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## Adv 1 - Innovation

#### **10 year analysis shows decline in innovation for the pharmaceutical industry.**

Terry and Lesser 19. [Colin is a Partner in the Life Sciences practice. He has been with Deloitte since 2011 working in the US firm, until 2014 when he moved to the UK practice. Colin’s client advisory work in the Life Sciences sector ranges across strategy and operations focused on the R&D function including operating model development and implementation as well as post-merger integration (PMI). These engagements have been serving client Boards and their senior leadership teams in R&D, Commercial and Supply Chain. Neil is a principal with Deloitte Consulting LLP in the Life Sciences strategy practice and a leader in the Research & Development strategy practice. He joined Deloitte in 1998 and works with life sciences executives creating and implementing strategies that drive productivity, efficiency, and value. He leads strategy, operating model design, productivity improvement, and large transformation initiatives within R&D and Regulatory Affairs. Neil is a frequent writer and speaker on R&D productivity.] 2019. Deloitte. “Ten Years On: Measuring the return from pharmaceutical innovation 2019.” Accessed 22 September 2021. <https://www2.deloitte.com/content/dam/Deloitte/uk/Documents/life-sciences-health-care/deloitte-uk-ten-years-on-measuring-return-on-pharma-innovation-report-2019.pdf> //MHES

Over the past ten years, our Measuring the return from pharmaceutical innovation series has tracked the return on investment that a cohort of 12 leading global biopharma companies might expect to achieve from their late-stage pipelines. For the past five years, we have also tracked the performance of an extension cohort of four, more specialised biopharma companies. This has enabled us to compare and contrast performance and deepen our insight into company and pipeline characteristics that drive R&D productivity. The analysis reveals a systemic cross-company, decade long decline in the productivity of R&D in our original cohort and a similar trajectory for our extension cohort. These findings reflect the R&D challenges of the industry more widely. While individual companies do experience short-term successes the effect of rising costs and declining sales on returns seems inescapable. A decade of analysis shows that all of our cohort companies have felt the impact of these challenges. This raises critical questions for the industry, the key one being how prepared are biopharma companies to transform their R&D modes? The answer will influence how companies determine their capital allocations over the next decade. At the pipeline level, key thresholds have been crossed more than half of pipelines are now biologics, and more than half of assets have been externally sourced. The implication remains the same-return on investment will not improve unless R&D productivity improves. The development of more targeted approaches to drug discovery and development is leading companies to adopt or optimise the use of much broader computational technology platforms. New, data driven R&D modes will inevitably emerge. With data and information driving drug development, we envisage some biopharma companies will become data organisations, while others will transition to a leaner, more focused science-based model with a research footprint within key innovation clusters and a growing revenue stream from specialty products and biologics. Within this changing landscape, what has stayed constant over the decade is that companies with deep knowledge of specific therapy areas consistently earn higher returns than those who go through cycles of re-invention in new therapy areas. This is a consistent observation that challenges some of the traditional value creation narratives. While it continues to be a challenge for leaders to unlock R&D productivity, we remain optimistic that the lessons from the last decade will help biopharma transition to a future where disease prevention and curative therapies transform care and improve the human condition. As always, we hope this report is engaging and thought provoking. We welcome feedback and look forward to discussing the implications of our findings.

#### **Patent thickets have created a tragedy of the anticommons – overlapping patent ownership results in underuse of biomedical inventions.**

