# 1NC

## 1

#### Interpretation: medicines is a generic bare plural. The aff may not defend that member nations of the World Trade Organization reduce intellectual property protections for a subset of medicines.

Nebel 19 Jake Nebel [Jake Nebel is an assistant professor of philosophy at the University of Southern California and executive director of Victory Briefs.] , 8-12-2019, "Genericity on the Standardized Tests Resolution," Briefly, https://www.vbriefly.com/2019/08/12/genericity-on-the-standardized-tests-resolution/ SM

Both distinctions are important. Generic resolutions can’t be affirmed by specifying particular instances. But, since generics tolerate exceptions, plan-inclusive counterplans (PICs) do not negate generic resolutions. Bare plurals are typically used to express generic generalizations. But there are two important things to keep in mind. First, generic generalizations are also often expressed via other means (e.g., definite singulars, indefinite singulars, and bare singulars). Second, and more importantly for present purposes, bare plurals can also be used to express existential generalizations. For example, “Birds are singing outside my window” is true just in case there are some birds singing outside my window; it doesn’t require birds in general to be singing outside my window. So, what about “colleges and universities,” “standardized tests,” and “undergraduate admissions decisions”? Are they generic or existential bare plurals? On other topics I have taken great pains to point out that their bare plurals are generic—because, well, they are. On this topic, though, I think the answer is a bit more nuanced. Let’s see why. 1.1 “Colleges and Universities” “Colleges and universities” is a generic bare plural. I don’t think this claim should require any argument, when you think about it, but here are a few reasons. First, ask yourself, honestly, whether the following speech sounds good to you: “Eight colleges and universities—namely, those in the Ivy League—ought not consider standardized tests in undergraduate admissions decisions. Maybe other colleges and universities ought to consider them, but not the Ivies. Therefore, in the United States, colleges and universities ought not consider standardized tests in undergraduate admissions decisions.” That is obviously not a valid argument: the conclusion does not follow. Anyone who sincerely believes that it is valid argument is, to be charitable, deeply confused. But the inference above would be good if “colleges and universities” in the resolution were existential. By way of contrast: “Eight birds are singing outside my window. Maybe lots of birds aren’t singing outside my window, but eight birds are. Therefore, birds are singing outside my window.” Since the bare plural “birds” in the conclusion gets an existential reading, the conclusion follows from the premise that eight birds are singing outside my window: “eight” entails “some.” If the resolution were existential with respect to “colleges and universities,” then the Ivy League argument above would be a valid inference. Since it’s not a valid inference, “colleges and universities” must be a generic bare plural. Second, “colleges and universities” fails the upward-entailment test for existential uses of bare plurals. Consider the sentence, “Lima beans are on my plate.” This sentence expresses an existential statement that is true just in case there are some lima beans on my plate. One test of this is that it entails the more general sentence, “Beans are on my plate.” Now consider the sentence, “Colleges and universities ought not consider the SAT.” (To isolate “colleges and universities,” I’ve eliminated the other bare plurals in the resolution; it cannot plausibly be generic in the isolated case but existential in the resolution.) This sentence does not entail the more general statement that educational institutions ought not consider the SAT. This shows that “colleges and universities” is generic, because it fails the upward-entailment test for existential bare plurals. Third, “colleges and universities” fails the adverb of quantification test for existential bare plurals. Consider the sentence, “Dogs are barking outside my window.” This sentence expresses an existential statement that is true just in case there are some dogs barking outside my window. One test of this appeals to the drastic change of meaning caused by inserting any adverb of quantification (e.g., always, sometimes, generally, often, seldom, never, ever). You cannot add any such adverb into the sentence without drastically changing its meaning. To apply this test to the resolution, let’s again isolate the bare plural subject: “Colleges and universities ought not consider the SAT.” Adding generally (“Colleges and universities generally ought not consider the SAT”) or ever (“Colleges and universities ought not ever consider the SAT”) result in comparatively minor changes of meaning. (Note that this test doesn’t require there to be no change of meaning and doesn’t have to work for every adverb of quantification.) This strongly suggests what we already know: that “colleges and universities” is generic rather than existential in the resolution. Fourth, it is extremely unlikely that the topic committee would have written the resolution with the existential interpretation of “colleges and universities” in mind. If they intended the existential interpretation, they would have added explicit existential quantifiers like “some.” No such addition would be necessary or expected for the generic interpretation since generics lack explicit quantifiers by default. The topic committee’s likely intentions are not decisive, but they strongly suggest that the generic interpretation is correct, since it’s prima facie unlikely that a committee charged with writing a sentence to be debated would be so badly mistaken about what their sentence means (which they would be if they intended the existential interpretation). The committee, moreover, does not write resolutions for the 0.1 percent of debaters who debate on the national circuit; they write resolutions, at least in large part, to be debated by the vast majority of students on the vast majority of circuits, who would take the resolution to be (pretty obviously, I’d imagine) generic with respect to “colleges and universities,” given its face-value meaning and standard expectations about what LD resolutions tend to mean.

