### 1

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

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

#### 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 different combinations of states and IP – 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 and functional limits checks PICs

#### Ground – spec guts core generics like innovation that rely on reducing IP for all intellectual property because specific types of IP 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

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

### 2

#### The member nations of the World Trade Organization ought to reform intellectual property protections for medicines using the mechanisms described by MSF ’17.

#### We allow secondary patents, but only under stricter patentability requirements, which solves innovation and high drug prices. MSF 17:

MSF ’17 – Médecins Sans Frontières [Doctors Without Borders - Médecins Sans Frontières (MSF) is an international, independent, medical humanitarian organisation that delivers emergency aid to people affected by armed conflict, epidemics, healthcare exclusion and natural or man-made disasters.], “A Fair Shot for Vaccine Affordability: Understanding and addressing the effects of patents on access to newer vaccines,” September, 2017. Accessed Aug. 12, 2021. <<https://msfaccess.org/sites/default/files/2018-06/VAC_report_A%20Fair%20Shot%20for%20Vaccine%20Affordability_ENG_2017.pdf>> AT

Countries can take a variety of steps to promote competition in vaccine manufacturing and help mitigate the complex patent thickets that could block, delay or increase uncertainties around access to multiple sources of vaccines. Governments should adopt public health-oriented IP policies, making full use of TRIPS flexibilities in both substantive and procedural aspects of national patent laws. Countries should:

• Encourage and accelerate follow-on development and competition of vaccines and vaccine technologies through the introduction and use of broad Bolar exemptions. This will support an early start for research and clinical studies by follow-on manufacturers, and support independent follow-on research and development.

• Apply strict patentability criteria for vaccine and vaccine technologies in patent examination and judicial proceedings. Countries should closely scrutinise patent applications concerning common methods of treatment, dosage forms and claims concerning specific age groups. Countries should reject trivial changes to known vaccine technologies, or composition patent applications that merely present the assembly of more ingredients using a known technology.

• Implement robust pre- and post-grant opposition procedures in national patent law systems that allow greater public scrutiny and opportunities to challenge unmerited patent applications from an early stage. Procedures that allow third-party observation but lack a mandatory hearing requirement could be improved to provide better transparency and accountability to the public.

• Improve use of compulsory licencing. Governments should strengthen the mechanisms of issuing compulsory licences to facilitate the most expedited access to multiple sources of vaccines and to safeguard public health.

• Strengthen technical capacity to ensure patent examiners apply strict patentability criteria and screen out unmerited applications in a timely manner. This will provide clarity on the patent landscape concerning important vaccines and technologies.

• Increase transparency of patent office filings to enable third parties to better understand the IP landscape, especially through procedures to promote disclosure of non-proprietary biological qualifier names74 of vaccines. Prospective manufacturers will be able to make decisions more efficiently if they understand the IP landscape clearly. Government procurement decision making will also be improved by addressing the current information asymmetry.

• Make full use of LDCs’ exemption from mandatory patent protection to accelerate access to quality assured follow-on new vaccines and encourage competition to improve affordability of vaccines.

• Demand that international organisations like WHO, Gavi, the Pan American Health Organization (PAHO) and the United Nations Children’s Fund (UNICEF) improve technical support for countries to: identify legal barriers, use flexibilities under IP laws and improve transparency of patent information to facilitate follow-on development and foster robust competition for new vaccines.75

### 3

#### The pharma industry is strong now but patents are key for continued economic growth. Batell and PhRMA 14:

Batell and PhRMA {Battelle is the world’s largest nonprofit independent research and development organization, providing innovative solutions to the world’s most pressing needs through its four global businesses: Laboratory Management, National Security, Energy, Environment and Material Sciences, and Health and Life Sciences. The Pharmaceutical Research and Manufacturers of America (PhRMA) represents the country’s leading pharmaceutical research and biotechnology companies, which are devoted to inventing medicines that allow patients to live longer, healthier, and more productive lives.}, 14 – “The U.S. Biopharmaceutical Industry: Perspectives on Future Growth and The Factors That Will Drive It,” http://phrma-docs.phrma.org/sites/default/files/pdf/2014-economic-futures-report.pdf//marlborough-wr//

Compared to other capital-intensive, advanced manufacturing industries in the U.S., the biopharmaceutical industry is a leader in R&D investment, IP generation, venture capital investment, and R&D employment. Policies and infrastructure that helped foster these innovative activities have allowed the U.S. to seize global leadership in biopharmaceutical R&D over the past 30 years. However, as this report details, other countries are seeking to compete with the U.S. by borrowing and building upon some of these pro-innovation policies to improve their own operating environment and become more favorable to biopharmaceutical companies making decisions about where to locate their R&D and manufacturing activities. A unique contribution of this report was the inclusion of the perspective of senior-level strategic planning executives of biopharmaceutical companies regarding what policy areas they see as most likely to impact the favorability of the U.S. business operating environment. The executives cited the following factors as having the most impact on the favorability of the operating environment and hence, potential growth of the innovative biopharmaceutical industry in the U.S.: • Coverage and payment policies that support and encourage medical innovation • A well-functioning, science-based regulatory system • Strong IP protection and enforcement in the U.S. and abroad The top sub-attribute identified as driving future biopharmaceutical industry growth in the U.S. cited by executives was a domestic IP system that provides adequate patent rights and data protection. Collectively, these factors underscore the need to reduce uncertainties and ensure adequate incentives for the lengthy, costly, and risky R&D investments necessary to develop new treatments needed by patients and society to address our most costly and challenging diseases. With more than 300,000 jobs at stake between the two scenarios, the continued growth and leadership of the U.S. innovative biopharmaceutical industry cannot be taken for granted. Continued innovation is fundamental to U.S. economic well-being and the nation’s ability to compete effectively in a globalized economy and to take advantage of the expected growth in demand for new medicines around the world. Just as other countries have drawn lessons from the growth of the U.S. biopharmaceutical sector, the U.S. needs to assess how it can improve the environment for innovation and continue to boost job creation by increasing R&D investment, fostering a robust talent pool, enhancing economic growth and sustainability, and continuing to bring new medicines to patients.