**Heller and Eisenberg 98**. [At Columbia, Heller is the Lawrence A. Wien Professor of Real Estate Law, and he has served as the Vice Dean for Intellectual Life. Before joining Columbia Law in 2002, Heller taught at the University of Michigan Law School where he received the L. Hart Wright Award for excellence in teaching. He has taught at NYU, UCLA, and Yale Law Schools and was a fellow at the Center for Advanced Study in the Behavioral Sciences. Prior to entering academia, he worked at the World Bank on post-socialist legal transition. Heller served as a law clerk for Judge James Browning of the 9th Circuit Court of Appeals. Rebecca S. Eisenberg, the Robert and Barbara Luciano Professor of Law, specializes in patent law and the regulation of biopharmaceutical innovation. She teaches courses about patent law, trademark law, international intellectual property law, and FDA law, and runs workshops about intellectual property and student scholarship. She has written and lectured extensively about the role of intellectual property in biopharmaceutical research, publishing in leading law reviews and scientific journals. She spent the 1999–2000 academic year as a visiting professor of law, science, and technology at Stanford Law School and the spring of 2012 as a visiting scholar at the Berkeley Center for Law & Technology. Professor Eisenberg has played an active role in public policy debates concerning the role of intellectual property in biopharmaceutical research, advising the National Institutes of Health and the National Academies of Science. She practiced law as a litigator in San Francisco. She joined the Michigan Law faculty in 1984.] 1 May 1998. Science Magazine, vol. 280, pp. 698-701. “Can Patents Deter Innovation? The Anticommons in Biomedical Research” Accessed 7 September 2021. <DOI: 10.1126/SCIENCE.280.5364.698> //MHES

Anticommons property can best be understood as the mirror image of commons property (3, 8). A resource is prone to overuse in a tragedy of the commons when too many owners each have a privilege to use a given resource and no one has a right to exclude another (9). By contrast, a resource is prone to underuse in a "tragedy of the anticommons" when multiple owners each have a right to exclude others from a scarce resource and no one has an effective privilege of use. In theory, in a world of costless bio- transactions, people could always avoid commons or anticommons tragedies by trading their rights (10). In practice, however, avoiding tragedy requires overcoming transaction costs, strategic behaviors, and aged cognitive biases of participants (11), with success more likely within close-knit communities than among hostile strangers (12-14). Once an anticommons emerges, collecting rights into usable private property is often brutal and slow (15). Privatization in postsocialist economies starkly illustrates how anticommons proper ty can emerge and persist (3). One promise of the transition to a free market was that new entrepreneurs would fill stores that socialist rule had left bare. Yet after several years of reform, many privatized storefronts remained empty, while flimsy metal kiosks, stocked full of goods, mushroomed on the streets. Why did the new merchants not come in from the cold? One reason was that transition governments often failed to endow any individual with a bundle of rights that represents full ownership. Instead, fragmented rights were distributed to various socialist-era stakeholders, including private or quasi-private enterprises, workers' collectives, privatization agencies, and local, regional, and federal governments. No one could set up shop without first collecting rights from each of the other owners. Privatization of upstream biomedical research in the United States may create anticommons property that is less visible than empty storefronts but even more economically and socially costly. In this setting, privatization takes the form of intellectual property claims to the sorts of research results that, in an earlier era, would have been made freely available in the public domain. Responding to a shift in U.S. government policy (4) in the past two decades, research institutions such as the National Institutes of Health (NIH) and major universities have created technology transfer offices to patent and license their discoveries. At the same time, commercial biotechnology firms have emerged in research and development (R&D) niches somewhere between the proverbial "fundamental" research of academic laboratories and the targeted product development of pharmaceutical firms (7). Today, upstream research in the biomedical sciences is increasingly likely to be "private" in one or more senses of the term-supported by private funds, carried out in a private institution, or privately appropriated through patents, trade secrecy, or agreements that re strict the use of materials and data. In biomedical research, as in postsocialist transition, privatization holds both promises and risks. Patents and other forms of intellectual property protection for upstream discoveries may fortify incentives to undertake risky research projects and could result in a more equitable distribution of profits across all stages of R&D. But privatization can go astray when too many owners hold rights in previous discoveries that constitute obstacles to future research (16). Upstream patent rights, initially offered to help attract further private investment, are increasingly regarded as entitlements by those who do research with public funds. A researcher who may have felt entitled to coauthorship or a citation in an earlier era may now feel entitled to be a coinventor on a patent or to receive a royalty under a material transfer agreement. The result has been a spiral of overlapping patent claims in the hands of different owners, reaching ever further upstream in the course of biomedical research. Researchers and their institutions may resent restrictions on access to the patented discoveries of others, yet nobody wants to be the last one left dedicating findings to the public domain. The problem we identify is distinct from the routine underuse inherent in any well- functioning patent system. By conferring monopolies in discoveries, patents necessarily increase prices and restrict use-a cost society pays to motivate invention and disclosure. The tragedy of the anticommons refers to the more complex obstacles that arise when a user needs access to multiple patented inputs to create a single useful product. Each upstream patent allows its owner to set up another tollbooth on the road to product development, adding to the cost and slowing the pace of downstream biomedical innovation.