#### It applies to medicines:

#### Upward entailment test – spec fails the upward entailment test because saying that nations ought to reduce IPP for one medicine does not entail that those nations ought to reduce IPP for all medicines

#### Adverb test – adding “usually” to the res doesn’t substantially change its meaning because a reduction is permanent

#### Vote neg:

#### Semantics outweigh:

#### T is a constitutive rule of the activity and a basic aff burden – they agreed to debate the topic when they came here

#### Jurisdiction – you can’t vote aff if they haven’t affirmed the resolution

#### It’s the only stasis point we know before the round so it controls the internal link to engagement – there’s no way to use ground if debaters aren’t prepared to defend it

#### Limits – there are countless affs accounting for thousands of medicines – unlimited topics incentivize obscure affs that negs won’t have prep on – limits are key to reciprocal prep burden – potential abuse doesn’t justify foregoing the topic and 1AR theory checks PICs

#### There are over 20,000 affs

FDA 11/18 [(U.S. Food and Drug Administration, federal agency of the Department of Health and Human Service) “Fact Sheet: FDA at a Glance,” 11/18/2020] JL

There are over 20,000 prescription drug products approved for marketing.

FDA oversees over 6,500 different medical device product categories.

There are over 1,600 FDA-approved animal drug products.

There are about 300 FDA-licensed biologics products.

#### Ground – spec guts core generics like innovation that rely on reducing IP for all medicines because individual medicines don’t affect the pharmaceutical industry broadly – also means there is no universal DA to spec affs

#### TVA solves – read as an advantage to whole rez

#### Paradigm issues:

#### Drop the debater – their abusive advocacy skewed the debate from the start

#### Comes before 1AR theory – NC abuse is responsive to them not being topical

#### Competing interps – reasonability invites arbitrary judge intervention and a race to the bottom of questionable argumentation

#### No RVIs – fairness and education are a priori burdens – and encourages baiting – outweighs because if T is frivolous, they can beat it quickly

#### Fairness is a voter ­– necessary to determine the better debater

#### Education is a voter – why schools fund debate

## 2

#### Interp – reductions are permanent

Reynolds 59. Judge (In the Matter of Doris A. Montesani, Petitioner, v. Arthur Levitt, as Comptroller of the State of New York, et al., Respondents [NO NUMBER IN ORIGINAL] Supreme Court of New York, Appellate Division, Third Department 9 A.D.2d 51; 189 N.Y.S.2d 695; 1959 N.Y. App. Div. LEXIS 7391 August 13, 1959)

