NEWSLETTER

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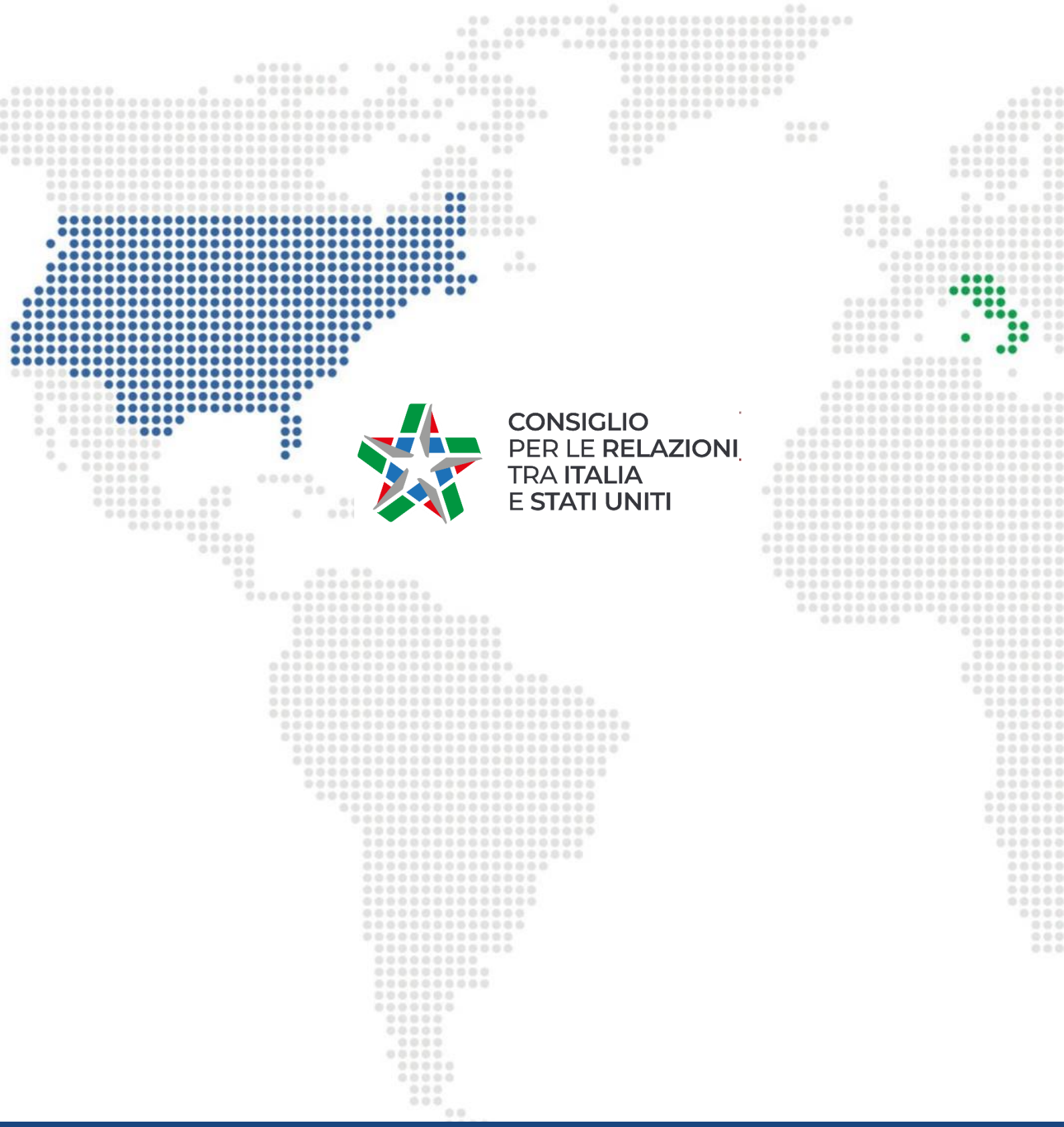

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ABOUT THE COUNCIL FOR THE UNITED STATES AND ITALY

The Council for the United States and Italy is a private non-profit organization, founded in Venice in 1983 by Gianni Agnelli and David Rockefeller, who served as honorary presidents until 2003. Marco Tronchetti Provera followed them as Chairman, then Sergio Marchionne until 2018. Domenico Siniscalco is the current Chairman, Gianni Riotta Executive Vice Chairman. The Council for the United States and Italy promotes and creates economic relations between Italy and the United States, linking them to Europe, Asia and Africa through knowledge and free trade. Its members are leaders in the economy, industry, finance, technology, services, consulting, law, and culture - a team in which economic growth is viewed as promoting humanity and wealth as a cultural value to be shared.

This monthly newsletter is prepared jointly by the Council for the United States and Italy and The European House - Ambrosetti.

WEBINAR | The future of globalization| May 6 @ 6.15pm

Moisés Naím *(Distinguished fellow at the Carnegie Endowment for International Peace)*

The term globalization carries different meaning and nuances in itself: it can be economic, scientific or diplomatic. Economic globalization, together with the broader economic system, are experiencing a process of rethinking, given their susceptibility to accidents and fractures. Because of frequent crashes, growing inequality and misalignment with climate change, it is necessary to realign the system.

Instead, scientific globalization is booming: its international endeavour proved during the Covid-19 pandemic that healthcare needs to be global, in terms of research and response.

Finally, it is possible to define diplomatic globalization as the politics and the alliances of the international system.

It is interesting to observe few characteristics of globalization. In the context of in international crises, such as a pandemic, a terroristic attack or a financial crash the reactions of governments carry far more consequences and are more durable in time compared than their triggering factors. As a result, people's lives change dramatically because of governmental actions, as it did after the 9/11 or with the spread of Covid-19.

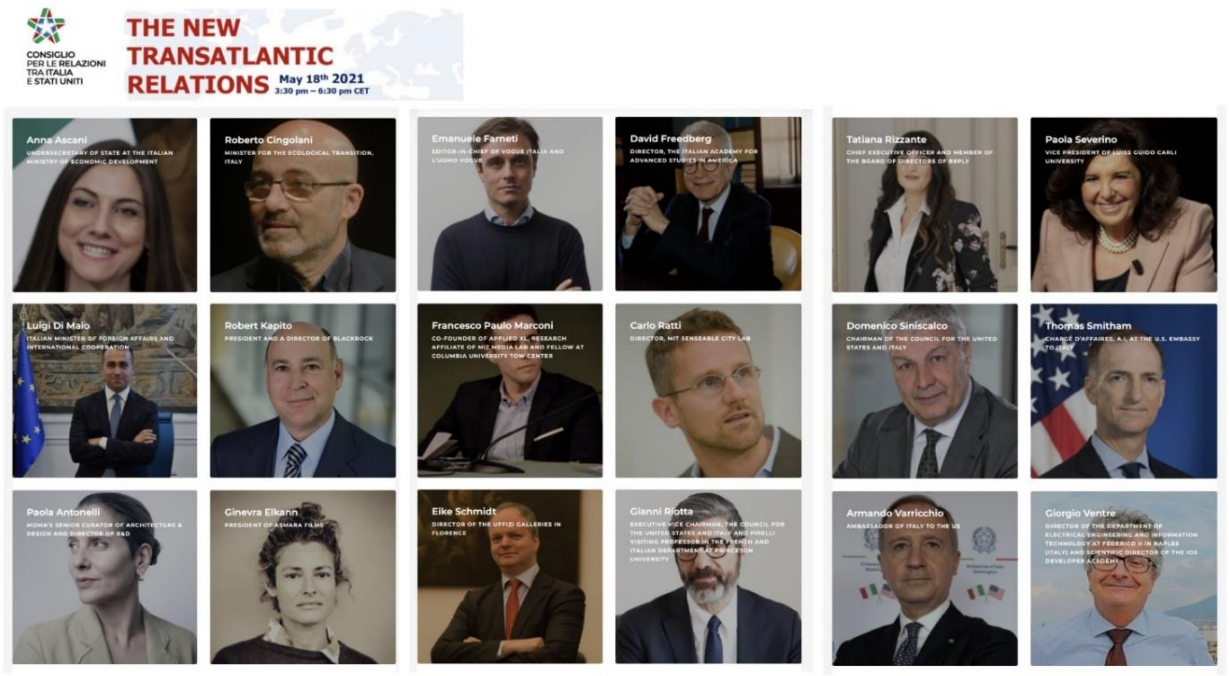
Secondly, ideas, institutions, realities and practices that were considered permanent have proven to be transitory, and vice versa: for example, democracy in the United States was believed to be the strongest in the world, but it is now under debate whether it will survive over the next decades. In contrast, elements that were deemed transitory are now here to stay such as remote work and telemedicine.