#### Secondary patents in particular are key to generating new treatments to medicines based on existing medicines. Evergreening does not stop production of generic versions of the orginial formulation

Christopher M. Holman, [senior scholar C-IP2] 18 - ("Why Follow-On Pharmaceutical Innovations Should Be Eligible For Patent Protection," Intellectual Property Watch, 9-21-2018, accessed 9-18-2021, https://www.ip-watch.org/2018/09/21/follow-pharmaceutical-innovations-eligible-patent-protection/)//ML

Why Protect Follow-On Innovation?¶ The attack on secondary pharmaceutical patents is based in part on the flawed premise that follow-on innovation is of marginal value at best, and thus less deserving of protection than the primary inventive act of identifying and validating a new drug active ingredient. In fact, follow-on innovation can play a critical role in transforming an interesting drug candidate into a safe and effective treatment option for patients. A good example can be seen in the case of AZT (zidovudine), a drug ironically described in the Guidelines as the “first breakthrough in AIDS therapy.” AZT began its life as a failed attempt at a cancer drug, and it was only years later that its potential application in the fight against AIDS was realized. Follow-on research resulted in a method-of-use patent directed towards the use of AZT in the treatment of AIDS, and it was this patent that incentivized the investment necessary to bridge the gap between a promising drug candidate and a safe, effective, and FDA-approved pharmaceutical. Significantly, because of the long lag time between the first public disclosure of AZT and the discovery of its use in the treatment of AIDS, patent protection for the molecule per se was unavailable. In a world where follow-on innovation is unpatentable, there would have been no patent incentive to invest in the development of the drug, and without that incentive AZT might have languished on the shelf as simply one more failed drug candidate.¶ Other examples of important drugs that likely never would have been made available to patients without the availability of a “secondary” patent include Evista (raloxifene, used in the treatment of osteoporosis and to reduce the risk of invasive breast cancer), Zyprexa (olanzapine, used in the treatment of schizophrenia), and an orally-administrable formulation of the antibiotic cefuroxime.¶ Pharmaceutical development is prolonged and unpredictable, and frequently a safe and effective drug occurs only as a result of follow-on innovation occurring long after the initial synthesis and characterization of a pharmaceutically interesting chemical compound. The inventions protected by secondary patents can be just as critical to the development of drugs as a patent on the active ingredient itself.¶ The Benefits of Follow-On Innovation The criticism of patents on follow-on pharmaceutical innovation rests on an assumption that follow-on innovation provides little if any benefit to patients, and merely serves as a pretense for extending patent protection on an existing drug. In fact, there are many examples of follow-on products that represent significant improvements in the safety-efficacy profile. For example, the original formulation of Lumigan (used to treat glaucoma) had an unfortunate tendency to cause severe hyperemia (i.e., redeye), and this adverse event often lead patients to stop using the drug, at times resulting in blindness. Subsequent research led to a new formulation which largely alleviated the problem of hyperemia, an example of the type of follow-on innovation that significantly benefits patients but that which would be discouraged by a patent regime that does not reward follow-on innovation.¶ Follow-on pharmaceutical innovation can come in the form of an extended-release formulation that permits the drug to be administered at less frequent intervals than the original formulation. Critics of secondary patents downplay the significance of extended-release formulations, claiming that they represent nothing more than a ploy to extend patent protection without providing any real benefit to patients. In fact, the availability of a drug that can be taken once a day has been shown to improve patient compliance, a significant issue with many drugs, particularly in the case of drugs taken by patients with dementia or other cognitive impairments. Extended-release formulations can also provide a more consistent dosing throughout the day, avoiding the peaks and valleys in blood levels experienced by patients forced to take an immediate-release drug multiple times a day.¶ Other examples of improved formulations that provide real benefits to patients are orally administrable formulations of drugs that could previously only be administered by more invasive intravenous or intramuscular injection, combination products that combine two or more active pharmaceutical agents in a single formulation (resulting in improved patient compliance), and a heat-stable formulation of a lifesaving drug used to treat HIV infection and AIDS (an important characteristic for use in developing countries with a hot climate).¶ “Evergreening” – an Incoherent Concept¶ Drug innovators are often accused of using secondary patents to “evergreen” the patent protection of existing drugs, based on an assumption that a secondary patent somehow extends the patent protection of a drug after the primary patent on the active ingredient is expired. As a general matter, this is a false assumption — a patent on an improved formulation, for example, is limited to that improvement and does not extend patent protection for the original formulation.¶ Once the patents covering the original formulation have expired, generic companies are free to market a generic version of the original product, and patients willing to forgo the benefits of the improved formulation can choose to purchase the generic product, free of any constraints imposed by the patent on the improvement. Of course, drug innovators hope that doctors and their patients will see the benefits of the improved formulation and be willing to pay a premium for it, but it is important to bear in mind that ultimately it is patients, doctors, and third-party payers who determine whether the value of the improvement justifies the costs.¶ Of course, this assumes a reasonably well-functioning pharmaceutical market. If that market breaks down in a manner that forces patients to pay higher prices for a patented new version of a drug that provides little real improvement over the original formulation, then it is the deficiency in the market which should be addressed, rather than the patent system itself.¶ For example, if a drug company is found to have engaged in some anticompetitive activity to block generic competition in the market for the original product once it has gone off patent, then antitrust and competition laws should be invoked to address that problem. If doctors are prescribing an expensive new formulation of a drug that provides little benefit compared to a cheaper, unpatented original product, then that is a deficiency in the market that should be addressed directly, rather than through a broadside attack on follow-on innovation. In short, if is found that secondary patents are being used in a manner that creates an unwarranted extension of patent protection, it is that misuse of the patent system which should be addressed directly, rather than through what amounts to an attack on the patent system itself.¶

### 4

#### The Aff’s portrayal of a world with reduced IP protections as an “information commons” where high drug prices is solved by deregulation perpetuates the neoliberal myth of increased competition ensuring a perfect market **Kapczynski 14** [(Amy, a Professor of Law at Yale Law School, Faculty Co-Director of the Global Health Justice Partnership, and Faculty Co-Director of the Collaboration for Research Integrity and Transparency. She is also Faculty Co-Director of the Law and Political Economy Project and cofounder of the Law and Political Economy blog. Her areas of research include information policy, intellectual property law, international law, and global health.) “INTELLECTUAL PROPERTY’S LEVIATHAN” Duke Law, Law & Contemporary problems, 2014. <https://scholarship.law.duke.edu/cgi/viewcontent.cgi?article=4710&context=lcp>] BC