#### It's empirically proven – patent thickets deck innovation and prevent access to commercially viable drugs.

Woolman et al 13**.** [Professor Stu Woolman is Elizabeth Bradley Chair of Ethics, Governance and Sustainable Development, University of the Witwatersrand Graduate School of Business Administration and Academic Director, Colloquia and Symposia, South African Institute for Advanced Constitutional, Public, Human Rights and International Law. He received his BA from Wesleyan University, his MA from Columbia University, his JD from Columbia Law School, and his PhD from the University of Pretoria. \*\* Dr. Elliott Fishman is Chief Executive Officer of Astrina Capital. He was, until recently, an Assistant Professor at the Howe School of Technology Management, Stevens Institute of Technology. He received his BSE from Duke University; his MBA from The Wharton School, University of Pennsylvania; and his PhD from the University of Pennsylvania. \*\*\* Dr. Michael Fisher is an Associate at Dechert LLP. He received his BS and MS from the University of Rochester, his JD from Columbia Law School, and his PhD from the University of Rochester.] 27 January 2013. The Intellectual Property Law Review, vol. 53, no. 1, pp. 1-38. “EVIDENCE OF PATENT THICKETS IN COMPLEX BIOPHARMACEUTICAL TECHNOLOGIES” Accessed 5 September 2021. <https://ipmall.law.unh.edu/sites/default/files/hosted\_resources/IDEA/idea-vol53-no1-woolman-fishman-fisher.pdf > //MHES