Finally, it was clear that change was happening at a speed rate, but it is now under acceleration: experts, organizations, governments identify the trend, determine its direction of evolution and try to predict the timeframe. It turns out that the actual transformation occurs faster than expected, as it happened with climate change.

However, the reactions of governments to these changes are lagging behind: while decarbonization processes, artificial intelligence and digital innovations occur, the gap between science and politics broadens. The acceleration of changes is expanding this gap.

Our times are seeing a change in the most consequential price: it used to be gold, then oil, commodities and now interest rates. The era of easy, accessible and cheap money is booming, but it is unsustainable in the long term: in order to avoid inflation, an exit strategy needs to be devised and put in place.

DIGITAL WORKSHOP | The new Transatlantic relations| May 18 @ 3.30pm



The Council of the United States and Italy organized in collaboration with the Italian Embassy in Washington a Digital Workshop titled "The new Transatlantic relations" on May 18th, 2021 with a digital format. The Workshop explored the future of artificial intelligence, culture as a development driver and new scenarios for economic and financial recovery in the post Covid-19 era.

After introductory remarks by **Domenico Siniscalco** *(Vice Chairman, Morgan Stanley and President of The Council for the US and Italy*), **Armando Varricchio** (*Ambassador of Italy to the United States*) and **Thomas Smitham** (*Chargé d'Affaires, United States Embassy to Italy*), the first panel analyzed artificial intelligence and its future. Under the moderation of **Gianni Riotta** (*Executive Vice Chairman, Council for the United States and Italy),* high-level experts on the topic provided their unique observations on the future of technology and artificial intelligence that will impact people, society, government and business. Thanks to **Anna Ascani** (*Italian Undersecretary, Ministry of Economic Development*), **Francesco Marconi** (*Computational journalist; Co-founder, Applied XL*), **Tatiana Rizzante** (*Ceo, Reply*), **Giorgio Ventre** (*Director, Apple Academy*) and **Paola Severino** (*Vice President, Luiss Guido Carli University*) for their precious contributions on the challenges and responsibilities of the technological world for an equitable and sustainable growth.

The second sessions investigated culture as a driver for development, reflecting on the role of artistic and cultural heritage of Italy and the United States. Culture can be elevated as a key-factor in the future competitiveness model of the two countries and in the fight against the current crisis. The moderator **Emanuele Farneti** (*Editor-in-Chief, Vogue Italy, L'Uomo Vogue, AD*) directed the exchange of views of our guest speakers **Ginevra Elkann** (*Film Producer and Director; President, Fondazione Pinacoteca Agnelli*), **David Freedberg** (*Pierre Matisse Professor of the History of Art at Columbia University and Director of the Italian Academy for Advanced Studies in America*), **Carlo Ratti** (*Director, MIT SENSEable City Lab*), **Paola Antonelli** (*MoMA's Senior Curator of Architecture & Design; Director of R&D)* and **Eike Schmidt** (*Director, Galleria Uffizi*).

Finally, **Robert Kapito** (*President, BlackRock*) and **Roberto Cingolani** (*Italian Minister for Ecological Transition*) participated in an open discussion on the way forward after Covid-19 that needs to bring innovation, resilience and environmental issues to the center of discussion. The new commitment towards sustainable growth is a challenge but mostly a precious opportunity for the years ahead.

In the closure of the Workshop, **Luigi Di Maio** (*Italian Minister of Foreign Affairs and International Cooperation*) reflected on the long-standing friendship and mutual trust between Italy and the United States thanks to shared principles and joint cooperation. Renewed and enhanced Transatlantic relations are key for the stability and the prosperity of the two countries and the world.

PROJECT SYNDICATE

Thanks to the collaboration with Project Syndicate all Members of the Council for the United States and Italy have unlimited access to the original contents of the platform.

EUROPE'S FUTURE

Margrethe Vestager *(Executive Vice-President of the European Commission for a Europe Fit for the Digital Age, and EU Commissioner for Competition)*

In recent years, the European Union has unveiled a series of ambitious legislative and regulatory packages to rein in problems endemic to the new digital economy. Can leading the world in tech governance help to establish Europe's place in the twenty-first century?

Recently, **Anu Bradford**, a professor at Columbia Law School and the author of The Brussels Effect: How the European Union Rules the World, sat down with European Commission Executive Vice-President Margrethe Vestager, one of the European Union's leading regulatory and economic-policy minds, to discuss key developments and trends in the digital economy. From privacy protection and antitrust action to online speech regulation and innovation policy, what happens in Europe's digital economy will have profound and far-reaching implications for the rest of the world in the years ahead.

Most of the Big Tech companies have been in the news lately. Let's start with Apple. The European Commission recently issued a statement saying that the company has abused its dominant position in the music streaming industry. This is one of several competition cases that you have brought against big American tech companies, including Google and Amazon. What, exactly, is your main concern with how Big Tech operates? Consumers love and depend on these companies' products, after all, and that reliance has grown during the pandemic. What is the concrete harm that an individual consumer experiences, and what would a more competitive marketplace look like?

A competitive marketplace, first of all, is an open marketplace where someone who wants to invest and innovate can do so. Recall the EU's first action against Google in 2010, over its Google Shopping service. In that case, there was little reason for a new market entrant to invest in its own shopping-comparison technology, because the services being provided never would have reached customers, owing to Google's control of search. The reference point for our policy is to embrace technology and innovation so that customers actually get more out of it. This is one reason why we have called in the cavalry with the Digital Markets Act (DMA), which the European Commission proposed this past December. We need to prevent what led to the Google Shopping case from happening again.

With respect to Apple, we have suspicions – and have concluded preliminarily – that the company is misusing its dominant position by way of its App Store. An iPhone user has nowhere else to go for applications. I live in Belgium, so if I am unhappy with Delhaize supermarkets, I can go to Carrefour (another supermarket chain). But if I buy an iPhone, I am locked into one app store. If we think of a digital app store as a supermarket, that lock-in seems really strange. When the DMA takes effect, these users can have other app stores on their phones.

The DMA is partly motivated by a recognition that the current toolkit for bringing cases against the Big Tech companies is not enough. You have fined Google around $10 billion, but those penalties haven't produced a competitive marketplace in internet search. How confident are you that the DMA will change that?

We think that it will make a real difference. In Europe, we have no ban on monopoly; what we ban is monopolistic behavior. A company is more than welcome to be successful and grow large in the EU. But with power comes responsibility. Under the DMA, a company that has been designated a gatekeeper will have a number of obligations, and will be subject to a number of prohibitions. These conditions will open up the marketplace.

It is important to remember that this is a special marketplace, because it is digital. We must account for features such as network effects, marginal costs approaching zero, markets in which users pay with their data, rather than with money. In my view, this is a market where you can have both giant gatekeepers and a vibrant ecosystem for entrepreneurship and innovation. As matters stand, however, there are a number of areas where we do not see the innovative responses that one would have expected. Take privacy. In a competitive market, you would expect there to be many more services meeting this basic consumer demand with privacy protections built in as the default.

You point to the intersection between privacy and competition law. Apple recently made waves with the release of a new anti-tracking feature on its devices. Many privacy advocates welcome the fact that the company seems to be innovating toward a value that we all consider to be important. But others see the move as an example of Apple entrenching its dominant position and curtailing competition. Other companies – especially Facebook – are seen to be the big losers. Were you delighted with this new feature, or do you have some concerns?

I was very positively surprised when I saw it. The feature is simple. Most people will understand what they're being asked when prompted with the question of whether they want a given app to track them even when they're not using it. This is an important lesson that we're still learning when it comes to enforcing privacy rights: we need to make it simple. Here, the only concern is that it should also apply to Apple itself. From my understanding so far, Apple claims that this is indeed the case. Equal treatment between different apps is important. But Apple has provided a push in favor of business models that rely on the provision of an actual service, not just the harvesting of data. With informed consent, users can make decisions about what they want to pay – in their own data – for these services.

