earths quota system is in clear violation of the WTO. The U.S. and others expect China to now act on its own and terminate the rare earths quota system. If this is not done voluntarily, the U.S. and the European Union have threatened to bring a follow-up action in the WTO, targeting rare earths. After this victory in the metals case, such an action against China would almost certainly succeed. More important, China has an extensive export quota system covering over 600 products. These are all basic materials considered by China to be vital to its internal security: energy, raw materials and food. Under the terms of the panel decision and appeal, it is now clear that China’s entire export quota system is in violation of the WTO. This recent decision on minerals therefore goes far beyond rare earths. It is a challenge to a vast and complicated system that the Chinese see as essential to national survival. Ron Kirk, the U.S. Trade Representative, described the success of the appeal as as a “tremendous victory” for the United States. In reality, the decision is bad for both the United States and China and for the members of the WTO as a whole. This case is a very hot issue in China. After the decision, assessments have appeared from the Chinese government, the Xinhua News Service (the Chinese government’s propaganda arm) and from general business commentators. The universal conclusion of the Chinese is that China has no intent whatsoever to comply with the terms of this decision or any other decision relating to its export quota program or to any other regulatory regime China deems in its national interest (such as China’s restrictions on importing print and audio-visual materials). The basic position set forth in the Chinese press has been as follows: Control of domestically produced raw materials, energy and food are vital to China’s national interest. China will not allow a trade law like the WTO to impact its pursuit of policies such as export quotas that are vital to its national interests. The attempt by the developed countries to use the WTO as a way to attack China’s national interest is unfair and shows bad intent. Such attempts will be rejected. China still intends to remain within the WTO so as to be able to obtain certain trade benefits. Rather than openly disregard the minerals decision, China will resort to “procedural games” (游戏规则) to render any response against China ineffective as a practical matter. China is proud of how it has used “procedural games” to avoid its responsibilities to respond to adverse WTO decisions and it openly states that it will continue to use this approach in these “national interest” cases. In fact, the term “procedural games” has become a standard feature of China’s trade policy vocabulary. This result is bad for supporters of the WTO trade system and it is bad for China. It is bad for the supporters because it exposes the weakness of the WTO dispute resolution process for resolving serious trade conflicts. China’s recent series of losses in the WTO justifies the US and other countries imposing major tariff and related trade sanctions against China, but no such sanctions have been imposed and China has concluded that no such sanctions will ever be imposed. China correctly believes that it can afford to ignore adverse WTO decisions because the complaining countries have no interest in actually imposing sanctions. We can thus expect China to continue ignoring most (all?) adverse WTO decisions against it. This will serve to progressively weaken the WTO trade system. The odd thing about the export quota case, however, is that China itself is likely to be the biggest loser. China is the major importer in the world of raw materials, energy and food products. China therefore absolutely requires an open and fair export system for such products. By acting to support mercantilist export quotas and other restrictions on the export of critical raw materials, China is acting directly against its own economic and national security interest. China’s control of the rare earths export market has convinced it that it can become a rare earths version of OPEC, giving them power to finally dictate terms to the developed world. This dream has blinded China to the real risks of its plan. Both China and the U.S. are acting recklessly in a way that serves to undermine the WTO trade system. The damage has been done. The WTO minerals ruling is just another nail in the coffin. The WTO has been murdered. China pulled the trigger and the U.S. and Europe supplied the gun.

#### WTO credibility doesn’t prevent war—no country arbitrates war in international financial institutions.

#### Trade doesn’t prevent war

Charles Miller, Poli Sci PhD, 14, lecturer at Australian National University’s Strategic and Defence Studies Centre, 4/7/14, “Globalisation and war,” http://www.aspistrategist.org.au/globalisation-and-war

John O’Neal and Bruce Russett’s work is perhaps the best known in this regard—and Steven Pinker cites them approvingly in his book The Better Angels of Our Nature. Analysing trade and conflict data from the nineteenth to the twenty-first centuries, they found that trade flows do have a significant impact in reducing the chances of conflict, even when taking a variety of other factors into account. But their conclusions have in turn been questioned by other scholars. For one thing, their model failed to take three things into account. First, it’s quite possible that peace causes trade rather than the other way around—no company wants to start an export business to another country if it anticipates that business linkages will be cut off by war further down the line. Second, conflict behaviour exhibits what’s called ‘network effects’ — if France and Germany are at peace, chances are Belgium and Germany will be too. And third, both the likelihood of conflict and the level of trade are influenced by the number of years a pair of countries has already been at peace—because prolonged periods of peace increase mutual trust. Take any of these factors into account, and studies have shown (here and here) that the apparent relationship between trade flows and peace disappears.