Row 1 of Figure 4 shows data for Lipitor, a best-selling drug; the number of patents upon which this drug relies (5); U.S. sales in billions of dollars in 2007 ($6.165); the manufacturer of the drug (Pfizer); the number of patent owners (or “assignees”) per drug of the various patents upon which the drug relies (1); and the number of licenses as reflected by USPTO data. b. Descriptive Statistics The following table provides descriptive statistics about drug sales by the U.S. pharmaceutical industry. The table summarizes information in the Appendix. We note that the median number of patents covering each drug was roughly three per drug while the median number of patents pharmaceutical companies licensed was one. The highest number of licenses was three, and the most frequent number of licenses was zero. These numbers provide further quantitative evidence of a strong thicket effect. Were patents to be licensed more easily, the highest number would be far greater than three. We also note that out of the top 200 drugs sold in the U.S. in 2007, thirty-eight (19%) had no currently enforceable patents associated with them. Whether patents had never covered them, or the patents covering them have now expired, these drugs are susceptible to competition from generic drug manufacturers and tend to sell at much lower margins than drugs covered by patents still in force. For drugs not covered by any unexpired patents, no thicket effects exist because it is not necessary to procure patent licenses. We therefore eliminated them from our study. c. Experimental Method As discussed in the hypothesis section above, we developed an equation designed to identify the presence of a strong thicket. Note that this strong thicket equation has two regions, each with a different form, depending on whether the value of N is greater than or less than NT. Strong thicket: P = P1 N for N < NT; and P = P1 N (1 – M (N – NT)) for N > NT. For the strong thicket equation, we calculated the frequency distribution of the top selling drugs having 0, 1, 2, 3, and 4 licenses. The results are reflected in the histogram above (Figure 3). Then we wrote a custom software program to regress these data points with the equation for the strong thicket. The resulting parameters, P1, NT and M were written to a file. We confirmed the fit of these parameters by using a chi-square test with two degrees of freedom for each function. IV. EMPIRICAL RESULTS AND DISCUSSION The regression of the strong thicket function yielded the following parameter values: P1 = 0.4136 NT = 0.7656 M = 0.3447 The results are presented graphically in Figure 6 below. Number of licenses Figure 6: Strong Thicket The salient observation is that the strong thicket curve intersects the zero probability line by the time a fourth license is required to commercialize a drug. In other words, virtually no possibility exists for a licensing manager to negotiate successfully with four separate patent owners. This conclusion provides compelling evidence for the presence of a patent thicket in complex biopharmaceutical technologies. V. CONCLUSIONS, IMPLICATIONS & FUTURE RESEARCH AGENDAS Rights to a unified patent estate, not just ownership of one patent, are usually necessary to manufacture and market a new drug. Our data shows that most commercialized drugs rely on two or more patents for their production process, formulation, or delivery system. Whenever a biopharmaceutical firm lacks all the requisite patent rights, it must negotiate licenses with other patentees. This requirement may explain the extensive number of intercompany partnerships, collaborations, and joint ventures in biotechnology.76 Our conclusions prompt two further questions. Should the industry generally sanction flexible patent licensing transactions? Or, should the industry maintain a more rigid, permanent assignment of patent rights? Our study suggests that biopharmaceutical patents are more often assigned than licensed. In fact, our data compilation in the Appendix reveals only 102 patent licensing agreements among the 200 leading pharmaceuticals. Given the extent of inter-firm cooperation, one would expect numerous licenses per drug. We found, however, that, on average, only one out of every two drugs relies on licensed-in patents. While approximately 50% of our sample depended on patents licensed from three patentees or less, there are no documented cases of drugs relying on rights from four or more patentees (Figure 6). The scarce number of licensing transactions and dearth of multipleparty transactions lends credence to the anticommons hypothesis of Heller and Eisenberg—that exponentially increasing transaction costs, heterogeneous interests, cognitive biases, and attributive biases impede innovation in biomedicine. Our theoretical model and empirical results support the existence of patent thickets with respect to the commercialization of drugs that require complex— as opposed to discrete—biopharmaceutical technologies. We quantify those thicket effects as follows: (1) it first appears significantly when the seller must acquire a license from two or more patent owners; (2) it becomes quite pronounced when the seller must acquire a license from three or more patent owners; and (3) where four or more patent owners exist, the thicket effect makes negotiating the necessary licenses virtually impossible. We derived mathematically parameters for the sharp drop off between steps (1) and (3) above. Numerous opportunities exist to extend this initial study. First, our data was sampled at the level of the patent license. We could not explore the underlying cause of any given patent thicket—despite new methods for their objective identification—because most of the information regarding the failure to secure a successful patent estate is rarely, if ever, made public. Are transaction costs, heterogeneous interests, cognitive biases, or attributive biases the greatest impediments to complex biopharmaceutical technology innovation? Or does (a) the onerous nature of FDA approval, (b) comparatively small potential markets for viable drugs, or (c) opting out (for myriad reasons) by companies that might otherwise bring a complex biopharmaceutical technology to market, provide complimentary, though not contradictory, explanations for this peculiar form of market failure? Second, our analysis benefitted from the ease by which we secured publicly accessible data. As a result, we have looked only at the U.S. biopharmaceutical industry. To what extent do thickets in complex biopharmaceutical technologies interfere with patent licensing activity and downstream commercialization of drugs in other parts of world? A study conducted in South Africa or Brazil might reveal a different pattern: this pattern would reflect a strong intellectual property rights regime that governs a somewhat less fecund biopharmaceutical research and development environment.77 One might expect diminished thicket effects in countries governed by more relaxed patent laws and compulsory licensing. France is an excellent example of such a jurisdiction. But for the comparison to be meaningful, one must simultaneously ask whether such jurisdictions produced significant amounts of commercially viable products within the domain of complex biopharmaceutical technologies. Finally, our study derived particular strong thicket functions and their parameters from relatively recent data. Future research may reveal whether our model is robust enough to be used for predictive purposes. Certain policy implications flow from our conclusion that strong patent thickets exist with respect to complex biopharmaceutical technologies. In recent years, there have been movements to reform the patent systems around the world and unwind some of the strength patent owners secured during the end of the last millennium.78 While a rigorously enforced patent system may optimize social welfare,79 such a patent system presupposes that economically rational actors can and will pre-negotiate agreements to resolve ownership of IP rights of downstream products.80 The observed failure of patent holders to pre-negotiate where four or more licenses are required suggests that market externalities create strong thickets that no licensing manger in the biopharmaceutical industry will be able to overcome.81 As we noted at the outset, most socially desirable drugs do not flow from discrete biopharmaceutical technologies that do not require negotiations. As a result, anyone concerned with the interaction of patents, innovation and socially desirable drugs ought to turn their attention to the vexed question of how we can best overcome the various obstacles to the commercial viability present in drugs derived from complex pharmaceutical technologies. A new and more nuanced regulatory regime can, and should, be designed to nudge patent holders and manufacturers into overcoming the various biases that create patent thickets and thereby prevent commercially viable drugs based upon complex biopharmaceutical technologies from being brought to market.82