DOING BUSINESS IN EUROPE

When we talk about Big Tech, we're almost always referring to American companies. As such, some in the United States have come to regard the EU's actions as a form of protectionism, driven by envy. How do you respond to this criticism?

Looking at the facts of the cases and the markets, it's really quite difficult to find any support for this "envy theory." After all, the first case – against Google Shopping – started with a complaint by US companies, many of which found that they could not do the business that they wanted to do in the EU market. Moreover, if you look at how many European businesses have been bought by tech giants over the last couple of years, you realize that – wow – they're coming to Europe for the innovation that is happening here. So, why are there no European giants in the business-to-consumer segment of the digital economy? One reason is that we have lacked the digital single market and the capital market needed to enable that kind of scaling up. We have been doing our best to correct both shortcomings, and these efforts will pave the way for the second phase of digitalization – industrial digitalization –which will center on health, energy, transportation, farming, and public services, where European markets are quite robust. There is already a lot of demand for innovation here, so it will be interesting to see how Europe fares.

But when foreign companies go shopping in Europe, they are sometimes backed by state subsidies, raising concerns about the integrity of the single market and the levelness of the playing field. To mitigate this, the European Commission recently unveiled a proposal to regulate foreign subsidies that support foreign companies operating in the EU, or even finance their acquisitions of European companies. What concrete impact do you expect from this regulation?

What we want to achieve is fairness. The EU has been controlling state aid for 60 years so that such aid doesn't lead to an uneven playing field or affect trade. This is something that European businesses live with. But there is a problem when they have competitors who can acquire European businesses or win a tender with help from a foreign state subsidy, or even rely on state subsidies to cover their operating costs. That is not fair competition. What we are proposing is simply a tool that will allow us to look at these issues, to say, "You must notify us if you have a subsidy on your books when seeking to acquire a European company or participate in a European tender process." If someone fails to do that, we should have the power to say, "If we receive the market information, if someone complains, if we think something is wrong here, we can investigate." And because it is not always easy to gain a party's cooperation, we are suggesting that we should be able to make a decision based on whatever information we have. That way, the parties in question have an incentive to give us more information, so that we can weigh all of the evidence about a given subsidy's effect. The hope is that this will create a deterrent. The best possible outcome is that when companies come here to do business, it is because they really want to do business, rather than to advance some other agenda.

We know that many Chinese companies are likely to be affected by this regulation. Have you heard any reactions from the Chinese government?

No, we have not. But it is also important to say that this is about ensuring fairness in the European marketplace. Many features of the proposal mirror our own thinking about state-aid controls on European member states. One hopes that people will see that the proposal is proportionate and balanced.

AUTONOMY AND SOVEREIGNTY

This discussion points to a broader concept that is becoming a buzzword nowadays: the idea of European strategic autonomy and digital sovereignty. There's a lot of debate about what these terms even mean. How would you define them? What would it mean for the EU to be digitally sovereign, and is that a feasible policy goal?

At the risk of complicating matters, we actually would call it "open strategic autonomy." One thing we have learned over the decades is that a big part of Europe's strength comes from its openness. Europe is a preferred trading partner for 74 countries. We work with people from all over the planet in business, research, innovation, and many other areas. But the world is changing. With new geopolitical patterns emerging, we must find the best ways to keep serving European interests. Usually, this is done in a global or multilateral manner. For example, it is in Europe's interest to have a World Trade Organization that works properly, and to maintain firm alliances within the International Telecommunication Union. In other areas, however, our interests are closer to home. For example, only 10% of all semiconductors are currently produced in Europe, and we want to increase that figure to 20% (of the most advanced kind) over the next ten years. Open strategic autonomy is not about doing everything yourself; but it is about doing more. Europe is a massive machine to regulate, so it is important to have the necessary hands-on experience to know what it is you're regulating. That is what I think of as digital sovereignty. But it is important that we put more muscle on the bones of this concept. It cannot remain a high-level, abstract debate indefinitely. What matters is what we do in a tangible sense, whether it be setting targets on advanced semiconductors, building our network of high-performance computers, or launching at least one quantum computer within the next five years.

Another critical area of innovation is artificial intelligence, which will be essential to Europe's pursuit of digital sovereignty and economic prosperity. Here, too, the EU has proposed a pathbreaking regulation, the Artificial Intelligence Act, both to encourage the uptake of AI and to protect European consumers and citizens against its attendant risks. Is this regulation striking the right balance between innovation and precaution? More broadly, how do you think about the relationship between innovation and regulation?

It may sound strange, but the point of the regulation is to embrace AI fully. That is how you ensure that customers feel safe and that those deploying the technology feel comfortable in the regulatory environment. The Artificial Intelligence Act embodies a pyramid metaphor. At the bottom, there are a lot of things left untouched by the regulation. At the next level – a website chatbot, for example – the only requirement is that the interaction be transparent: people should know they're interacting with digital code. It gets a bit trickier when you get closer to the top of the pyramid, because that is where one finds technologies that could pose a risk to our fundamental values. There have already been cases where AI used by social services or law enforcement has been shown to be biased. When it comes to social affairs, you want to be seen as who you are, not merely as an iteration of a particular gender, race, or social background. So, the regulation requires that the AIs used in decisions about hiring, mortgages, and so forth be built on a foundation of high-quality data. The decisions need to be explainable. There must be a human in the loop, and the most stringent cybersecurity measures need to be in place. By ensuring a basic level of trust, the regulation should be an enabling factor for the market. People should be able to say, "We want to use this service because we can be confident that the fundamentals are taken care of."
At the very tip-top of the pyramid are cases where we would simply say, "This cannot be. This goes against our values." Here, I'm thinking of things like remote biometric identification in public spaces, with governments devising social scoring for individuals. This should be prohibited, perhaps with the exception of using remote biometric identification for a limited time to prevent an imminent terrorist attack or to find a missing child. Again, the point here is to enable the best uses of the technology. To do that, we need to focus on specific cases and the associated risks to ensure that we are being proportional. We should be mindful of all the amazing things that AI is already helping us do and will help us do in the future. We should enable innovation for these uses, and the regulation helps to do this by creating the trust needed to open the market. A completely unregulated environment for AI is not what gives us the best innovation. We also must open up financing of AI. Following up to the regulatory proposal, we have also issued a new coordinated plan for AI investment, so that more money can be deployed for innovation in this domain.

THE SPEECH WARS

AI also powers the algorithms on social-media platforms, determining which speech is amplified and which silenced. The EU's recently proposed Digital Services Act (DSA) seems aimed at introducing more transparency and accountability here. Will it establish democratic oversight over online speech? Who, in your view, should be deciding which speech is harmful and which is permitted?

That decision is for EU member states. The DSA is not about content; it's about the processes needed to ensure that digital services work in a way that supports decisions made in our democracies about what is legal or illegal. Different member states will make different decisions concerning hate speech. Some will be very strict, others less so, depending on a number of factors such as cultural issues and how a country conducts its public discourse. Comparing just the Danes and the Swedes, we would expect two very different approaches. The DSA will ask two things of platforms. First, they will have to set up a mechanism for users to complain or seek redress if their posts or entire profiles are removed. That way, these decisions will not feel so one-sided. Second, the DSA will require general risk assessments. Tech companies will need to ask themselves whether their platforms will invite threats to democracy, and what they can do to mitigate those risks.

Remember, social media can be a great enabler of democracy; but it can also be the opposite. I work with a program to help more women engage in politics, and a recurring issue that we face is online hate speech and harassment that is clearly aimed at discouraging women's participation. At the same time, these platforms create opportunities for people to voice their ideas and interact with others. Ultimately, I think that full democracy will have a physical side and a virtual side. We need to ensure that the virtual side is enhancing our democracy, not undermining it.

One of the hardest questions is where to draw the line between robust freedom of speech and curtailing the kind of hate speech that undermines dignity and democracy itself. In the US, where people have traditionally embraced a very broad notion of freedom of speech, many are growing uncomfortable with the lack of speech boundaries online. But at the same time, there are strong objections to the idea of the government or a private corporation regulating speech. One experimental solution, Facebook's so-called supreme court – an independent oversight board – has been in the news lately. What are your views on this version of democratic oversight? Does this approach meet your criteria of transparency and accountability?