Over the last decade or so, a powerful set of critiques has emerged to contest the dominant account just sketched out as well as the contemporary state of IP law.12 These arguments have come from many directions, some even arising from scholars who previously were champions of the dominant account.13 The most prominent and potent line of theoretical critique in the legal literature has come in the guise of arguments for free culture and the “information commons” and has been most influentially articulated by Lawrence Lessig and Yochai Benkler.14 Both have stressed the problems with expansive exclusive rights regimes in information and have also sketched a set of actually existing alternatives to market-based exclusionary forms of information and cultural production. Lessig has written a series of influential books that have made him a “rock star of the information age,”15 particularly for young Internet and free-culture activists. He has argued powerfully, for example, that existing copyright law is in deep conflict with the radical new possibilities for creativity in the digital age. As he points out, when a mother posting a video of her toddler dancing to a Prince song on YouTube is threatened with a $150,000 fine for copyright infringement, something has gone seriously awry.16 Lessig also contends that copyright law today is too long, too expansive, and instantiates a “permission culture” that is antithetical to free expression in the age of the remix.17 As he puts it, “the Internet has unleashed an extraordinary possibility for many to participate in the process of building and cultivating a culture that reaches far beyond local boundaries,” creating the possibility of markets that “include a much wider and more diverse range of creators,” if not stifled by incumbents who use IP law to “protect themselves against this competition.”18 Benkler’s work has also been extraordinarily formative in the field, particularly for his insights into the multiplicity of modes of information production. As he has stressed, the conventional justification for IP does not account for the many successful and longstanding modes of market nonexclusionary information production.19 For example, attorneys write articles to attract clients, software developers sell services customizing free and opensource software for individual clients, and bands give music away for free to increase revenues from touring or merchandise.20 More pathbreaking still is Benkler’s account of the importance of “commons-based peer production,” a form of socially motivated and cooperative production exemplified by the volunteer network that maintains Wikipedia or the groups of coders who create open-source software products such as the Linux operating system.21 In the digital networked age, as Benkler describes, the tools of information production are very broadly distributed, “creating new opportunities for how we make and exchange information, knowledge, and culture.”22 These changes have increased the relative role in our information economy of nonproprietary production and facilitate “new forms of production [that] are based neither in the state nor in the market.”23 Because commons-based peer production is not hierarchically organized and is motivated by social dynamics and concerns, it also offers new possibilities for human development, human freedom, a more critical approach to culture, and more democratic forms of political participation.24 This line of critique has been profoundly generative and has helped launch an important new conceptualization of the commons as a paradigm. That paradigm, as a recent book puts it, “helps us ‘get outside’ of the dominant discourse of the market economy and helps us represent different, more wholesome ways of being.”25 Proponents of the commons concept draw upon contemporary articulations of successful commons-based resource management by Elinor Ostrom and her followers.26 They do mobilize retellings of the political and economic history of the commons in land in Europe before enclosure,27 and recent evidence from psychology and behavioral economics that suggests that humans have deep tendencies toward cooperation and reciprocation.28 They argue that A key revelation of the commons way of thinking is that we humans are not in fact isolated, atomistic individuals. We are not amoebas with no human agency except hedonistic “utility preferences” expressed in the marketplace. No: We are commoners—creative, distinctive individuals inscribed within larger wholes. We may have unattractive human traits fueled by individual fears and ego, but we are also creatures entirely capable of self-organization and cooperation; with a concern for fairness and social justice; and willing to make sacrifices for the larger good and future generations.29 This stands, of course, as a powerful rebuke to the neoliberal imaginary, which “constructs and interpellates individuals as . . . rational, calculating creatures whose moral autonomy is measured by their capacity for ‘self-care’— the ability to provide for their own needs and service their own ambitions.”30 III Given this radical—and, in my view, critically important—attempt to rethink the subject at the core of neoliberal accounts, it is all the more striking that proponents of the commons often appear to adopt a neoliberal image of the state. For example, the introduction to a recently edited volume that gathers writings on the commons from seventy-three authors in thirty countries (entitled, tellingly, The Wealth of the Commons: A World Beyond Market and State) has this to say: The presumption that the state can and will intervene to represent the interests of citizens is no longer credible. Unable to govern for the long term, captured by commercial interests and hobbled by stodgy bureaucratic structures in an age of nimble electronic networks, the state is arguably incapable of meeting the needs of citizens as a whole.31 The commons, they suggest, is a concept that seeks not only to liberate us from predatory and dysfunctional markets, but also from predatory and dysfunctional states. Something immediately seems incongruous here. If people are inherently cooperative reciprocators, why are states irredeemably corrupt? After all, as Harold Demsetz famously wrote in his 1967 attack on Arrow’s optimism about state production of information, “[g]overnment is a group of people.”32 Lessig, one of the progenitors of the language of the commons in the informational domain, often leads with a similar view of the state: [I]f the twentieth century taught us one lesson, it is the dominance of private over state ordering. Markets work better than Tammany Hall in deciding who should get what, when. Or as Nobel Prize-winning economist Ronald Coase put it, whatever problems there are with the market, the problems with government are more profound.33 Lessig reveals his own sense of the power of this conception of the state when he seeks to tar IP law with the same brush; we should rebel against current IP law, he suggests, because we should “limit the government’s role in choosing the future of creativity.”34 Benkler is more measured but admits as well to viewing the state as “a relatively suspect actor.”35 We should worry, he suggests, that direct governmental intervention “leads to centralization in the hands of government agencies and powerful political lobbies,”36 a view that echoes the neoliberal account described above. It should perhaps not surprise us that leading critics of neoliberal information policy embrace a neoliberal conception of the state. After all, neoliberalism is not merely an ideology, but also a set of policy prescriptions that may have helped to call forth the state that it has described. As David Harvey puts it, “[t]he neoliberal fear that special-interest groups would pervert and subvert the state is nowhere better realized than in Washington, where armies of corporate lobbyists . . . effectively dictate legislation to match their special interests.”37 There are, it must be said, few areas of law that better exemplify this problem than IP law. For example, Jessica Litman has documented the astonishing process through which the 1976 Copyright Act was drafted, in which Congress delegated most of the drafting to interest groups that were forced to negotiate with one another.38 Other scholars have offered similarly startling accounts of the genesis of the most important IP treaty today, the TradeRelated Aspects of Intellectual Property Rights (TRIPS) Agreement. TRIPS came into force in 1996, revolutionizing international IP law by both imposing new standards and by rendering them enforceable through the WTO’s disputeresolution system, which authorizes trade retaliation to enforce its judgments. Most countries in the world are members of TRIPS, and the Agreement introduced, for developing countries in particular, substantial new obligations, such as the obligation to grant patents on medicines and food-related inventions. Several excellent histories of the treaty have been written, documenting its beginnings as a brash idea proposed by “twelve chief executive officers (representing pharmaceutical, entertainment, and software industries).”39 As Susan Sell has described, the TRIPS Agreement was a triumph of industry organizing. Through TRIPS, Industry revealed its power to identify and define a trade problem, devise a solution, and reduce it to a concrete proposal that could be sold to governments. These private sector actors succeeded in getting most of what they wanted from a global IP agreement, which now has the status of public international law.

#### Attempts to reform the WTO are neoliberal attempts to sustain the US regime of accumulation – the contradictions of neoliberalism are why credibility is low, not IP protection

Bachand 20 [(Remi, Professor of International Law, Département des sciences juridiques, member of the Centre d’études sur le droit international et la mondialisation (CÉDIM), Université du Québec à Montréal, Canada) “What’s Behind the WTO Crisis? A Marxist Analysis” The European Journal of International Law, 8/12/2020. https://academic.oup.com/ejil/article-abstract/31/3/857/5920920?redirectedFrom=fulltext] BC