#### **Pharmaceutical innovation key to combat antibiotic-resistant bacteria.**

Bagozzi et al 20. [Daniela Bagozzi -- Senior Information Officer, Tarik Jasarevic--Spokesperson / Media Relations, Fadela Chaib--Communications Officer and Spokesperson] 17 January 2020. World Health Organization. “Lack of new antibiotics threatens global efforts to contain drug-resistant infections.” Accessed 22 September 2021. <<https://www.who.int/news/item/17-01-2020-lack-of-new-antibiotics-threatens-global-efforts-to-contain-drug-resistant-infections>> //MHES

Declining private investment and lack of innovation in the development of new antibiotics are undermining efforts to combat drug-resistant infections, says the World Health Organization (WHO). Two new reports reveal a weak pipeline for antibiotic agents. The 60 products in development (50 antibiotics and 10 biologics) bring little benefit over existing treatments and very few target the most critical resistant bacteria (Gram-negative bacteria). While pre-clinical candidates (those in early-stage testing) are more innovative, it will take years before they reach patients. “Never has the threat of antimicrobial resistance been more immediate and the need for solutions more urgent,” says Dr Tedros Adhanom Ghebreyesus, Director-General of WHO. “Numerous initiatives are underway to reduce resistance, but we also need countries and the pharmaceutical industry to step up and contribute with sustainable funding and innovative new medicines.” The reports (Antibacterial agents in clinical development – an analysis of the antibacterial clinical development pipeline and its companion publication, Antibacterial agents in preclinical development) also found that research and development for antibiotics is primarily driven by small- or medium-sized enterprises with large pharmaceutical companies continuing to exit the field. Clinical development review WHO in 2017 published the priority pathogens list, 12 classes of bacteria plus tuberculosis that are posing increasing risk to human health because they are resistant to most existing treatments. The list was developed by a WHO-led group of independent experts to encourage the medical research community to develop innovative treatments for these resistant bacteria. Of the 50 antibiotics in the pipeline, 32 target WHO priority pathogens but the majority have only limited benefits when compared to existing antibiotics. Two of these are active against the multi-drug resistant Gram-negative bacteria, which are spreading rapidly and require urgent solutions. Gram-negative bacteria, such as Klebsiella pneumoniae and Escherichia coli, can cause severe and often deadly infections that pose a particular threat for people with weak or not yet fully developed immune systems, including newborns, ageing populations, people undergoing surgery and cancer treatment. The report highlights a worrying gap in activity against the highly resistant NDM-1 (New Delhi metallo-beta-lactamase 1), with only three antibiotics in the pipeline. NDM-1 makes bacteria resistant to a broad range of antibiotics, including those from the carbapenem family, which today are the last line of defence against antibiotic-resistant bacterial infections. “It’s important to focus public and private investment on the development of treatments that are effective against the highly resistant bacteria because we are running out of options,” says Hanan Balkhy, WHO Assistant Director-General for Antimicrobial Resistance. “And we need to ensure that once we have these new treatments, they will be available to all who need them.” On a more positive note, the pipeline for antibacterial agents to treat tuberculosis and Clostridium difficile (which causes diarrhea) is more promising, with more than half of the treatments fulfilling all the innovation criteria defined by WHO. Preclinical development review The pre-clinical pipeline shows more innovation and diversity, with 252 agents being developed to treat WHO priority pathogens. However, these products are in the very early stages of development and still need to be proven effective and safe. The optimistic scenario, the report indicates, is for the first two to five products to become available in about 10 years.