Section 83's counterpart with regard to nondisability pensioners, section 84, prescribes a reduction only if the pensioner should again take a public job. The disability pensioner is penalized if he takes any type of employment. The reason for the difference, of course, is that in one case the only reason pension benefits are available is because the pensioner is considered incapable of gainful employment, while in the other he has fully completed his "tour" and is considered as having earned his reward with almost no strings attached. It would be manifestly unfair to the ordinary retiree to accord the disability retiree the benefits of the System to which they both belong when the latter is otherwise capable of earning a living and had not fulfilled his service obligation. If it were to be held that withholdings under section 83 were payable whenever the pensioner died or stopped his other employment the whole purpose of the provision would be defeated, i.e., the System might just as well have continued payments during the other employment since it must later pay it anyway. The section says "reduced", does not say that monthly payments shall be temporarily suspended; it says that the pension itself shall be reduced. The plain dictionary meaning of the word is to diminish, lower or degrade. The word "reduce" seems adequately to indicate permanency. Aside from the practical aspect indicating permanency other indicia point to the same conclusion. From 1924 (L. 1924, ch. 619) to 1947 (L. 1947, ch. 841) a provision appeared in the Civil Service Law which read substantially as follows: "If the pension of a beneficiary is reduced for any reason, the amount of such reduction shall be transferred from the pension reserve fund to the pension accumulation fund during that period that such reduction is in effect." (See L. 1924, ch. 619, § 2 [Civil Service Law, § 58, subd. 4]; L. 1947, ch. 841 [Civil Service Law, § 66, subd. e].) This provision reappears in the 1955 Retirement and Social Security Law as subdivision f of section 24. This provision is useful for interpretative purposes. Since it prescribes that moneys not paid because of reduction should be transferred back to the accumulation fund the conclusion is inescapable that such reductions were meant to be permanent. If temporary suspensions were intended this bookkeeping device would result in a false picture of the funds, i.e., the reserve fund would be depleted when it would contain adequate funds to meet eventual payments 57\*57 to present pensioners. Likewise, the accumulation fund would be improperly inflated with respect to the present pensioners. Section 64 of the Retirement and Social Security Law (§ 85 under the 1947 act) provides that any disability pension must be reduced by the amount payable pursuant to the Workmen's Compensation Law if applicable. In Matter of Dalton v. City of Yonkers (262 App. Div. 321, 323 [1941]) this court interpreted "reduce" to mean "offset" in holding that under then section 67 (relating to Workmen's Compensation benefits as do its successors sections 85 and 64), pensions were to be offset by compensation benefits. This is merely another indication that "reduce" means a diminishing of the pension pursuant to a given formula rather than a mere recoverable, temporary suspension during the time other benefits or salaries are being received by the pensioner. (Also, cf., Retirement and Social Security Law, § 101 [§ 84 under the 1947 act].)

#### Violation – they don’t defend permancence

#### Negate –

#### Limits and topic lit – their model allows adding on infinite random suspensions to IP protections, anything from conditioning IP protections on human rights to monopolistic tendencies – the core of the debate is reducing IP protections, not temporarily suspending them

## 3

#### CP: mem nations should implement price controls on medicines

Solves the aff 🡪 lower prices

## 4

#### The United States federal government should:

#### - substantially increase production and global distribution of the COVID-19 Vaccine, specifically providing all necessary vaccines to India, Latin America, and South Africa, and

#### - cooperate with allies to achieve increased production and global distribution of the COVID-19 Vaccine.

#### The US should take the lead – otherwise, China and Russia will use vaccine diplomacy to advance foreign policy goals. The counterplan alone solves and reinvigorates US leadership.

Gayle et al 21. [(HELENE GAYLE is President and CEO of the Chicago Community Trust and has served in global health and development roles with CARE, the Centers for Disease Control and Prevention, and the Bill & Melinda Gates Foundation. GORDON LaFORGE is a Senior Researcher at Princeton University and a lecturer at Arizona State University’s Thunderbird School of Global Management. ANNE-MARIE SLAUGHTER is CEO of New America and former Director of Policy Planning at the U.S. State Department) “America Can—and Should—Vaccinate the World,” Foreign Affairs, March 19, 2021. <https://www.foreignaffairs.com/articles/united-states/2021-03-19/america-can-and-should-vaccinate-world>] TDI