To offer our own explanation, we must recall two aspects of our theoretical framework. The first is Robert Cox’s claim113 that the function of international organizations is to ensure the creation and reproduction of hegemony. To be more accurate, they serve, if we follow his argument, to defend and to expand the ‘mode of production’ (we elected to substitute this term for the concept of ‘regime of accumulation’ that appears to be more appropriate for our means) of the dominant social classes of the dominant state. Joining this idea with the école de la régulation and social structure of accumulation theory writing114 according to which a regime of accumulation needs some regulation institutions to help resolve its contradictions (and ensure profits and capital accumulation to dominant social classes), we can conclude that the Geneva organization’s function in the US hegemonic order is to make sure that neoliberalism works well enough to provide a satisfying rate of profit for US capitalists. Going in that direction, Kristen Hopewell shows that the WTO’s creation participated in a shift in global governance from ‘embedded liberalism’ to neoliberalism115 and was slated to be an important part of that governance. Using the conceptual framework developed earlier, we can infer that the WTO was thus given a regulation function that was to ensure the operationalization of counteracting factors to the fall of the rate of profit for US capitalists. Now, as we have seen, the US rate of profit has been extremely unstable in the last two decades and Chinese expansion (and that of other ‘emerging countries’) allows one to predict that the situation could easily worsen in the future. Consequently, it should come as no surprise that the crisis that has been striking neoliberalism for the last 20 years may also result in a crisis of the organizations that are supposed to manage its contradictions, especially the WTO. Concretely, this organization seems unable to fulfil its regulatory function anymore, which is to ensure US capitalists a good rate of profit and opportunities to operationalize enough counteracting factors to negate its fall. To go further, we now need to return to Stephen Gill’s claim that the function of an international organization is to limit political and economic possibilities. It is to exclude, in other words, options that are incompatible with the social order promoted by the hegemon from what is possible and achievable.116 Effectively, the WTO was created to play such a role. Indeed, promoting liberalization of goods and services, protecting (notably intellectual) property rights and attacking subsidies (in non-agriculture sectors), just to give a few examples, all serve to severely reduce state interventions into the economy and to circumscribe or at least to strongly impede the turn towards an alternative model to neoliberalism

#### Neoliberalism rips apart communal bonds to maintain the illusion that structural inequalities are individual problems – the impact is systemic victim-blaming, poverty, and violence.

Smith 12 [(Candace, author for Societpages, cites Bruno Amable, Associate Professor of Economics at Paris School of Economics) “Neoliberalism and Individualism: Ego Leads to Interpersonal Violence?” Sociology Lens is the associated site for Sociology Compass, Wiley-Blackwell’s review journal on all fields sociological] AT

There appears to be a link between neoliberalism, individualism, and violence. In reference to the association between neoliberalism and individualism, consider neoliberalism’s insistence that we do not need society since we are all solely responsible for our personal well-being (Peters 2001; Brown 2003). From a criminological standpoint, it is not hard to understand how this focus on the individual can lead to violence. According to Hirschi’s (1969) social control theory, for instance, broken or weak social bonds free a person to engage in deviancy. Since, according to this theory, individuals are naturally self-interested, they can use the opportunity of individualization to overcome the restraining powers of society. Bearing in mind neoliberalism’s tendency to value the individual over society, it could be argued that this ideology is hazardous as it acts to tear apart important social bonds and to thereby contribute to the occurrence of ego-driven crimes, including violent interpersonal crimes. Such a thought suggests that as neoliberalism becomes more prominent in a country, it can be expected that individualism and, as a result, interpersonal violence within that country will increase. When it comes to individualization, this idea is one of the fundamental aspects of neoliberalism. In fact, Bauman (2000:34) argues that in neoliberal states “individualization is a fate, not a choice.” As Amable (2011) explains, neoliberals have realized that in order for their ideology to be successful, a state’s populace must internalize the belief that individuals are only to be rewarded based on their personal effort. With such an ego-driven focus, Scharff (2011) explains that the process of individualization engenders a climate where structural inequalities are converted into individual problems.

#### The alt is to reject the aff in favor of a critique that cultivates educated hope - evaluate the aff and alt on the level of ideological commitments – these policies won’t happen which takes out consequentialism good offense – BUT until we unlearn the assumption that getting government out of the way will let markets flourish and solve all our problems, we'll never be able to engage in robust, communitarian policymaking that truly centers human need and our obligations to others. Wilson 17:

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New Stories for New Worlds As we will see in our mapping of the neoliberal conjuncture, competition's totalizing yet tenuous power over our everyday lives is rooted in what Keating calls “status quo stories”—those stories that get told in popular culture, and that we often tell ourselves, which cement our relationship to our present conjuncture and our investment in the world as we currently know it. She explains: Generally spoken with great certainty, these and similar comments (commands, really) reflect unthinking affirmation of the existing reality and a stubborn, equally unthinking resistance to change. Because we believe that our status-quo stories represent accurate factual statements about ourselves, other people, and the world, we view them as permanent, unchanging facts. This belief in the status-quo's permanence becomes self-fulfilling: We do not try to make change because change is impossible to make. “It's always been that way,” we tell ourselves, “so why waste our energy trying to change things?” “People are just like that-it's human nature, so plan accordingly and alter your expectations! There's no point in trying to change human nature!" Status-quo stories trap us in our current circumstances and conditions; they limit our imaginations because they prevent us from envisioning alternate possibilities.10 Status-quo stories double down on reality, making it seem like those socially constructed forces impinging on us are natural rather than historical, political, and subject to change. “Status-quo stories have a numbing effect,” Keating writes. “When we organize our lives around such stories or in other ways use them as ethical roadmaps or guides, they prevent us from extending our imaginations and exploring additional possibilities."11 One of my students aptly described neoliberal culture as a “status-quo storytelling machine.” To keep us living in competition, neoliberalism generates a host of status-quo stories about the naturalness and inevitability of self-enclosed individualism. Indeed, we might say that self-enclosed individualism operates as the foundational status quo story of neoliberal culture, where competition has become synonymous with all of life. Self-enclosed individualism keeps us not only divided from one another, but also actively pitted against each other. We are stuck in an oppositional consciousness that refuses to acknowledge our social interconnections, even though, as our shared anxieties suggest, we've never had more in common than right now! No matter where we are or what we're doing, neoliberal culture encourages us to see each other through a competitive lens that makes the transformation of our social world, and ourselves, impossible. We become incapable of acknowledging how our fortunes and fates are entwined with those of others who are living very different realities. We become callous and hardened to the suffering of others. We see suffering and death everywhere, and while this might register as bad or wrong or upsetting, we nonetheless stay stuck within the horizons of our own self-enclosed bubbles. The devastating powers of status-quo stories are clear in so many of the conversations we have on college campuses about power, privilege, and difference. In fact, I started teaching courses on neoliberal culture to help my students understand the broader histories and contexts that were impinging on these conversations and making them so fraught, and ultimately so unproductive. Time and time again, in open community forums and classroom discussions of systemic inequalities, I watched students voice painful personal experiences only to get nowhere. Indeed, when asked to consider various forms of privilege, many of my white, male students get defensive. The idea that they haven't earned their place through their own decisions and hard work, but rather benefited from inherited wealth and opportunity, means that they are not good people from the perspective of neoliberalism. Talking about issues of privilege threatens to diminish their sense of self and individual value, so they recoil from conversations that ask them to see their place within broader legacies of settler colonialism, patriarchy, and capitalism. Accordingly, they hold on tight to status-quo stories of self-enclosed individualism to protect themselves, doubling down on their privilege to secure their status in a competitive world. However, it is important to see that status-quo stories of self- enclosed individualism also inform my students from historically oppressed and marginalized groups. These students suffer daily: they live in an environment that professes to celebrate “diversity,” while, in the context of their own lives, they are reminded again and again just how much they don't belong or matter. Not surprisingly, they demand “safe spaces” and protection for themselves and their peers, and they often draw hard lines between allies and enemies. Here too though, we see neoliberal stories at work. What matters for my students, and rightly so, is the way that “microaggressions”—those daily, mundane experiences of discrimination that accumulate over time-diminish their own capacities for flourishing as self-enclosed individuals. My point here is not to suggest that privileged students and marginalized students are the same because they are both invested in a version of self-enclosed individualism. Rather, my point is they share a situation; despite their different and unequal social positions, they have similar feelings-of defensiveness and a fear of failure—and status-quo stories in common. These commonalities do not imply evenness or equality, but rather interconnection, that is, a shared conjuncture. It is the recognition of this conjunctural interconnection that can thread our lives together and open up possibilities for more egalitarian futures. However, living in competition and the oppositional consciousness it demands obscure these commonalities and the interconnections that could bring students into new relations with one another. As a result, we stay caught up in the world as we know it. We stay stuck in competition, even though we all are yearning for different worlds. We desperately need new stories, stories that offer us different pathways to each other. As Keating puts it, we need stories that help us move from “me” to “we” consciousness.12 However, this book is not going to write these new stories for you. Rather, the goal of this book is to provide you with the resources for writing these new stories in and through your own lives. The Work of Critique Ultimately, writing new stories will require a new sense of yourself and your world, as well as what is possible, and realizing this new sense will require, first and foremost, cultivating a deeply critical orientation toward the world as we currently know and experience it. This critical orientation dislodges the sense of inevitability of neoliberalism, self-enclosed individualism, and living in competition; it knows that things don't have to be this way and, thus, senses the possibilities for resistance and transformation that are everywhere. It is so crucial to understand that this critical orientation is not simply about saying that aspects of neoliberal culture are “bad” or "wrong.” Rather, the work of critique is about seeing the flows of power and ways of thinking that make the neoliberal conjuncture possible and hold it together. Critique is therefore a mode of knowing—a form of everyday intellectual work—that is aimed at exposing the myriad workings of power and its status-quo stories. As Michel Foucault explains, “A critique is not a matter of saying that things are not right as they are. It is a matter of pointing out on what kinds of assumptions, what kinds of familiar, unchallenged, unconsidered modes of thought the practices that we accept rest.”13 To clarify Foucault's idea, let's think back to the student discussions of power and privilege discussed above. The work of critique is not simply about pointing out privilege, although this is, of course, vital work. The work of critique goes beyond pointing out what's wrong and seeks to unravel the socially constructed conjuncture in which these problems emerge and get negotiated. For only then can we step outside of the competitive, oppositional consciousness of neoliberal culture and begin to imagine a radically different future built on equality and shared security. This work of dislodging the inevitability of our conjuncture and its status-quo stories is hard but vital intellectual work that requires not only critique of our social world, but also transformation of ourselves. Indeed, truly critical work is always profoundly disruptive of our own identities and knowledges. This work can be immensely painful, as it strips away the certainty and comfort provided by status-quo stories. This work can also be, and should be, immensely joyful and life-giving, as it enables us to free ourselves from the status-quo stories and devastating limitations they put on our lives, imaginations, and social relationships. This mix of pain and joy at the heart of critical work comes from the way that critique asks us to “lose confidence” in our world. As feminist theorist Sara Ahmed writes, Losing confidence: it can be a feeling of something gradually going away from you, being eroded. You sense the erosion. You might stumble, hesitate, falter; things might gradually unravel so you end up holding onto the barest of threads. It might be an experience in the present that throws things up, throws you off balance.... When you lose confidence it can feel like you are losing yourself: like you have gone into hiding from yourself.4 Losing confidence in your world is thus a form of existential crisis —you are disoriented; your world is shattered. At the same time, losing confidence in status-quo stories means gaining confidence for resistance and transformation. We become bolder, less anxious, more optimistic, capable of social interconnection, political intervention, and acting on and from a place of commonality. This is real freedom. Critique is ultimately about unlearning our world so that we might reconstruct it anew. Losing confidence in neoliberal culture means being able to say no to it in the conduct of our daily lives. In these capacities for resistance, we gain confidence that another world might actually be better, worth opening ourselves up to, worth fighting for. We begin to cultivate what Henry Giroux calls educated hope. Educated hope is not “a romanticized and empty” version of hope; rather, it is a form of hope enabled by critique that “taps into our deepest experiences and longing for a life of dignity with others, a life in which it becomes possible to imagine a future that does not mimic the present.” With educated hope, our sense of who we are and of what might be possible shifts in profound ways. This is when those new worlds we are longing for open up. What’s to Come Each of the chapters that follow offer a variety of intellectual tools for mapping the neoliberal conjuncture. Taken together, they are designed to produce a holistic and thick understanding of neoliberalism and its myriad powers to shape our identities, sensibilities, social worlds, and political horizons. Having a thick understanding of neoliberalism means that you feel in your bones that there is nothing natural or inevitable about neoliberalism and its status-quo stories. It means that you understand that neoliberalism is the outcome of a range of contingent historical processes that have consequences across social, political, economic, and cultural fields. In other words, by the end of our journey, you'll know how our neoliberal conjuncture has been, and continues to be, constructed. You'll also, therefore, be able to sense the other worlds on the horizon that are just waiting to be constructed, so long as, together, we can develop the resources, capacities, and stories of interconnection for bringing them into being. More specifically, the book is divided into two sections. The first section, titled “Critical Foundations,” focuses on cultivating a broad, critical orientation toward neoliberal culture. The first chapter charts the rise of neoliberal hegemony through four historical phases. The goal is to illustrate exactly how competition came to be the driving cultural force in our everyday lives. As we will see, there is nothing natural or inevitable about neoliberalism. It was a political and class-based project to remake capitalism and liberal democracy that was conceived, organized for, and eventually won. In the second chapter, we delve into the world of neoliberal theory and its critical consequences. Here we'll explore exactly what neoliberal thinkers believe about the state, markets, and human actors, and what distinguishes neoliberalism from earlier schools of liberal thought. We'll also interrogate what I call the four Ds—disposability, dispossession, disimagination, and de- democratization—which, taken together, enable us to clearly see and articulate what is so devastating about the rise of neoliberalism. The third chapter examines the cultural powers specific to neoliberalism. Neoliberalism advances through culture, specifically through the promotion of an enterprise culture that works to impose competition as a norm across all arenas of social life. In order to see and specify how neoliberalism works through culture, we take contemporary education as a case study and unpack the entangled cultural powers of neoliberal governmentality, affect, and ideology. The second section is titled “Neoliberal Culture.” In these chapters, we explore the worlds of neoliberal labor, affect, and politics respectively, tracing what happens when our everyday lives as workers, individuals, and citizens become organized around living in competition. The fourth chapter examines how neoliberalism turns everyday life into a “hustle,” where all the contexts of daily life become animated by the demands of neoliberal labor. At stake here are the ways in which we are all hustling to get by, yet we stay radically divided from one another along lines of gender, race, and class thanks to the norm of self- enterprise. The next chapter hones in on what it feels like to inhabit enterprise culture by exploring neoliberal affect and the care of the self. As we already know, living in competition breeds widespread anxiety, not to mention depression and illness, making self-care an ongoing, pressing problem of everyday life. While neoliberal culture offers us plenty of tools for self-care that ultimately keep us stuck in our self-enclosed individualism, this chapter also considers how self-care might be a site for resistance and political intervention. The final chapter focuses on neoliberal politics, tracing what happens to citizenship and social action in our contemporary conjuncture. As we'll see, neoliberalism privatizes our political horizons by remaking democracy into a market competition for visibility and equality. Throughout this mapping of the neoliberal conjuncture, we will engage in a mode of critical work that will, hopefully, enable you to unlearn neoliberalism and thus begin to write new stories about our conjuncture—including both our commonalities and differences—and the alternative worlds we are yearning for. Indeed, our critical work will only matter to the extent that it opens up our individual and collective horizons to a future beyond living in competition.