I think it's a good idea. Part of being a responsible business is setting up your own mechanisms for accountability and transparency. But it's not necessarily enough, either for transparency or from the standpoint of protecting the public interest. You will have your user terms and conditions, but then you will also have your approach to engaging with the wider society. My guess is that there will usually be a large degree of overlap between the two. But it is important to have transparency so that we can keep discussing issues in the gray zone – such as speech that is harmful but not illegal. This is not a discussion that can be finalized once and for all. That is why we need processes for maintaining transparency, and these processes must be anchored in a legal framework that applies the same rules to everyone. So, no, we cannot rely just on individual business. Even though I think Facebook has improved – a lot of obviously illegal things are now being taken down – I also think these processes should be anchored in legislation that is created, debated, and adopted by our elected representatives.

THE BRUSSELS EFFECT

The Big Tech firms are being regulated by several jurisdictions; but the EU has been most vigorous in developing new legal frameworks, and these have proven to have a wide global reach – what I call the "Brussels effect." A prime example is Europe's General Data Protection Regulation. Companies have complied with the GDPR across their global operations, because doing so is easier and less expensive than maintaining different practices in different countries. Similarly, norms on hate speech have emerged through various codes of conduct that these companies negotiated with the EU. And many other governments have used EU law as a template for their own regulatory regimes. So, I'm curious whether you have global consumers in mind when you are drafting regulations. And what is the advantage for the EU when EU law gets replicated across the global marketplace?

I think you are right about the "Brussels effect." Europe was way ahead of the curve when it passed the GDPR. Many others are now starting to catch up with legislation that is similar, though not exactly the same. I think India is the latest example, along with a number of US states. When we draft legislation for Europe, what we try to do is to make our values a real thing in everyday life. But our values are not just European. I think we share something fundamental with most democracies when it comes to respecting the integrity and the dignity of each individual. That's not just a European notion. It's also an American, Japanese, and South African notion. I think that is why our legislation inspires others, and I hope it continues to do so, because we need the world's democracies to come together. We will not have a global DSA or DMA. But maybe we will have a legal alignment and a shared mindset. Over the last couple of years, more and more people, and more and more jurisdictions, have started to think along the same lines about these issues. That is a dramatic change. The task now is to figure out how to translate that shared mindset into legislative frameworks. Of course, I hope that Europe can inspire here, too. But I'm also humbled by the fact that others are following the same path not necessarily because ours is the best way of doing things, but because it reflects a fundamental impulse of democracy. Again, we need democracies to come together. There is an emerging systemic rivalry between democracies and non-democracies. I think that we in the EU should show that democracies can deliver for people in everyday life.

Of course, under former US President Donald Trump, there was a deep transatlantic divide on many policy issues, including those concerning the digital economy. There was a lot of talk about not seeing eye to eye on regulation, data flows, digital taxes, or antitrust. Some of these differences remain quite entrenched. Nonetheless, many would say that the US is now moving closer to the European position. The US Federal Trade Commission and Department of Justice have begun to pursue antitrust action against some of the big digital companies. In a tweet, Jake Sullivan, US President Joe Biden's national security adviser, welcomed the EU's AI regulation and affirmed America's willingness to work with other likeminded countries in regulating these technologies. Finally, we are also seeing potential progress in digital-services taxation, with the US exploring avenues for global cooperation on corporate taxes more generally. Given these developments, are you optimistic for a return to closer transatlantic alignment?

Well, I'm an optimist, whether it is by nature or by choice, because I find that pessimists never get anything done. Why would they, if they assume things will be worse tomorrow? But mine isn't optimism for its own sake. It reflects the facts. Major changes are underway within the US and in terms of geopolitics. I am encouraged by the fact that in discussions about taxation, antitrust, and privacy, we are already in a very different place than we were a few years ago. That doesn't mean we will agree on everything. But we are paving the way to something really fundamental: democracies working together. Consider a small but illustrative example of why it matters so much in today's systemic rivalry that democracies can form a united front. Last year at the International Telecommunication Union, China advanced a proposal that would basically have turned the architecture of the internet upside down, making it far more centralized and controllable by governments. A number of democracies came together to reject this proposal, and we should be glad they did. But constant vigilance will be needed to ward off these threats to the system, and to show that democracies need other democracies in order to deliver for their citizens.

THE NEXT CHAPTER

Let's put your optimism to test. Building on the idea of the EU as a global regulatory superpower, can Europe also become a technology power? When will we see a European tech giant to rival the likes of Google, Amazon, Apple, Facebook, and Microsoft? What will it take?

I mentioned earlier that we are starting the second chapter of digitalization. The past ten years were about business-to-consumer growth. Next will be industrial digitalization of health, transport, energy, farming, and public services. Public goods and services are Europe's strong suits. Our highly advanced energy systems are undergoing the transition to renewables, and we are equally advanced in farming.
There is very strong demand for technological solutions that will enable these sectors to develop and transform themselves dramatically in the coming years. Europe has the industrial and entrepreneurial culture to drive this era of digitalization. To handle all of the data that is now being generated, new types of digital companies will emerge. But many will be business-to-business, so you won't necessarily hear about them as much as you hear about the services you use on your smartphone every day. Nonetheless, business is fundamental to how our society works, and the digitization of industries will be especially exciting in the European context. There are so many things that we simply cannot do without digital technologies. For example, it's probably not even possible to fight climate change without digital tools. I think the latest estimates suggest that 20% of emissions can be dealt with over the next ten years using digital means.

So, what do you expect the world to look like in ten years? That's a long time in the digital economy. Will European values ultimately prevail, leaving us with a more human-centric, fair, inclusive, and democratic digital economy?

I always fear this kind of question. So much has happened in the last ten years, and the only thing I see as a fil rouge – a red thread running through it – is a struggle to make our societies more inclusive. The 2008 financial crisis was awful in many respects, but one of the worst parts was people getting laid off and feeling like they had been fired not just from a job but from their society. Many had nowhere to go, and we have been dealing with the legacy of this ever since. I just got back from the Portuguese-hosted Porto Social Summit, where I saw European heads of state and government, employers, union leaders, and civil-society groups coming together to recognize the need for an inclusive society that is not detrimental to growth. Witnessing that, I think many things will be quite different in ten years, and that we will have made progress in helping everyone feel more of a sense of belonging in society.

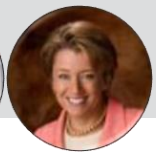
What is the most important legacy that you want to leave behind as the most powerful regulator of the technology industry?

What gets me out of bed every morning is the work of pushing for each and every one of us to see that we have choices, and that our choices make a difference. I find that recognition to be really empowering. Everyone should be able to feel that what they do makes a difference, and this is especially true in the marketplace. When you have an open, contestable marketplace, consumers and citizens have choices and can make a difference.
Likewise, in a democracy, individual contributions can make a difference. For me, it is this act of empowering and enabling that drives what I do, and determines what I would like to achieve. With digitalization, we may finally be able to fulfil some of the promises that we have been hearing for decades when it comes to health, education, and other issues. That would be my humble wish.

SPEED THE JAB

Even as many rich countries free themselves from the pandemic's grip, COVID-19 cases and deaths are surging in several regions, enabling dangerous new variants to emerge. Only universal immunization can end the cycle of misery – but achieving it will require more than a temporary waiver of vaccine manufacturers' intellectual-property rights.

WILL CORPORATE GREED PROLONG THE PANDEMIC

Joseph E. Stiglitz (*Nobel laureate in economics and professor at Columbia University*)
Lori Wallach (*Director of Public Citizen's Global Trade Watch*)

The shortfall in global COVID-19 vaccine production could be closed if manufacturers around the world were granted access to the necessary technology and knowledge. But first, the US and other key governments must recognize the drug companies' opposition to this solution for the deadly rent-seeking that it is.

NEW YORK – The only way to end the COVID-19 pandemic is to immunize enough people worldwide. The slogan "no one is safe until we are all safe" captures the epidemiological reality we face. Outbreaks anywhere could spawn a SARS-CoV-2 variant that is resistant to vaccines, forcing us all back into some form of lockdown. Given the emergence of worrisome new mutations in India, Brazil, South Africa, the United Kingdom, and elsewhere, this is no mere theoretical threat.