These initiatives come not a moment too soon. In tackling the worst global crisis of a lifetime, the United States has so far been upstaged. Russia and China have aggressively marketed and distributed their vaccines to foreign countries, largely to advance foreign policy goals. Russia is using the jab to bolster its image and investment prospects and to drive a wedge between EU countries. China is donating doses to gain leverage in territorial disputes and expand its influence under the Belt and Road Initiative. Both Moscow and Beijing have moved to undercut the United States in its own backyard by supplying vaccines to Latin America**.** The Biden administration is right to want to take the lead in vaccinating the world, for a host of reasons both self-interested and altruistic. But it should not fall into the trap of trying to beat Russia and China at their own game—handing out vaccines to specific countries based on their geostrategic importance and the amount of attention they are receiving from rival powers. Rather, Biden should pursue abroad the sort of “all in” unity approach that he has proclaimed at home. His administration should focus less on strategic advantage than on vaccinating the largest number of people worldwide in the shortest amount of time. In so doing, the United States would concentrate on what the world’s peoples have in common—susceptibility to this and many other viruses—regardless of the nature of their governments. ALL IN AND ALL OUT The United States has successfully mobilized its own and international resources to respond to regional crises in the past. In 2003, President George W. Bush started the U.S. President’s Emergency Plan for AIDS Relief, the largest global health program focused on a single disease in history. PEPFAR brought together U.S. agencies, private companies, and local civil society groups to help sub-Saharan Africa and Southeast Asia get the AIDS crisis under control, saving millions of lives. In 2004, a tsunami in the Indian Ocean caused more than 220,000 deaths and billions in damage, and the United States led an urgent, similarly inclusive humanitarian relief and recovery effort that rescued victims, hastened reconstruction, and built lasting goodwill in South and Southeast Asia. Biden can improve on Bush’s precedent by going global, and he has already taken steps toward doing so. Under President Donald Trump, the United States refused to participate in the COVID-19 Vaccine Global Access (COVAX) Facility, an international partnership that aims to guarantee COVID-19 vaccine access for the entire world. The Biden administration reversed this stance immediately and contributed $4 billion, making the United States the largest donor to the effort. Still, even if COVAX meets the ambitious target of delivering two billion doses to developing nations by the end of 2021, it will be able to vaccinate only 20 percent of those countries’ populations. Just imagine, however, what could happen if Washington were to treat COVID-19 as the equivalent of the enemy in a world war or the pandemic as a global version of the regional AIDS and Ebola epidemics of years past. Imagine, in other words, what all-out mobilization would look like if the **United States treated the COVID-19 pandemic like the global threat** that it is. The Biden administration is right to want to take the lead in vaccinating the world. Washington would lead a multilateral, whole-of-society effort to help COVAX vaccinate the world. The government would activate the military and call upon allies in the G-7 and NATO for a major assistance operation that speeds the flow of vaccine supplies and strengthens delivery systems. As it has pledged to do in the Quad summit deal, the U.S. government would use the State Department, U.S. Agency for International Development (USAID), Centers for Disease Control and Prevention (CDC), and other civilian agencies and development programs to help countries with their national vaccination programs. And it would enlist companies, nonprofits, and civil society organizations to help increase vaccine production, raise funding, and provide technical assistance to foreign counterparts. The U.S. government should undertake exactly such an effort, right now: an all-out response for an all-in global vaccination campaign. Such a campaign would advance U.S. economic and security interests and reboot American global leadership after years of decline. Rather than perpetuate the transactional, friend-by-friend vaccine diplomacy of China and Russia, a U.S.-led vaccine effort could invigorate a new multilateralism that is more pragmatic and inclusive than the twentieth-century international order and better adapted to tackling twenty-first-century global threats. Washington would do well to remember that if COVID-19 does come back, authoritarian governments will be able to lock down their populations more quickly and effectively than democracies will, so even in competitive terms, America’s best bet really is to eradicate the novel coronavirus. The United States has a momentous opportunity to prove both that democracy can deliver and that American ideals truly are universal. By offering a model of global cooperation that draws on a far wider range of resources than any one government can provide, the United States can lead a vaccine effort that builds on the strengths of its open and pluralist society. President Biden would demonstrate unequivocally that the United States is not only “back” but looking—and leading—far ahead.

#### Maintenance of the ILO is key to reduce a host of existential threats – establishes great-power peace.

Brands 18. [(Hal Brands is a Henry Kissinger Distinguished Professor at Johns Hopkins University’s School of Advanced International Studies, Scholar at the American Enterprise Institute. “America’s Global Order Is Worth Fighting For, Bloomberg Opinion, Politics & Policy,” August 14, 2018, Bloomberg. <https://www.bloomberg.com/opinion/articles/2018-08-14/america-s-global-order-is-worth-fighting-for>] TDI