# Case

### Adv

**Alt causes -- evergreening doesn't extend patent for the original product**

**Holman 20** [Chris Holman, Senior Fellow for Life Sciences & Senior Scholar @ Center for Intellectual Property x Innovation Policy, Professor at the University of Missouri-Kansas City School of Law. "Why Pharmaceutical Follow-On Innovation Should Be Eligible For Patent Protection", Geneva Network, 2-7-2020, accessed 9-5-2021, https://geneva-network.com/research/why-pharmaceutical-follow-on-innovation-should-be-eligible-for-patent-protection/] HWIC

Drug innovators are often accused of using secondary patents to “evergreen” the patent protection of existing drugs, based on an assumption that a secondary patent somehow extends the patent protection of a drug after the primary patent on the active ingredient is expired. As a general matter, this is a false assumption — a patent on an improved formulation, for example, is limited to that improvement and does not extend patent protection for the original formulation.

Once the patents covering the original formulation have expired, generic companies are free to market a generic version of the original product, and patients willing to forgo the benefits of the improved formulation can choose to purchase the generic product, free of any constraints imposed by the patent on the improvement. Of course, drug innovators hope that doctors and their patients will see the benefits of the improved formulation and be willing to pay a premium for it, but it is important to bear in mind that ultimately it is patients, doctors, and third-party payers who determine whether the value of the improvement justifies the costs.

Of course, this assumes a reasonably well-functioning pharmaceutical market. If that market breaks down in a manner that forces patients to pay higher prices for a patented new version of a drug that provides little real improvement over the original formulation, then it is the deficiency in the market which should be addressed, rather than the patent system itself.

For example, if a drug company is found to have engaged in some anticompetitive activity to block generic competition in the market for the original product once it has gone off patent, then antitrust and competition laws should be invoked to address that problem. If doctors are prescribing an expensive new formulation of a drug that provides little benefit compared to a cheaper, unpatented original product, then that is a deficiency in the market that should be addressed directly, rather than through a broadside attack on follow-on innovation. In short, if is found that secondary patents are being used in a manner that creates an unwarranted extension of patent protection, it is that misuse of the patent system which should be addressed directly, rather than through what amounts to an attack on the patent system itself.

#### All critiques of evergreening are wrong—it’s essential to encourage competition in the market, and improvements come in increments.

Thomas 09

John R. Thomas (Georgetown Law Center faculty, Visiting Scholar at the Congressional Research Service, inaugural Thomas Alva Edison Visiting Scholar at the U.S. Patent and Trademark Office);

Although the practice of evergreening has attracted considerable criticism, many observers believe these critiques are misplaced. Indeed, some consider the term “evergreening” to be inappropriate, and even derogatory in nature.62 They explain that the patent laws promote both original and improvement inventions, that most technological advance occurs incrementally, that improvements may be developed by competitors of the original innovator, that many improvement patents cover advances that are of considerable medical significance, and that patents on improvements may not impede the ability of competitors to market products that were covered by expired patents on original technologies. This report reviews these assertions in turn. First, these observers note that the patent system allows patents to be obtained on both original and improvement technologies. As a result, the patent law encourages the development of both kinds of inventions. They also explain that under the Patent Act, each invention must fulfill a number of requirements in order to be subject to patent protection. Among these criteria are that the invention must be novel,63 nonobvious,64 and fully disclosed in an application submitted to the USPTO.65 These statutory standards are applied neutrally to each kind of invention, whether it may be characterized as an “original” (such as a medication that has never been previously approved by the FDA) or an “improvement” (such as a new formulation of a known medication). Patent law experts believe that these legal standards appropriately recognize that most technological progress occurs on an incremental basis. Attorney Ivar Kaardal explains that “most patents ... are granted for incremental, or even insignificant, technological advances.”66 Some observers believe that, on an individual or collective basis, patents on more marginal improvements may provide the public with valuable sources of technological information. As Jeanne C. Fromer, a member of the Fordham Law School faculty, states: while there are a rising number of patents for incremental technical advances, which individually might not be commercially or informationally valuable, the collectivity of incremental advances provides essential information for further innovation in many areas… Some commentators also believe the critique that many “evergreen” patents represent trivial variations of earlier technologies is misplaced. They assert that many patented improvements provide significant practical benefits. For example, a new formulation may make a known medication easier to use, leading to greater patient compliance, or cause fewer side effects.68 Observers also note that the developer of the “original” product is not always the same entity as the developer of “improvement” technologies. Sometimes competitors of the “original” patent proprietor, including generic drug companies, develop and patent the improvements.69 The ability of any innovator to obtain a patent is said to encourage competition among different firms, both in innovation and in the marketplace.70

#### DIDN’T READ - The purpose of evergreening is to make money—medical advances are direct effects of the money big pharma makes.

Collier 13

Roger Collier (consultant specializing in health care policy issues, CEO of national healthcare consulting firm, Principal-in-Charge off KPMG’s national health and welfare consulting practice); “Drug patents: the evergreening problem”; CMAJ Vol. 185, Issue 9; June 11, 2013; <https://www.cmaj.ca/content/185/9/E385/tab-e-letters>; EMJ

“Typically, when you evergreen something, you are not looking at any significant therapeutic advantage. You are looking at a company’s economic advantage,” says Dr. Joel Lexchin, a professor in the School of Health Policy and Management at York University in Toronto, Ontario. “The response from the brand side is that they are trying to protect their markets so they can further invest in R&D [research and development]. And even if they make a modification to a drug, doctors are still quite able to prescribe the generic version of the older product. Having said that, the brand-name companies put an awful lot of money into marketing the newer version, and that marketing is designed to affect what doctors do.” Evergreening has been a hot topic of late because of the recent ruling by India’s Supreme Court to refuse to grant Swiss pharmaceutical company Novartis a patent for a new version of its cancer drug Gleevec (imatinib mesylate), or Glivec, as it’s known in some countries. Novartis claims the drug is more easily absorbed into the blood and, considering it is used to fight leukemia, that is enough of an improvement to warrant patent protection. But India’s trade and industry minister, Anand Sharma, has defended the decision, and was quoted by Agence France-Presse as saying it was “absolutely justified under the law” and that India’s patent law “does not accept evergreening.”