Worse, vaccine production is currently nowhere close to delivering the 10-15 billion doses needed to stop the spread of the virus. By the end of April, only 1.2 billion doses had been produced worldwide. At this rate, hundreds of millions of people in developing countries will remain unimmunized at least until 2023.

It is thus big news that US President Joe Biden's administration has announced it will join the 100 other countries seeking a COVID-19 emergency waiver of the World Trade Organization intellectual-property (IP) rules that have been enabling vaccine monopolization. Timely negotiations of a WTO agreement temporarily removing these barriers would create the legal certainty governments and manufacturers around the world need to scale up production of vaccines, treatments, and diagnostics. Last fall, former President Donald Trump recruited a handful of rich-country allies to block any such waiver negotiations. But pressure on the Biden administration to reverse this self-defeating blockade has been growing, garnering the support of 200 Nobel laureates and former heads of state and government (including many prominent neoliberal figures), 110 members of the US House of Representatives, ten US Senators, 400 US civil-society groups, 400 European parliamentarians, and many others.

AN UNNECESSARY PROBLEM

The scarcity of COVID-19 vaccines across the developing world is largely the result of efforts by vaccine manufacturers to maintain their monopoly control and profits. Pfizer and Moderna, the makers of the extremely effective mRNA vaccines, have refused or failed to respond to numerous requests by qualified pharmaceutical manufacturers seeking to produce their vaccines. And not one vaccine originator has shared its technologies with poor countries through the World Health Organization's voluntary COVID-19 Technology Access Pool.

Recent company pledges to give vaccine doses to the COVID-19 Vaccines Global Access (COVAX) facility, which will direct them to the most at-risk populations in poorer countries, are no substitute. These promises may assuage drug companies' guilt, but won't add meaningfully to the global supply.

As for-profit entities, pharmaceutical corporations are focused primarily on earnings, not global health. Their goal is simple: to maintain as much market power as they can for as long as possible in order to maximize profits. Under these circumstances, it is incumbent on governments to intervene more directly in solving the vaccine supply problem.

A COMMONSENSE SOLUTION

In recent weeks, legions of pharmaceutical lobbyists have swarmed Washington to pressure political leaders to block the WTO COVID-19 waiver. If only the industry was as committed to producing more vaccine doses as it is to producing specious arguments, the supply problem might already have been solved.

Instead, drug companies have been relying on a number of contradictory claims. They insist that a waiver is not needed, because the existing WTO framework is flexible enough to allow for access to technology. They also argue that a waiver would be ineffective, because manufacturers in developing countries lack the wherewithal to produce the vaccine.

And yet, drug companies also imply that a WTO waiver would be too effective. What else are we to make of their warnings that it would undermine research incentives, reduce Western companies' profits, and – when all other claims fail – that it would help China and Russia beat the West geopolitically? Obviously, a waiver would make a real difference. That is why drug companies are opposing it so vehemently. Moreover, the "market" confirms this thinking, as evidenced by the sharp decline in the major vaccine-makers' share prices just after the Biden administration's announcement that it will engage in waiver negotiations. With a waiver, more vaccines will come online, prices will fall, and so too will profits. Still, the industry claims that a waiver would set a terrible precedent, so it is worth considering each of its claims in turn.

BIG PHARMA'S BIG LIES

After years of passionate campaigning and millions of deaths in the HIV/AIDS epidemic, WTO countries agreed on the need for compulsory IP licensing (when governments allow domestic firms to produce a patented pharmaceutical product without the patent owner's consent) to ensure access to medicines. But drug companies never gave up on doing everything possible to undermine this principle. It is partly because of the pharmaceutical industry's tight-fistedness that we need a waiver in the first place. Had the prevailing pharmaceutical IP regime been more accommodating, the production of vaccines and therapeutics already would have been ramped up.

The argument that developing countries lack the skills to manufacture COVID vaccines based on new technologies is bogus. When US and European vaccine makers have agreed to partnerships with foreign producers, like the Serum Institute of India (the world's largest vaccine producer) and Aspen Pharmacare in South Africa, these organizations have had no notable manufacturing problems. There are many more firms and organizations around the world with the same potential to help boost the vaccine supply; they just need access to the technology and know-how.

For its part, the Coalition for Epidemic Preparedness Innovations has identified some 250 companies that could manufacture vaccines. As South Africa's delegate at the WTO recently noted:

"Developing countries have advanced scientific and technical capacities… the shortage of production and supply [of vaccines] is caused by the rights holders themselves who enter into restrictive agreements that serve their own narrow monopolistic purposes putting profits before life."

While it may have been difficult and expensive to develop the mRNA vaccine technology, that doesn't mean production of the actual shots is out of reach for other companies around the world. Moderna's own former director of chemistry, Suhaib Siddiqi, has argued that with enough sharing of technology and know-how, many modern factories should be able to start manufacturing mRNA vaccines within three or four months.

Drug companies' fallback position is to claim that a waiver is not needed in light of existing WTO "flexibilities." They point out that firms in developing countries have not sought compulsory licenses, as if to suggest that they are merely grandstanding. But this supposed lack of interest reflects the fact that Western pharmaceutical companies have done everything they can to create legal thickets of patents, copyrights, and proprietary industrial design and trade secret "exclusivities" that existing flexibilities may never cover. Because mRNA vaccines have more than 100 components worldwide, many with some form of IP protection, coordinating compulsory licenses between countries for this supply chain is almost impossible.

Moreover, under WTO rules, compulsory licensing for export is even more complex, even though this trade is absolutely essential for increasing the global vaccine supply. The Canadian drug maker Biolyse, for example, is not permitted to produce and export generic versions of the Johnson & Johnson vaccine to developing countries after J&J rejected its request for a voluntary license.

Another factor in the vaccine supply shortage is fear, both at the corporate and the national level. Many countries worry that the United States and the European Union would cut off aid or impose sanctions if they issued compulsory licenses after decades of threats to do so. With a WTO waiver, however, these governments and companies would be insulated from corporate lawsuits, injunctions, and other challenges.

THE PEOPLE'S VACCINES

This brings us to the third argument that the big pharmaceutical companies make: that an IP waiver would reduce profits and discourage future research and development. Like the previous two claims, this one is patently false. A WTO waiver would not abolish national legal requirements that IP holders be paid royalties or other forms of compensation. But by removing the monopolists' option of simply blocking more production, a waiver would increase incentives for pharmaceutical companies to enter into voluntary arrangements. Hence, even with a WTO waiver, the vaccine makers stand to make heaps of money. COVID-19 vaccine revenue for Pfizer and Moderna just in 2021 is projected to reach $15 billion and $18.4 billion, respectively, even though governments financed much of the basic research and provided substantial upfront funds to bring the vaccines to market. To be clear: The problem for the pharmaceutical industry is not that drug manufacturers will be deprived of high returns on their investments; it is that they will miss out on monopoly profits, including those from future annual booster shots that doubtless will be sold at high prices in rich countries.

Finally, when all of its other claims fall through, the industry's last resort is to argue that a waiver would help China and Russia gain access to a US technology. But this is a canard, because the vaccines are not a US creation in the first place. Cross-country collaborative research into mRNA and its medical applications has been underway for decades. The Hungarian scientist Katalin Karikó made the initial breakthrough in 1978, and the work has been ongoing ever since in Turkey, Thailand, South Africa, India, Brazil, Argentina, Malaysia, Bangladesh, and other countries, including the US National Institutes of Health.
Moreover, the genie is already out of the bottle. The mRNA technology in the Pfizer-produced vaccine is owned by BioNTech (a German company founded by a Turkish immigrant and his wife), which has already granted the Chinese producer Fosun Pharma a license to manufacture its vaccine. While there are genuine examples of Chinese firms stealing valuable IP, this isn't one of them. Besides, China is well on its way to developing and producing its own mRNA vaccines. One is in Phase III clinical trials; another can be stored at refrigerator temperature, eliminating the need for cold chain management.