The first argument is easily disposed of. Yes, the postwar world has been thoroughly imperfect, featuring nuclear arms races, genocides, widespread poverty and other scourges. But the world has always been imperfect, and by any meaningful comparison, the last seven decades have been a veritable golden age. The liberal international economic order has led to an explosion of domestic and global prosperity: According to World Bank data, both U.S. and global per capita income have increased roughly three-fold (in inflation-adjusted terms) since 1960, with U.S. gross domestic product increasing nearly six-fold. The U.S. system of alliances and forward military deployments has contributed critically to the longest period of great-power peace in modern history, and the incidence of war and conquest more broadly have dropped dramatically. The number of democracies in the world has increased from perhaps a dozen during World War II to well over 100 today; respect for basic human rights has also reached impressive levels. As a bevy of scholarship has shown, the policies that the U.S. has pursued and the international order it has built have contributed enormously and directly to these outcomes. If the liberal international order can’t be considered a smashing success, no international order could be. The second critique is also overstated. It is true that Washington, like all great powers throughout history, has been willing to bend the rules to get its way. It is hard to reconcile Cold War-era interventions in Guatemala, Chile and other countries with a professed solicitude for human rights and democracy; the Iraq War of 2003 is only one instance in which the U.S. brushed aside the concerns of international organizations such as the U.N. Security Council. Likewise, when the U.S. government determined that the Bretton Woods system of monetary relations no longer suited its interests in the 1970s, it terminated that scheme and insisted on creating a more favorable one. But again, the proper standard here is not sainthood but reality. And the U.S. has generally enlisted its power in the service of universal values such as democracy and human rights; it has, more often than not, promoted a positive-sum international system in which like-minded nations can be secure and wealthy. This goes back to the very beginning of the liberal order: Washington did not seek to hold its defeated adversaries in subjugation after World War II; it rebuilt Japan and western Germany into thriving, democratic allies that became fierce economic competitors to the U.S. The U.S. has taken this approach not simply because it wanted to do good in the world — powerful as this motivation is — but because of a hard-headed desire to do good for itself. In an interdependent global environment, American officials have long calculated, the U.S. cannot divorce its own well-being from that of the wider world. And in contrast to how other great powers — Imperial Japan, for instance, or the Soviet Union — ruled their spheres of influence, American behavior has been positively enlightened. It is this relatively benign behavior that has convinced so many countries to tolerate American leadership — and it is the emergence of a darker form of U.S. hegemony under the Trump administration that so profoundly worries them today. As for the third critique, the premise is right, but the conclusion can easily go too far. It is always dangerous to become so enraptured by past achievements that one loses sight of the need for adaptation in the future. This is particularly true today, because the strength of the liberal order is being tested from within and without, by issues ranging from unequal burden-sharing among American allies to the ambivalence of the American people themselves. There is little evidence to suggest, however, that either American power or the liberal order it supports have eroded so dramatically that Washington’s postwar project cannot be sustained. Quite the contrary — the U.S. is likely to remain the world’s strongest power for decades to come.

#### The cp comparatively solves better – IP rights don’t hinder vaccine cooperation, but manufacturing capacity is the current constraint.

Hans Sauer 6-17 [(Deputy General Counsel, Biotechnology Industry Organization.) “Web event — Confronting Joe Biden’s proposed TRIPS waiver for COVID-19 vaccines and treatments” https://www.aei.org/wp-content/uploads/2021/06/210617-Confronting-Joe-Bidens-proposed-TRIPS-waiver.pdf?x91208&x91208] TDI