Perhaps, though, conceiving of globalisation solely in terms of trade flows is mistaken. Alternative indicators of globalisation include foreign direct investment, financial openness and the levels of government intervention in economic relations with the rest of the world. Data on those variables is less extensive than on trade flows, usually dating back only to the post World War II period. But some analysts, such as Patrick McDonald and Erik Gartzke, have argued that a significant correlation can be found between them and a reduction in the probability of conflict. Those findings, newer than O’Neal and Russett’s, haven’t yet been subjected to the same intense scrutiny, so may in turn be qualified by future research.

What does all that mean for the policy-maker? The statistical evidence certainly doesn’t tell us that globalisation has made war in East Asia impossible. ‘Cromwell’s law’ counsels us that a logically conceivable event should never be assigned a probability of zero. The most we could conclude is that globalisation has made such an occurrence much less likely. There’s some hopeful numerical evidence that globalisation does indeed have that effect, but the evidence isn’t so compelling that we can substitute an economic engagement policy for a security policy. By all means, let’s continue to promote trade in the Asia-Pacific. But we should also continue to be prepared for scenarios which are unlikely but would be hugely damaging if they were to occur.

### 1NC – Developing Countries

#### India no longer in crisis – cases have massively decreased and the worst of COVID is over – thumps the link.

#### Non-uq - India has already developed their own vaccine – is already being administered.

[Mallapaty](https://www.nature.com/articles/d41586-021-02385-x#author-0) ’21 (Smriti, an editor at the Nature Index, and has also worked as a freelance journalist reporting on science and environment based out of Kathmandu, Nepal. She has a master of science degree in environmental technology from Imperial College London, **“India’s DNA COVID vaccine is a world first – more are coming,** September 2, 2021, <https://www.nature.com/articles/d41586-021-02385-x>) chris

**India has approved a new COVID-19 vaccine** that uses circular strands of DNA to prime the immune system against the virus SARS-CoV-2. Researchers have welcomed news of the first DNA vaccine for people to receive approval anywhere in the world, and say many other DNA vaccines might soon be hot on its heels. ZyCoV-D, which is administered into the skin without an injection, has been found to be 67% protective against symptomatic COVID-19 in clinical trials, and will probably **start to be administered in India this month**. Although the efficacy is not particularly high compared to that of many other COVID-19 vaccines, the fact that it is a DNA vaccine is significant, say researchers. It is proof of the principle that DNA vaccines work and can help in controlling the pandemic, says Peter Richmond, a paediatric immunologist at the University of Western Australia in Perth. “This is a **really important step forward in the fight to defeat COVID-19** globally, because it demonstrates that we have another class of vaccines that we can use.” Close to a dozen DNA vaccines against COVID-19 are in clinical trials globally, and at least as many again are in earlier stages of development. DNA vaccines are also being developed for many other diseases. “If DNA vaccines prove to be successful, this is really the future of vaccinology” because they are easy to manufacture, says Shahid Jameel, a virologist at Ashoka University in Sonipat, India. Fast-tracked development The urgency of combating COVID-19 has fast-tracked the development of vaccines that use genetic technology, such as messenger RNA and DNA vaccines, says David Weiner, director of the Vaccine & Immunotherapy Center at the Wistar Institute in Philadelphia, Pennsylvania. RNA vaccines were quicker to show strong immune responses in clinical trials; they have now been delivered to hundreds of millions of people around the world. But DNA vaccines have a number of benefits, because they are easy to produce and the finished products are more stable than mRNA vaccines, which typically require storage at very low temperatures. ZyCoV-D was **developed** by **Indian pharmaceutical firm Zydus Cadila**, headquartered in Ahmedabad. On 20 August, India’s drug regulator [authorized the vaccine](https://www.pib.gov.in/PressReleasePage.aspx?PRID=1747669) for people aged 12 and older. The efficacy figure of 67% came from trials involving more than 28,000 participants, which saw 21 symptomatic cases of COVID-19 in the vaccinated group and 60 among people who received a placebo. ZyCoV-D contains circular strands of DNA known as plasmids, which encode the spike protein of SARS-CoV-2, together with a promoter sequence for turning the gene on. Once the plasmids enter the nuclei of cells, they are converted into mRNA, which travels to the main body of the cell, the cytoplasm, and is translated into the spike protein itself. The body’s immune system then mounts a response against the protein, and produces tailored immune cells that can clear future infections. Plasmids typically degrade within weeks to months, but the immunity remains. Both DNA and mRNA vaccines have been under development since the 1990s, says Weiner. The challenge for DNA vaccines is that they need to make it all the way to the cell nucleus, unlike mRNA vaccines, which just need to get to the cytoplasm, says Jameel. So, for a long time, DNA vaccines struggled to induce potent immune responses in clinical trials, which is why they had been approved for use as [vaccines only in animals](https://www.nature.com/articles/nrg2432), such as horses, until now.