HOW THE US COULD REALLY LOSE

For those focused on geopolitical issues, the bigger source of concern should be America's failure to date to engage in constructive COVID-19 diplomacy. The US has been blocking exports of vaccines that it is not even using. Only when a second wave of infections started devastating India did it see fit to release its unused AstraZeneca doses. Meanwhile, Russia and China have not only made their vaccines available; they have engaged in significant technology and knowledge transfer, forging partnerships around the world, and helping to speed up the global vaccination effort.
With daily infections continuing to reach new highs in some parts of the world, the chance of dangerous new variants emerging poses a growing risk to us all. The world will remember which countries helped, and which countries threw up hurdles, during this critical moment.
The COVID-19 vaccines have been developed by scientists from all over the world, thanks to basic science supported by numerous governments. It is only proper that the people of the world should reap the benefits. This is a matter of morality and self-interest. We must not let drug companies put profits ahead of lives.

NEXT STEPS FOR PEOPLE'S VACCINES

Jayati Ghosh (*Executive Secretary of International Development Economics Associates and professor of Economics at the University of Massachusetts Amherst)*

The Biden administration's decision to stop opposing a proposed COVID-19 waiver of certain intellectual-property rights under World Trade Organization rules is a welcome move. But ending the pandemic also requires scaling up knowledge and technology transfer, as well as public production of vaccine supplies.

NEW DELHI – The Biden administration's decision to stop opposing a proposed COVID-19 waiver of certain intellectual-property rights under World Trade Organization rules is a welcome move. The US Trade Representative acknowledges that "the extraordinary circumstances of the COVID-19 pandemic call for extraordinary measures." While affirming that it "believes strongly in intellectual property protections," the Biden administration, "in service of ending this pandemic, supports the waiver of those protections for COVID-19 vaccines." Already, the US decision may be persuading other rich-country holdouts in Europe and elsewhere to follow suit.
While the rapid development of COVID-19 vaccines was a truly impressive achievement, it has been tarnished by constraints on global vaccine supply and the related inequities in distribution. As of May 4, less than 8% of the world's population had received even one dose of any COVID-19 vaccine, while just ten rich countries accounted for 80% of all vaccinations. The reason is not just that rich countries have been buying up all available doses; it is also that there simply have not been enough doses to go around. But this scarcity itself is largely artificial. Vaccine production has been limited by pharmaceutical companies' refusal to share knowledge and technology. Though the companies producing the approved vaccines have benefited from public subsidies and publicly funded research, they nonetheless have taken advantage of patent protections to maintain a monopoly, limiting production to their own factories and a select few other companies to whom they have granted licenses. These patents are enshrined and enforced internationally through the WTO's Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), which allows for action to be taken against countries that provide compulsory licenses allowing "someone else to produce a patented product or process without the consent of the patent owner." It is this threat of legal action that led a majority of WTO members to propose a temporary waiver for COVID-19 drugs, vaccines, diagnostics, and other technologies needed to fight the pandemic. And yet, even this minor step has been blocked in the WTO TRIPS Council, because (mostly) rich countries have been prioritizing pharma companies' interests over global health.

A waiver has become all the more urgent with the coronavirus on the rampage across South America and India, where a near-complete breakdown of overstretched health services is resulting in a catastrophic loss of life. Worse, the rapid spread of the virus has already given rise to dangerous new variants. We absolutely must vaccinate as many people as possible before vaccine-resistant variants emerge.

Temporarily waiving IP rights is essential, but it is only the first step. A waiver agreement would address the previously insurmountable legal side of the problem. But much more will need to be done to make a "People's Vaccine" universally available as soon as possible.

The next step is to push for concrete measures to facilitate the transfer of knowledge and technology. From Canada to Bangladesh, many potential vaccine producers with the required facilities have so far been denied the licenses and technical know-how to proceed. Not a single pharmaceutical company has joined the World Health Organization's voluntary facility for sharing technology, the COVID-19 Technology Access Pool (C-TAP).

Governments in the United States, Europe, and elsewhere, having given large subsidies to develop the approved vaccines, can and should pressure the companies to share the knowledge that public money helped provide. We know this can be done, because the Biden administration has already persuaded Johnson & Johnson to share its technology with Merck to boost domestic production of its single-dose vaccine. Surely the other companies that have benefited from public support could be pressured to do the same with producers around the world.

In the meantime, the TRIPS waiver could increase vaccine production in other ways as well. Moderna, which relied almost completely on US government funding, has already declared that it will not enforce its patent. But its mRNA vaccine uses some knowledge that it has licensed (and paid for) from other companies, which could in turn sue any other producer using the same technology.

The TRIPS waiver would eliminate this possibility, allowing production to be scaled up rapidly. With Moderna now indicating that it will produce three billion doses in 2022 alone, the mRNA vaccines are apparently quite amenable to expanded production. They are also said to be easily adapted to account for new variants.

The case for public production of such vaccines is clear. "For less than the US government spends on the COVID-19 response daily," notes the health advocacy organization PrEP4All, "it can build a facility to produce enough mRNA vaccine manufacturing capacity to vaccinate the entire world in one year, with each dose costing only $2."

The case for public production becomes even stronger when one considers that private vaccine producers have little financial incentive to meet current global needs. Once the pandemic is contained, the demand for vaccines is likely to revert to much lower "normal" levels. To win the race against the virus, we must build and deploy public manufacturing capacities in the US and other countries. And when COVID-19 is brought to heel, these facilities should be maintained for future pandemics.

The world desperately needs the TRIPS waiver and stronger measures to ensure the transfer of knowledge and technology to produce COVID-19 vaccines. But we also need to start preparing for equally exceptional circumstances in the future. The knowledge on which our health and prosperity depend must be both publicly funded and publicly disseminated.

FORGET THE VACCINE PATENT WAIVER

Pinelopi Koujianou Goldberg *(Professor of Economics at Yale University and former World Bank Group chief economist)*

While momentum builds behind a proposal to waive patents on COVID-19 vaccines, removing intellectual property protection would not accelerate the global immunization effort. The sooner the world recognizes that production capacity is not the problem, the better.

NEW HAVEN – The surge of COVID-19 cases and deaths in India shows that the pandemic is far from over. While most developing countries in Asia and Africa managed to keep their death tolls low over the past year, it is only a matter of time before the new, more contagious variants that have emerged in India and elsewhere spread to countries that seemed to have their infections under control. Absent a miracle – such as a mutation that renders the virus less lethal – only universal vaccination can end this cycle of misery.

With that goal in mind, a global movement has emerged to demand a World Trade Organization waiver of patent protections for COVID-19 vaccines (as well as treatments and diagnostics). But patent protections are not the primary cause of the vaccine-supply bottleneck. If anything, a waiver might divert scarce materials from vaccine production facilities that are already up and running, not to mention discourage investments in pharmaceuticals to ward off future pandemics. Intellectual-property protection for pharmaceuticals has a long, uncomfortable history, especially in developing countries.

When the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) was signed in 1995, an overwhelming majority of economists – including those strongly in favor of free trade – condemned it. They objected to an agreement that obliges all WTO member states to recognize and enforce patents in all fields of technology, including pharmaceuticals. While the case for general patent protection has a strong foundation in economic principles, there is no rationale for harmonizing patent protection across rich and poor countries.

As I argued in 2010, the pharmaceutical industry at the time was losing only a tiny sliver of its profits from patent infringements in developing countries. And worse, IP enforcement could result in lost or delayed access to life-saving medicines in countries that would no longer be able to produce or import generic versions of patented drugs.

Against this historical backdrop, the demand for a COVID-19 patent waiver is understandable. The problem is that the underlying issues have changed fundamentally. As a recent World Bank working paper by Ruchir Agarwal and Tristan Reed finds, "production capacity for vaccines does not appear to be the binding constraint" in global procurement. After all, there are now at least ten COVID-19 vaccines with a demonstrated efficacy above 50% (the threshold set by the US Federal Drug Administration in its June 30, 2020, "guidance for industry"). Though efficacy varies across vaccines and variants tested, all of the vaccines being administered provide significant protection against hospitalization and death. Moreover, the ten companies producing them have production targets for 2021 that would be sufficient to vaccinate 93% of world population.

What's the issue, then? According to Agarwal and Reed, it is that companies are reluctant to activate their existing production capacity without pre-purchase commitments. There is currently a large gap between the number of doses that could be produced and the number that have been pre-ordered. And, as one would expect, this gap is unevenly distributed. High-income countries have ordered more doses than they need and thus will end up with a surplus, whereas lower-income countries are far behind in pre-purchasing vaccines.