#### Antimicrobial resistance is an existential threat, it’s nonlinear, and has an invisible tipping point

Silverman ’16 (Rachel Silverman – MPhil with Distinction in Public Health @ the University of Cambridge, Senior Policy Analyst and Assistant Director of Global Health Policy @ the Center for Global Development, focusing on global health financing and incentive structures, “Confronting Antimicrobial Resistance: Can We Get to Collective Action?” 19 April 2016, https://www.cgdev.org/blog/confronting-antimicrobial-resistance-can-we-get-collective-action)

Antimicrobial resistance is already causing huge harm – and the worst is yet to come. To open the panel, Dr. Chan issued a serious warning about the size and scope of the AMR threat: “everyone will be affected if we do not address this problem.” AMR is already responsible for an estimated 700,000 global deaths each year, 50,000 of which take place in the US and Europe. Extensively drug-resistant (XDR) tuberculosis—cases where the most effective first- and second-line drugs are rendered useless—infected an estimated 47,000 people worldwide in 2014, only one ‘last-line’ antimicrobial is available to reliably treat gonorrhea, and few new antimicrobial drugs are in the development pipeline. According to the latest review, AMR could cause 10 million deaths each year by 2050, with knock-on effects draining many trillions from the global economy. Summers suggested that AMR and potential pandemics, alongside climate change and nuclear proliferation, represent the top three existential threats to life on earth as we know it. And as Dr. Chan explained, the worst-case scenario implies the end of modern medicine as we know it. Even worse, Summers suggested that AMR seems like a “quintessential non-linear phenomenon, and therefore more dangerous.” Year by year the effects are small and mostly invisible. But at some point in the future they could suddenly become catastrophic, like a “levee that doesn’t hold and unleashes a flood.” Dr. Chan concurred that “the tipping point is not predictable because…microbes are invisible. We don’t even know when they’re going to make the switch” to become resistant to existing drugs. Antimicrobial efficacy is a global public good threatened by serious market failures.

## **Adv 2 - China**

#### **Thickets lock in monopolies, deterring biosimilars and their domestic manufacture.**

Brill and Robinson 5/24. [Alex Brill is the CEO of Matrix Global Advisors (MGA). He previously served on the staff of the House Ways and Means Committee and the White House Council of Economic Advisers. Christy Robinson is a director at MGA.] 24 May 2021. Matrix Global Advisors. “How Patent Thickets Constrain the US Biosimilars Market and Domestic Manufacturing” Accessed 12 September 2021. <<http://getmga.com/wp-content/uploads/2021/05/PatentThickets_May2021_FINAL.pdf>> //MHES