But contrary to what Lori said, there are genuine real problems in the supply chain that are not caused by patents, that are simply caused by the unavailability and the constraints on existing capacity. There is in this world such a thing as maxed-out capacity that just can’t be increased on a dime. It’s not all due to intellectual property. This is true for existing vaccines as well as for vaccine raw materials. There are trade barriers. There are export restrictions that we should all be aware of and that we need to work on. And there are very real political, I think, interests in finding an explanation for how we got to this place that absolve governments around the world from their own policy decisions that they made in the past. In the United States, again, it was the declared policy of the previous administration, as well as this one, that we would vaccinate healthy college kids and go all down the line and offer a vaccine to everybody who wants it before we start sharing any with grandmothers in Burkina Faso. That was the policy. You can agree with it or disagree with it, but that was policy. We had export restrictions in place before a lot of other countries did. And that, too, contributed to unequal access of vaccines around the world. Another thing that was predictable was that politicians and governments around the world who want to be seen as proactive, on the ball, in control, for a long time were actually very indecisive, very unsure about how to address the COVID problem, which has so many dimensions. Vaccines are only one of those. But with respect to vaccines, not many governments took decisive action, put money on the table, put bets on multiple horses, before we knew whether these vaccines would work, would be approved. And it was governments in middle-income countries who now, I think, justifiably are concerned that they’re not getting fast enough access, who didn’t have the means and who didn’t have the decision-making structure to place the same bets on multiple horses, if you will, that were placed in the relatively more wealthy, global North and global West. But there is, I think, a really good and, with hindsight, predictable explanation of how we got to this place, and I think it teaches us something about how to fix the problem going forward. So why will the waiver not work? Well, first of all, with complex technology like vaccines, Lori touched on it, reverse engineering, like you would for a small molecule drug, is much more difficult if not impossible. But it depends very much more than small molecule drugs on cooperation, on voluntary transfer of technology, and on mutual assistance. We have seen as part of the pandemic response an unprecedented level of collaborations and cooperation and no indication that IP has stood in the way of the pandemic response. The waiver proponents have found zero credible examples of where IP has actually been an obstacle**,** where somebody has tried to block somebody else from developing a COVID vaccine or other COVID countermeasure, right? It’s not there. Second, the myth of this vast global capacity to manufacture COVID vaccines that somehow exists out there is unsubstantiated and frankly, in my opinion, untrue. But there is no such thing as vast untapped, idle capacity that could be turned around on a dime to start making COVID vaccines within weeks or even months. This capacity needs to be built; it needs to be established. And at a time when time is of the essence to beat this pandemic, starting capacity-building discussions is helpful, but it won’t be the answer to beat this pandemic. It will be the answer if we do everything right to beating the next pandemic. And if we learn any lesson of this, and then I will stop, is that the COVID waiver as well as the situation in which we find ourselves — if anything, it’s a reminder that we definitely have to take global capacity-building more seriously than we did in the past. That is true for the global North, as well as for middle-income countries — all of whom have to dedicate themselves much more determinedly to pandemic preparedness. And there’s a need to invest both in preparedness and in public health systems that hasn’t happened in the wake of past pandemic threats. This is what we will need to do. We will need to reduce export restrictions, and we will need to rededicate ourselves to preparing for the next pandemic. As far as this pandemic goes, there are 11 vaccines around the world that are already being shot into arms, only four of which come from the global North. How many more vaccines do we want? I don’t know, maybe 11 is enough if we start making more of them. But there are manufacturers around the world who know how to do this — including in China, including in India, and including in Russia. All developed their homegrown vaccines, apparently without interference by IP rights, right? So let’s make more of those. I think that’s going to be the more practical and realistic answer to solving the problem. And we need to lean on governments to stop export controls and to dedicate themselves to more global equity.

## 5

#### Biotech industry strong now

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

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

What about SPACs?

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

Fundamentals continue strong

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

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

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

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

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

More innovation on the horizon

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

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

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

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

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

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

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

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

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

#### IP enables critical information sharing

Simon 6/25 [(Brenda, professor at California Western School of Law, research interests focus on how technological developments affect intellectual property and information law, former teaching fellow for the Law, Science and Technology LL.M. Program at Stanford Law School, and a research fellow in the Stanford Center for Law and the Biosciences, JD from UC Berkeley School of Law) “Patents, Information, and Innovation,” Brooklyn Law Review, 6/25/2020] JL

Patents play numerous roles in encouraging the exchange of information during the investment-seeking process in the medical device industry. One role is reducing the likelihood that the medical device will be expropriated. The risks of expropriation at this stage vary depending on the circumstances, which were set forth from a theoretical perspective in Part I and will be contextualized with examples from the medical device industry in this Part. Some of the variables in assessing expropriation risks, and consequently the function of patents in enabling information exchange, include whether the medical device is self-disclosing and easily reverse engineered, the importance of reputational and industry norms, and whether staging disclosure over time is an option.222 Time and resource constraints may limit the efficacy of some of these alternative mechanisms to patents in mitigating the risks of expropriation.223

Apart from their ability to ensure exclusivity, patents have an independent function of providing a useful signal to investors about information distinct from the medical device invention, such as resource allocation and the experience of the executive team, similar to their role in the biotechnology industry.224 An issued patent can also provide an indication about the viability of the invention, such as the ability to limit competition, extend the first mover advantage, and provide an independent source of value to the company through licensing or sale.225