Under these circumstances, efforts to increase capacity by relaxing patent protections would do nothing to accelerate vaccinations in lower-income countries. A far more promising strategy is to help lower-income countries purchase vaccines, while channeling surplus doses from richer countries to wherever they are needed most. To a large extent, this strategy is already being implemented, thanks to the efforts of the COVAX Advanced Market Commitment facility, together with concessional loans by multilateral institutions such as the World Bank, and regional initiatives such as the one being led by the African Union. Remarkably, Agarwal and Reed show that the COVAX AMC facility and the AU initiative already have ensured that most African countries have ordered enough vaccines to cover at least 50% of their populations.

Still, three critical challenges remain. First, closing the pre-purchase gap of 350 million vaccines will requires an additional $4 billion – a trivial cost relative to the potential benefit of achieving worldwide immunity. Providing this support, either through additional funding for the COVAX AMC facility or by sending surplus vaccines to developing countries as soon as possible, should not be too difficult or costly for high-income countries to manage.

Second, the World Bank needs to relax its conditions for extending loans for vaccine pre-purchases. Currently, such loans can be used only for vaccines approved by three stringent regulatory authorities (SRAs) in three different regions. Among these are Japan and certain Western countries, which prioritize approval of vaccines intended for their own populations. They have little incentive to grant emergency-use authorization to alternative vaccines that have shown high efficacy in Phase 3 trials, such as Bharat Biotech's Covaxin (India), and Gamaleya's Sputnik V (Russia), Sinovac Biotech's CoronaVac (China). Extending the list of national regulators classified as SRAs would go a long way toward increasing lending for vaccine purchases.

Finally, existing vaccine manufacturers will be unable to meet their production targets if vaccine nationalism gives rise to export restrictions on critical inputs and raw materials. We saw such behavior early in the pandemic with respect to personal protective equipment, but the resulting export restrictions proved short-lived. One hopes the same will be true for vaccines. International cooperation and coordination will be crucial in the coming months.

There are many ways for advanced economies to assist poorer countries in vaccinating their populations as soon as possible. But relaxing patent protections – however appealing the idea may be in other contexts – is not one of them. The focus should be on providing additional funding and less restrictive lending for pre-ordering vaccines, and on funneling surpluses from high-income countries to the rest of the world.

THE RIGHT INCENTIVES FOR GLOBAL VACCINE ACCESS


Michele Goodwin (*Professor at the University of California, Irvine*)

Gregory Shaffer (*Professor at the University of California, Irvine*)

A temporary intellectual-property waiver for COVID-19 vaccines will not boost access, because the main obstacle isn't patents, but trade secrets. With political will, however, the threat of an IP waiver can help shift vaccine producers' incentives and catalyze mass production for low- and middle-income countries.

IRVINE, CALIFORNIA – The COVID-19 pandemic continues to reveal shocking underlying infrastructural inequalities around the world. While the United States rapidly rolls out vaccines even to children, countries like India suffer devastating numbers of fatalities each day. India recently reported more than 340,000 daily coronavirus cases – nearly half the global total – and the country seemingly has no end to its crisis in sight.

In response to intensifying political pressure to reduce low-income countries' suffering, US President Joe Biden's administration now supports a waiver of intellectual-property (IP) rights for COVID-19 vaccines so long as the pandemic lasts. This development has elicited two competing responses. Some commentators regard the new US stance as a paradigm shift in the US position that will affect IP protection. But others predict that Biden's new stance will have no impact on vaccine access. Both positions fail to capture the bigger picture. First, IP protection will continue, including for COVID-19 vaccines in wealthy countries where pharmaceutical firms reap enormous profits. Second, with political will, the threat of a waiver can help shift patent-holding companies' incentives and catalyze mass production of COVID-19 vaccines for low- and middle-income countries. The argument that Biden's policy is destined to, or should, fail is thus unhelpful to US diplomacy and global cooperation during the pandemic.

The effort to achieve global vaccination confronts massive incentive problems. Private pharmaceutical companies responsible to shareholders seek to maximize profits. The longer the pandemic lasts, the more likely it is that new coronavirus variants will require adjusting and distributing new vaccines, and thus the more these firms will profit. Meanwhile, rich-country governments face conflicting short- and long-term incentives. In the short term, domestic politics encourage vaccine nationalism, leading governments to contract for an exclusive vaccine supply. The US government, for example, has imposed a de facto ban on vaccine exports through its agreements with private companies. But because viruses know no borders, these governments face the longer-term threat of new imported variants against which current vaccines may be ineffective. Such pathogens would pose a clear risk to citizens' lives and health, and to countries' economic well-being.

In parallel, there is a growing strategic rivalry between the US and China for control of the commanding heights of biotech production. The Pharmaceutical Research and Manufacturers of America (PhRMA), a trade group, plays off this fear to demand control of its trade secrets. And trade secrets, not patent rights to COVID-19 vaccines, are clearly the major obstacle to ensuring wider access to COVID-19 vaccines (especially mRNA vaccines).

Technically, these trade secrets are not an IP right, but are instead protected by "unfair competition" law. The question is how to compel pharmaceutical companies to provide their trade secrets to other manufacturers to produce the vaccines, subject to a non-disclosure agreement and compensation on a cost or cost-plus basis. Simply put, the incentives of patent-holding companies must shift. Compared to an IP waiver, it is in these firms' interest to sign contracts with manufacturers subject to non-disclosure agreements, thereby enabling mass production of vaccines for low- and middle-income countries.

The threat of a waiver can thus encourage and compel pharmaceutical companies to enter such arrangements. Wealthy countries can bolster these incentives by pooling resources, including through the COVID-19 Vaccine Global Access (COVAX) facility. After all, they have an enormous advantage over poorer economies that are grappling with endemic poverty and unequal negotiating power.

To reach a deal, a critical mass of rich countries – as well as other vaccine producers, including China and Russia – should agree not to benefit from any waiver, including from any compensation arrangement. Pharmaceutical companies then could continue to profit as before. And all countries – in both the Global North and South – would benefit, including from the reduction of the risks posed by new virus variants. Nonetheless, the waiver negotiations at the World Trade Organization risk becoming symbolic, thus distracting from needed action. The threat of the IP waiver must be real to persuade companies to contract voluntarily for mass global vaccine production. In parallel, a sufficient number of developing countries could issue, or threaten to issue, compulsory licenses – with the support of the US, the European Union, and other countries from the Global North – to enhance their negotiating leverage.

This is not a revolutionary change, because the protection of IP rights has always been subject to public-health requirements. But, because the central difficulty lies with trade secrets and not with patents, the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) is not the main problem. Even without it, pharmaceutical companies still would have no incentive to release their trade secrets. Paradoxically, TRIPS could now offer a potential benefit by enabling countries to wield the waiver threat to encourage firms to enter the necessary contracts. The Biden administration should act in this vein.

Over 3.4 million people have now died from COVID-19, and millions more lives could be lost as novel variants of the virus threaten to prolong the pandemic. Thoughtful, immediate action on vaccines is needed as a matter of moral and practical urgency. For the Biden administration, that means taking steps now to shift the pharmaceutical industry's incentives.

VACCINE LICENSING, PRODUCTION, AND GLOBAL DISTRIBUTION

Michael Spence (*Nobel laureate in economics and professor of Economics Emeritus and a former dean of the Graduate School of Business at Stanford University*

Although much of the current COVID-19 vaccine debate is focused on the question of waivers for intellectual-property rights, the transfer of knowledge and technology is only the first part. Equally important are global manufacturing capacity and pricing, either of which could still pose a problem.

MILAN – At this point in the pandemic, the key question is whether vaccine production can be ramped up quickly enough to allow most people to be vaccinated relatively soon. But implicit in that question is another: whether and under what circumstances it is appropriate to suspend domestic and internationally agreed intellectual-property rights. The matter is being discussed in the World Trade Organization now that US President Joe Biden's administration has surprisingly come out in support of a COVID-19 waiver, exposing a rift between Western governments.

Most agree that if any set of conditions justifies a waiver, this pandemic surely meets them. The millions of lives threatened by the virus ought to trigger a shared sense of humanity. And vaccination is a public good, because everyone's safety ultimately depends on everyone else's. In some cases, governments have co-invested with companies in vaccine development, strengthening the case for mandatory licensing. But whatever we do to provide it must not produce adverse or unintended consequences that could impair our responses to future crises of this kind.