#### No brink ev – India already suffered the worst of COVID and rates are only a small percentage of what they were.

#### Alt causes to Indo-Pak war – religious tensions, Kashmir disputes, jets being shot down.

#### No risk of Indo-Pak war

Sehgal and Rajaraman 18 (2018, Emeritus Professor of Theoretical Physics at Jawaharlal Nehru University, "'India-Pakistan nuke war not a realistic possibilty', says leading nuclear expert Ramamurti Rajaraman", Firstpost, https://www.firstpost.com/india/india-pakistan-nuke-war-not-a-realistic-possibilty-says-leading-nuclear-expert-ramamurti-rajaraman-3880145.html)

Q: The conflict between India and Pakistan has intensified in the last three years. If the situation worsens, is there a likelihood that India could launch a pre-emptive first strike against Pakistan if it feared an imminent nuclear strike? Of course, this could mean a marked reversal of our no-first use (NFU) policy. On the other hand, if India goes in for more surgical strikes, can Pakistan use a conventional attack as a pretext to attack India? A: The conflict between India and Pakistan during the past three years has been limited to Jammu and Kashmir. These conflicts may continue and may also occasionally intensify. There may also be a lot of heated rhetoric from both sides. But I don’t think there is any realistic possibility of those conflicts developing into a full-scale war, let alone one with any serious chances of a nuclear strike by Pakistan. Notice that there has been no mainland attack by Pakistan based terrorists since the 2008 Mumbai attacks. I feel that this is because Pakistan military and its Inter-Services Intelligence do appreciate the fact that the next time there is an attack of that magnitude, India would have to retaliate in a serious manner. It is true that the Pakistan Army maintains a hostile posture towards India as a matter of policy. But that is done largely for domestic consumption and for maintaining its pre-eminence in the Pakistani power structure. If push comes to shove, the leadership in both countries are too responsible to let matters go anywhere near a nuclear threshold. So, there is no question of India conducting a pre-emptive strike on Pakistan in anticipation of a nuclear attack from them. I don’t think India will reverse its NFU policy, even though some analysts, for the want of anything better to write about, keep harping on it. That would be a very unwise thing to do diplomatically.

#### Libya, War on Terror conflicts, Central Africa Civil War, Rwandan genocide, countless other wars all thump instability and great power draw-in. What happens in Africa stays in Africa.

#### No Africa war

Barrett 05 [(Robert Barrett, PhD Conflict & Post Doctoral Fellow, Conflict Analysis - University of Calgary & Principal and Senior Partner De Novo Group LLC) “Understanding the Challenges of African Democratization through Conflict Analysis,” IACM 18th Annual Conference, June 1, 2005]

Westerners eager to promote democracy must be wary of African politicians who promise democratic reform without sincere commitment to the process. Offering money to corrupt leaders in exchange for their taking small steps away from autocracy may in fact be a way of pushing countries into anocracy. As such, world financial lenders and interventionists who wield leverage and influence must take responsibility in considering the ramifications of African nations who adopt democracy in order to maintain elite political privileges. The obvious reason for this, aside from the potential costs in human life should conflict arise from hastily constructed democratic reforms, is the fact that Western donors, in the face of intrastate war would then be faced with channeling funds and resources away from democratization efforts and toward conflict intervention based on issues of human security. This is a problem, as Western nations may be increasingly wary of intervening in Africa hotspots after experiencing firsthand the unpredictable and unforgiving nature of societal warfare in both Somalia and Rwanda. On a costbenefit basis, the West continues to be somewhat reluctant to get to get involved in Africa’s dirty wars, evidenced by its political hesitation when discussing ongoing sanguinary grassroots conflicts in Africa. Even as the world apologizes for bearing witness to the Rwandan genocide without having intervened, the United States, recently using the label ‘genocide’ in the context of the Sudanese conflict (in September of 2004), has only proclaimed sanctions against Sudan, while dismissing any suggestions at actual intervention (Giry, 2005). Part of the problem is that traditional military and diplomatic approaches at separating combatants and enforcing ceasefires have yielded little in Africa. No powerful nations want to get embroiled in conflicts they cannot win – especially those conflicts in which the intervening nation has very little interest. It would be a false statement for me to say that there has never been a better time to incorporate the holistic insights of conflict analysis. The most opportune time has likely come and gone. Yet, Africa remains at a crossroads – set amidst the greatest proliferation of democratic regimes in history. It still has a chance. Yet, it is not only up to the West, but also Africans themselves, to stand against corruption, to participate in civil society and to ultimately take the initiative in uncovering and acknowledging the deep underlying issues perpetuating African conflict in order to open the door to democratic advancement and global interaction. Analysis will be the key that unlocks that door.