**UQness LBL**

#### PFAD--1] 22% of new drugs being innovative is a lot 2] its not a q of percentage but actual number--even if its more old than new theres still a lot of new medicines being created

#### Arnold Ventures--evergreening may create monopolies over specific drugs but not the drug market in general--that encourages innovation of new unpatented techniques or looking into more drugs which is good and what 1AC Hotez talks about--turns case and means they have zero internal link

#### Radhakrishnan--Only warrant is “pharma companies don’t spend a lot on R&D” which 1] is not true, the ev says its 1/6 which is a ton for big companies 2] is non-unique

### UQness

#### Investment in pharma high, waves of innovation

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]

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.

#### Innovation high now

Kenan 6-9, The Frank Hawkins Kenan Institute of Private Enterprise develops and promotes innovative, market-based solutions to vital economic issues. With the belief that private enterprise is the cornerstone of a prosperous and free society, the institute fosters the entrepreneurial spirit to stimulate economic prosperity and improve the lives of people in North Carolina, across the country and around the world. Kenan Institute, 6-9-21, “Turbocharging Healthcare Innovation” <https://kenaninstitute.unc.edu/kenan-insight/turbocharging-healthcare-innovation/> brett

As COVID-19 began to spread around the globe, companies and entrepreneurs stepped up to develop new technologies and redeploy existing technologies in their portfolio to tackle the disease and cope with the constraints it brought. The pandemic forced telemedicine into the mainstream and brought mRNA vaccine technology to the forefront. At the same time, new technologies such as CRISPR gene editing and artificial intelligence (AI) approaches have been finding their niche for speeding up drug discovery and development.

Healthcare innovation was already on the fast train before the pandemic. Now, it’s been turbocharged. In this Kenan Insight, we explore why the 2021 Trends in Entrepreneurship Report names emerging technology in the healthcare industry as a key trend for entrepreneurship, along with some of the challenges that come with fast-moving technology advances.

A trajectory of explosive growth

The healthcare industry has experienced extraordinary growth over the past four decades. Big pharma is driving much of this boom, accounting for 10% of the U.S. economy’s overall R&D spending at the end of 2020.1 The medical device industry, expected to generate $54.5 billion over the next four years, is another important player.2 This growth is catching the attention of investors. In 2020, health tech startups raised approximately $14 billion in venture capital funding, nearly double that of 2019.3 CB Insights estimates there are now 51 healthcare unicorns, defined as startups valued at $1 billion or more.

Health-tech venture funding reached record levels in 2020

Chart, bar chart, histogram

Description automatically generated

Source: Deloitte analysis of Rock Health’s Digital Health Funding Database

Innovation is a critical driver in the healthcare sector. Increasing rates of innovation can be seen in the sharp rise of U.S. patents granted for pharmaceuticals and medical devices in recent years. Between 2013 and 2019, more than 60,000 pharmaceutical patents and more than 125,000 medical device patents were granted.4 Today, there are more than 18,500 drugs at various stages of the development process worldwide.5

Maturing technologies

The increasing numbers of patent applications, clinical trials and collaborations are leading indicators of a vibrant and growing biopharmaceutical ecosystem. However, the proliferation of innovation tools, rather than just innovative products, is what will allow the next generation of pharmaceutical drugs to be discovered more quickly and more efficiently, to provide more effective treatments and to target diseases that have so far evaded our collective intervention efforts. As scientists learn more about human genes and their connection to diseases, these insights can feed into tools that make drug R&D faster, less expensive and more precise.

AI technology has matured to the point where it can now be used reliably to analyze huge amounts of data and solve extremely complex problems. This has made AI attractive to the pharmaceutical industry as a tool that can enable more efficient identification of new drugs and drug targets. In 2020, drug discovery was the focus area that received the most private AI investment, with more than $13.8 billion invested globally. This was 4.5 times higher than the total for 2019.6

CRISPR gene editing is another hot technology that is enabling the development of more innovative and accurate therapeutic strategies. This tool is making it easier to determine the genes and proteins that cause or prevent disease and thus to identify new targets for potential drugs. As of the second quarter of 2020, there were 724 active companies around the world focused on using or developing CRISPR technology and almost 50 clinical trials involving CRISPR.7

mRNA was certainly one of the brightest technology stars of 2020. After decades of research, mRNA proved to be the ideal solution for developing a highly effective COVID-19 vaccine at record speed. However, this is likely only the beginning of the story for mRNA. Therapies based on mRNA technology are being developed to treat malaria, cancer and multiple sclerosis and we’ll likely see more mRNA-based vaccines designed to fight a host of current and future infectious diseases. As of February 2021, CB Insights reports more than 520 ongoing clinical trials worldwide that were applying mRNA technology to more than 20 disease classes.8

#### Pharma innovation high now – monetary incentive is the biggest factor.

**Swagel 21** Phillip L. Swagel, Director of the Congressional budget office 4-xx-2021, "Research and Development in the Pharmaceutical Industry," Congressional Budget Office, <https://www.cbo.goc/publication/57126#_idTextAnchor020> SJ//DA