We need to start with a basic question: would the proposal under discussion waive IP rights, or would it simply allow for compulsory licensing, under which the company retains its IP rights and the right to earn a return from them? Of the two, compulsory licensing is preferable. By acknowledging that the creator is entitled to a return, it would minimize the adverse effect on future incentives.

Of course, an important variable is what, exactly, is being licensed. Are we talking about the chemical composition of the drug itself, or does the license extend to all of the technology embedded in a scaled-up production process? Increasing global production would most likely require both. But, because proprietary manufacturing technology is not necessarily drug-specific, mandatory licensing in this case could affect the production of other drugs, raising concerns about fairness and the rate of return on investment. Moreover, transferring production technology is not always easy.

Manufacturing capacity is another significant variable. How much is there now, and how much more would need to be built quickly to ensure high-quality output if IP is transferred? Whatever the precise answers, the point is that even if the IP issue can be resolved, manufacturing and distribution will remain binding constraints, alongside a third key variable: price.

Public-health experts and policymakers generally have balked at charging for vaccination, because it would run counter to the objective of immunizing everyone. But in the current context, the customers buying the vaccines are primarily governments or multilateral institutions, which means that there are at least two prices to be determined. One is the mandated royalty paid to the original producers, presumably the companies licensing the IP. But then there is the price paid by governments to those licensees, which may or may not be domestic companies.

The overarching long-term priority is to preserve the incentives for major drug companies to invest heavily and rapidly in the response to the next crisis – as they did in this one. These are risky investments. The royalties, in the aggregate, need to be set to produce substantial returns for the successful producers, and also a return on IP embedded in the manufacturing technology. More to the point, the incentive must remain strong enough to persuade all such companies to take on the risk of failure. Some will argue that the return to successful vaccine producers is already high from sales to developed countries. That may well be true, but we can't simply assume it. It is a question that will need to be sorted out in the WTO. Less uncertain are the principles that must be upheld now and in future crises like this one. For the investing company, the expected returns on vaccine development (which includes the probability of failing) should be neither inappropriately low nor prohibitively high. It is a common mistake to look only at the returns to the companies that succeed.

The fairest way to think about this is to base prices on the per capita income of the country whose government is buying the vaccines. (Depending on their mission, aid agencies and nonprofits can further subsidize purchases.) But since discriminating between countries opens the possibility that unscrupulous entrepreneurs and governments may game the system via trans-shipping, an international institution like the United Nations ideally would negotiate for and buy large quantities of vaccines for distribution to countries below a certain income level.

The COVID-19 Vaccine Global Access (COVAX) facility, launched in 2020 by the World Health Organization, Gavi, the Vaccine Alliance, and the Coalition for Epidemic Preparedness Innovations, is intended to do this, with funding from advanced economies. It is a good idea and should be retained.

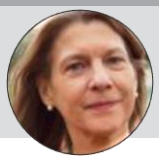
But while it has made progress in acquiring and distributing vaccines, it is underfunded and subject to the same supply problems (vaccine nationalism, licensing requirements, and manufacturing bottlenecks) as developing countries typically face.

It is to be expected that countries where vaccines are developed will meet their own needs first. As such, the only real solution at the global level is to scale up manufacturing capacity in as many places as possible.

In considering the lessons learned so far from this crisis, two final points stand out. First, critical decisions should not be made unanimously, with everyone wielding a veto. That is a recipe for delay and inaction. Instead, we need a responsible, broadly representative body like the UN to declare a global emergency, which should then trigger pre-specified arrangements. Negotiating global manufacturing and IP choices in the middle of a pandemic is not ideal.

Second, there remains a large and urgent peak-load problem in manufacturing. Peak-load capacity is expensive, because although it is not used most of the time, its absence during moments of crisis can result in much higher mortality and longer disruptions. The private sector cannot solve this problem. Insofar as there is a global public interest in carrying excess pharmaceutical manufacturing capacity, governments, in the aggregate, must figure out how to pay for it.

BUILDING VACCINE TRUST, WHILE MANAGING RISK



Heidi J. Larson *(Founding Director of the Vaccine Confidence Project and professor of anthropology and risk at the London School of Hygiene & Tropical Medicine)*

How risks associated with some COVID-19 vaccines are managed, communicated, and – most important – perceived will be crucial to sustaining public confidence in immunization drives. People's trust in policymakers, experts, and institutions will be as important as trust in the vaccines themselves.

LONDON – Hugging your parents. Meeting your grandchild for the first time. Laughing with friends – in person! COVID-19 vaccines promise to bring us closer to our loved ones and enjoy the sort of moments we have missed over the past 14 months. The delight of those already immunized is clear: on social media, people are self-documenting and sharing their vaccination moment with the message "I'm protected!"

We cannot afford to lose that enthusiasm, even in the face of recently reported rare instances of blood clotting following some COVID-19 vaccinations.

How those risks are managed, communicated, and – most important – perceived will be crucial to sustaining public confidence in COVID-19 immunization drives. And in this context, people's trust in policymakers, experts, and institutions will be as important as trust in the vaccines themselves. Our leaders need to be transparent in their actions and recognize that every day of delay and indecision regarding vaccine communication provides fertile ground for anxiety and misinformation – much of it online.

To reassure the public, we need to change our approach and talk about risk management as an ongoing process, which is the approach scientists and regulatory authorities follow when they evaluate vaccines. Governments create vaccine-safety monitoring systems to observe signs of any possible risks and ensure that guidance is based on the latest data. This is an iterative process and finding a rare side effect means that the system is working.

Scientists and regulators use the same process for any medication, from over-the-counter painkillers to chemotherapy drugs, but it is often invisible to the public. By contrast, COVID-19 vaccines have been designed, approved, and administered under a global spotlight, with every step in the development process and every report of a potential risk magnified and shared around the world. As a result, rare side effects seem more common than they actually are, making it more difficult for the public to evaluate the risk.

The public is capable of managing risk: we do it individually and collectively every time we leave the house, drive a car, or take medication, for example. But people need clear information. In the case of the reported blood clots, this means ensuring that they understand not only the possible risks related to getting a COVID-19 vaccine, but also the risk of choosing not to receive one. Health-care providers and vaccinators must also clearly communicate the possible signs and symptoms of a serious vaccine reaction and help people understand when they should seek immediate treatment.

This is true of all vaccines. Although vaccines are highly effective and save 2-3 million lives globally each year, anxiety about them is not new. The first anti-vaccine league emerged in Britain in the nineteenth century, after the government made smallpox vaccination compulsory. Some thought that vaccination – then known as "variolation" – was unnatural and "against God's plan." But while vaccination was far riskier than it is today, many thought the risk well worth taking in the face of a devastating epidemic.

Today, we face COVID-19 – another lethal pathogen that has affected everyone in some way. At the Vaccine Confidence Project, we are monitoring social media globally to understand people's questions and concerns regarding COVID-19 vaccines, as well as trust-building successes. The most frequent theme we see – in over 200 languages – is an impatient call to put the pandemic behind us. And vaccines are central to achieving this. But, for some, eagerness alone will not be enough to motivate them to get vaccinated. They will first need to feel more confident.

At an individual level, therefore, people need to be able to ask questions about COVID-19 vaccines without being treated dismissively and get the information and support they need to make educated decisions. Doctors and nurses are some of the most trusted members of society, so it is important that they make time to listen to their patients' concerns in an empathetic manner. But they also need to have the latest information and guidance to communicate to patients and to reinforce their own confidence in COVID-19 vaccination.

At the policy level, governments need to invest in short- and long-term communication and public engagement to support vaccine delivery. And policymakers and scientific institutions must become more agile and learn to speak to the public directly and transparently about important findings.

The key is not only to get vaccine information right, but also to make it relevant to people's questions, and to build trust by responding in ways that make sense in the context of their daily lives. When the next crisis hits, with different risks, the public will remember how their concerns were addressed during this one.

It is perfectly normal to have questions about vaccines. How we answer them will make all the difference. If we respond well now, and bolster public confidence, we have the chance to establish a relationship of trust that will serve as a solid foundation to meet whatever health crisis comes next.