One survey of twenty venture capital fund managers looked at the importance of intellectual property protection in assessing the risk-return ratio of portfolio companies .226 For medical device companies, respondents ranked intellectual property protection third, after reimbursement and regulatory concerns at the FDA.227 The authors of the survey reasoned that intellectual property protection was a concern of venture fund managers, given the high patenting rates among venture-backed companies and that the size of medical device companies necessitated "their reliance on patent protection to maintain barriers to market entry by competitors ."228 Additionally, court decisions that cast doubt on whether patent protection would be available for some medical devices have also raised concerns.229

#### Biopharmaceutical innovation is key to prevent future pandemics and bioterror – turns case

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As key actors in the healthcare innovation landscape, pharmaceutical and life sciences companies have been called on to develop medicines, vaccines and diagnostics for pressing public health challenges. The COVID-19 crisis is one such challenge, but there are many others. For example, MERS, SARS, Ebola, Zika and avian and swine flu are also infectious diseases that represent public health threats. Infectious agents such as anthrax, smallpox and tularemia could present threats in a bioterrorism context.1 The general threat to public health that is posed by antimicrobial resistance is also well-recognised as an area in need of pharmaceutical innovation. Innovating in response to these challenges does not always align well with pharmaceutical industry commercial models, shareholder expectations and competition within the industry. However, the expertise, networks and infrastructure that industry has within its reach, as well as public expectations and the moral imperative, make pharmaceutical companies and the wider life sciences sector an indispensable partner in the search for solutions that save lives. This perspective argues for the need to establish more sustainable and scalable ways of incentivising pharmaceutical innovation in response to infectious disease threats to public health. It considers both past and current examples of efforts to mobilise pharmaceutical innovation in high commercial risk areas, including in the context of current efforts to respond to the COVID-19 pandemic. In global pandemic crises like COVID-19, the urgency and scale of the crisis – as well as the spotlight placed on pharmaceutical companies – mean that contributing to the search for effective medicines, vaccines or diagnostics is essential for socially responsible companies in the sector. 2 It is therefore unsurprising that we are seeing industry-wide efforts unfold at unprecedented scale and pace. Whereas there is always scope for more activity, industry is currently contributing in a variety of ways. Examples include pharmaceutical companies donating existing compounds to assess their utility in the fight against COVID19; screening existing compound libraries in-house or with partners to see if they can be repurposed; accelerating trials for potentially effective medicine or vaccine candidates; and in some cases rapidly accelerating in-house research and development to discover new treatments or vaccine agents and develop diagnostics tests.3,4 Pharmaceutical companies are collaborating with each other in some of these efforts and participating in global R&D partnerships (such as the Innovative Medicines Initiative effort to accelerate the development of potential therapies for COVID-19) and supporting national efforts to expand diagnosis and testing capacity and ensure affordable and ready access to potential solutions.3,5,6 The primary purpose of such innovation is to benefit patients and wider population health. Although there are also reputational benefits from involvement that can be realised across the industry, there are likely to be relatively few companies that are ‘commercial’ winners. Those who might gain substantial revenues will be under pressure not to be seen as profiting from the pandemic. In the United Kingdom for example, GSK has stated that it does not expect to profit from its COVID-19 related activities and that any gains will be invested in supporting research and long-term pandemic preparedness, as well as in developing products that would be affordable in the world’s poorest countries.7 Similarly, in the United States AbbVie has waived intellectual property rights for an existing combination product that is being tested for therapeutic potential against COVID-19, which would support affordability and allow for a supply of generics.8,9 Johnson & Johnson has stated that its potential vaccine – which is expected to begin trials – will be available on a not-for-profit basis during the pandemic.10 Pharma is mobilising substantial efforts to rise to the COVID-19 challenge at hand. However, we need to consider how pharmaceutical innovation for responding to emerging infectious diseases can best be enabled beyond the current crisis. Many public health threats (including those associated with other infectious diseases, bioterrorism agents and antimicrobial resistance) are urgently in need of pharmaceutical innovation, even if their impacts are not as visible to society as COVID-19 is in the immediate term. The pharmaceutical industry has responded to previous public health emergencies associated with infectious disease in recent times – for example those associated with Ebola and Zika outbreaks.11 However, it has done so to a lesser scale than for COVID-19 and with contributions from fewer companies. Similarly, levels of activity in response to the threat of antimicrobial resistance are still low.12 There are important policy questions as to whether – and how – industry could engage with such public health threats to an even greater extent under improved innovation conditions.