**Every year, the U.S. pharmaceutical industry develops a variety of new drugs that provide valuable medical benefits. Many of those drugs are expensive and contribute to rising health care costs for the private sector and the federal government. Policymakers have considered policies that would lower drug prices and reduce federal drug expenditures. Such policies would probably reduce the industry’s incentive to develop new drugs.** In this report, the Congressional Budget Office assesses trends in spending for drug research and development (R&D) and the introduction of new drugs. CBO also examines factors that determine how much drug companies spend on R&D: expected global revenues from a new drug; cost to develop a new drug; and federal policies that affect the demand for drug therapies, the supply of new drugs, or both. What Are Recent Trends in Pharmaceutical R&D and New Drug Approvals? T**he pharmaceutical industry devoted $83 billion to R&D expenditures in 2019. Those expenditures covered a variety of activities, including discovering and testing new drugs, developing incremental innovations such as product extensions, and clinical testing for safety-monitoring or marketing purposes. That amount is about 10 times what the industry spent per year in the 1980s, after adjusting for the effects of inflation.** The share of revenues that drug companies devote to R&D has also grown: **On average, pharmaceutical companies spent about one-quarter of their revenues (net of expenses and buyer rebates) on R&D expenses** in 2019, which is **almost twice as large a share of revenues as they spent in 2000.** That revenue share is larger than that for other knowledge-based industries, such as semiconductors, technology hardware, and software. The number of new drugs approved each year has also grown over the past decade. On averace, the Food and Drug Administration (FDA) approved 38 new drugs per year from 2010 through 2019 (with a peak of 59 in 2018), which is 60 percent more than the yearly average over the previous decade. **Many of the drugs that have been approved in recent years are “specialty drugs.” Specialty drugs generally treat chronic, complex, or rare conditions, and they may also require special handling or monitoring of patients**. Many specialty drugs are biologics (large-molecule drugs based on living cell lines), **which are costly to develop, hard to imitate, and frequently have high prices.** Previously, most drugs were small-molecule drugs based on chemical compounds. Even while they were under patent, those drugs had lower prices than recent specialty drugs have. Information about the kinds of drugs in current clinical trials indicates that much of the industry’s innovative activity is focused on specialty drugs that would provide new cancer therapies and treatments for nervous-system disorders, such as Alzheimer’s disease and Parkinson’s disease. **What Factors Influence Spending for R&D?** Drug companies’ R&D spending decisions depend on three main factors: Anticipated lifetime global revenues from a new drug, **Expected costs to develop a new drug**, and Policies and programs that influence the supply of and demand for prescription drugs. Various considerations inform companies’ expectations about a drug’s revenue stream, including the anticipated prices it could command in different markets around the world and the expected global sales volume at those prices (given the number of people who might use the drug). The prices and sales volumes of existing drugs provide information about consumers’ and insurance plans’ willingness to pay for drug treatments. Importantly, when drug companies set the prices of a new drug, they do so to maximize future revenues net of manufacturing and distribution costs. A drug’s sunk R&D costs—that is, the costs already incurred in developing that drug—do not influence its price. **Developing new drugs is a costly and uncertain process, and many potential drugs never make it to market. Only about 12 percent of drugs entering clinical trials are ultimately approved for introduction by the FDA. In recent studies, estimates of the average R&D cost per new drug range from less than $1 billion to more than $2 billion per drug**. Those estimates include the costs of both laboratory research and clinical trials of successful new drugs as well as expenditures on drugs that do not make it past the laboratory-development stage, that enter clinical trials but fail in those trials or are withdrawn by the drugmaker for business reasons, or that are not approved by the FDA. Those estimates also include the company’s capital costs—the value of other forgone investments—incurred during the R&D process. Such costs can make up a substantial share of the average total cost of developing a new drug. The development process often takes a decade or more, and during that time the company does not receive a financial return on its investment in developing that drug. The federal government affects R&D decisions in three ways. First, it increases demand for prescription drugs, which encourages new drug development, by fully or partially subsidizing the purchase of prescription drugs through a variety of federal programs (including Medicare and Medicaid) and by providing tax preferences for employment-based health insurance. Second, the federal government increases the supply of new drugs. It funds basic biomedical research that provides a scientific foundation for the development of new drugs by private industry. Additionally, tax credits—both those available to all types of companies and those available to drug companies for developing treatmentscof uncommon diseases—provide incentives to invest in R&D. Similarly, deductions for R&D investment can be used to reduce tax liabilities immediately rather than over the life of that investment. Finally, the patent system and certain statutory provisions that delay FDA approval of generic drugs provide pharmaceutical companies with a period of market exclusivity, when competition is legally restricted. During that time, they can maintain higher prices on a patented product than they otherwise could, which makes new drugs more profitable and thereby increases drug companies’ incentives to invest in R&D. Third, some federal policies affect the number of new drugs by influencing both demand and supply. For example, federal recommendations for specific vaccines increase the demand for those vaccines and provide an incentive for drug companies to develop new ones. Additionally, federal regulatory policies that influence returns on drug R&D can bring about increases or decreases in both the supply of and demand for new drugs. Trends in R&D Spending and New Drug Development Private spending on pharmaceutical R&D and the approval of new drugs have both increased markedly in recent years, resuming a decades-long trend that was interrupted in 2008 as generic versions of some top-selling drugs became available and as the 2007–2009 recession occurred. **In particular, spending on drug R&D increased by nearly 50 percent between 2015 and 2019.** Many of the drugs approved in recent years are high-priced specialty drugs for relatively small numbers of potential patients. By contrast, the top-selling drugs of the 1990s were lower-cost drugs with large patient populations. R&D Spending R&D spending in the pharmaceutical industry covers a variety of activities, including the following: Invention, or research and discovery of new drugs; Development, or clinical testing, preparation and submission of applications for FDA approval, and design of production processes for new drugs; Incremental innovation, including the development of new dosages and delivery mechanisms for existing drugs and the testing of those drugs for additional indications; Product differentiation, or the clinical testing of a new drug against an existing rival drug to show that the new drug is superior; and Safety monitoring, or clinical trials (conducted after a drug has reached the market) that the FDA may require to detect side effects that may not have been observed in shorter trials when the drug was in development. In real terms**, private investment in drug R&D among member firms of the Pharmaceutical Research and Manufacturers of America (PhRMA), an industry trade association, was about $83 billion in 2019, up from about $5 billion in 1980 and $38 billion in 2000**.1 Although those spending totals do not include spending by many smaller drug companies that do not belong to PhRMA, the trend is broadly representative of R&D spending by the industry as a whole.2 A survey of all U.S. pharmaceutical R&D spending (including that of smaller firms) by the National Science Foundation (NSF) reveals similar trends.3 Although total R&D spending by all drug companies has trended upward, small and large firms generally focus on different R&D activities. **Small companies not in PhRMA devote a greater share of their research to developing and testing new drugs,** many of which are ultimately sold to larger firms (see Box 1). By contrast, a greater portion of the R&D spending of larger drug companies (including those in PhRMA) is devoted to conducting clinical trials, developing incremental “line extension” improvements (such as new dosages or delivery systems, or new combinations of two or more existing drugs), and conducting postapproval testing for safety-monitoring or marketing purposes.

#### 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

As the pandemic spread across the globe in early 2020, biotech leaders were initially pessimistic, reassessing their cash position and financing constraints. When McKinsey and BioCentury interviewed representatives from 106 biotech companies in May 2020,4 half of those interviewed were expecting delays in financing, and about 80 percent were tight on cash for the next two years and considering trade-offs such as deferring IPOs and acquisitions. Executives feared that valuations would decline because of lower revenue projections and concerns about clinical-trial delays, salesforce-effectiveness gaps, and other operational issues.

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](https://www.mckinsey.com/industries/pharmaceuticals-and-medical-products/our-insights/on-pins-and-needles-will-covid-19-vaccines-save-the-world), 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](https://www.mckinsey.com/business-functions/m-and-a/our-insights/a-new-prescription-for-m-and-a-in-pharma) 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.

Looking forward, the combination of advances in biological science and accelerating developments in technology and artificial intelligence has the potential to take innovation to a new level. A [recent report](https://www.mckinsey.com/industries/pharmaceuticals-and-medical-products/our-insights/the-bio-revolution-innovations-transforming-economies-societies-and-our-lives) from the McKinsey Global Institute analyzed the profound economic and social impact of biological innovation and found that biomolecules, biosystems, biomachines, and biocomputing could collectively produce up to 60 percent of the physical inputs to the global economy. The applications of this “Bio Revolution” range from agriculture (such as the production of nonanimal meat) to energy and materials, and from consumer goods (such as multi-omics tailored diets) to a multitude of health applications.