There is no mistaking the intent behind originators’ efforts to obtain, on a single product, scores of patents with overlapping protections — many sought well after the product has launched. During his tenure as Food and Drug Administration (FDA) Commissioner, Scott Gottlieb (2018) described patent thickets around reference biologics as “purely designed to deter the entry of approved biosimilars.” As such, patent thickets have strictly negative consequences for US patients and payors, without the countervailing benefits that appropriate intellectual property protection offers. These negative consequences are all the greater because patent thickets have proven to be such an effective way for originators to preserve monopolies and continue to charge high prices. A recent analysis from the Biosimilars Council (2019) estimated the cost of patent thickets to US patients and payors by looking at the biosimilars that had been approved by the FDA but were unable to launch because of patent thickets. The analysis found that, from 2012 to 2018, the US healthcare system lost out on $7.6 billion that biosimilars of five reference biologics (Avastin®, Enbrel® Herceptin®, Humira®, and Rituxan®) could have saved. Of these five biologics, Enbrel® and Humira® — with 2019 US sales of more than $5 billion and nearly $15 billion, respectively — still do not have biosimilar competitors on the market. If left unchecked, patent thickets will continue to prevent savings from being realized on other biologics. Demonstrating the scale of US patent thickets, a 2018 study from I-MAK documented the excessive number of patents that originators obtained on the 12 best-selling drugs in the United States, eight of which are biologics (Avastin®, Enbrel®, Eylea®, Herceptin®, Humira®, Lantus®, Remicade®, and Rituxan®). According to I-MAK (2018), the number of granted US patents on these eight biologics ranged from 41 (on Enbrel®) to 132 (on Humira®). To better understand the sheer magnitude of patent thickets on US reference biologics, consider comparable patent litigation in Germany and the UK, the two largest European biologics markets, related to the 20 FDA-approved biosimilars that have European counterparts. The UK has seen only 16 patents asserted and Germany only one patent asserted compared to the 279 patents that have been asserted in the United States for these reference biologics. (See Section V for a more in-depth look at the drastically higher number of patent litigations in the United States compared with Germany and the UK, and a discussion of why patent thickets are a bigger problem in the United States.) Factors Contributing to Patent Thickets Certain factors within the US patent system facilitate originators’ efforts to establish patent thickets around reference biologics. These include incentives and opportunities for originators to seek patents, costs and uncertainties for potential competitors in challenging patents, and longstanding issues at the US Patent and Trademark Office (PTO), among other factors. INCENTIVES AND OPPORTUNITIES TO BUILD PATENT THICKETS As mentioned above, originators have a strong incentive to amass as many patents as possible on reference biologics with high asset value. They also have ample opportunity to accumulate patents. There is no cap on the number of patent applications an originator can file for a single product, and patent applications can be filed long after a product is established on the market. Originators face relatively low barriers in applying for patents, as the direct cost to obtain a patent and maintain it until it expires is typically less than $25,000. US patent applications for the eight best-selling biologics identified in I-MAK (2018) averaged 147 per product, with 53 percent of these applications resulting in patents. To date, there is no statutory prohibition on creating a patent thicket to inhibit biosimilar competition (Richards et al., 2020). Lawmakers have lately made proposals aimed at curtailing this behavior, but, for now, it is entirely up to biosimilar manufacturers to clear or find ways to work around the scores of patents that originators are able to obtain. COSTS AND UNCERTAINTIES FOR CHALLENGERS Biosimilar manufacturers face substantial cost and uncertainty in challenging a patent, particularly compared to the ease with which originators can obtain patents. Patent litigation is time-consuming and costly. While legislation in 2011 created an avenue for challenging a patent at the PTO and avoiding the cost of a lawsuit, this is still an expensive endeavor. The process, known as inter partes review (IPR), has a median cost of $324,000 (Richards et al., 2020) and is more expensive when a biologic is in question — likely up to $1 million per IPR per patent. Biosimilar manufacturers face substantial cost and uncertainty in challenging a patent, particularly compared to the ease with which originators can obtain patents. Also problematic is the fact that an IPR may go nowhere. After a petition for IPR is filed, it is submitted to the Patent Trial and Appeal Board (PTAB) within the PTO, but the PTAB can simply decline to institute review at its discretion. Since 2015, the PTAB’s rate of institution has been falling. In fiscal year 2016, 67 percent of petitions were instituted, dropping to 56 percent in fiscal year 2020 (PTAB, 2020). The timing of an IPR can also be tricky. In the United States, biosimilar applicants are hindered from filing IPRs early because a company that has not yet filed an application with the FDA may not have standing to appeal a negative IPR decision. Additionally, a company that files an IPR can lose standing to appeal if development of the drug at issue is stalled while the IPR appeal is pending. A 2020 Federal Circuit case illustrates the risks for a biosimilar manufacturer in challenging a patent at an early stage. The case centered around Pfizer filing for IPR to challenge the validity of Chugai’s patents relating to Ruxience®. Several of the IPRs failed, and Pfizer sought to appeal the decision to the Federal Circuit. The court noted that Pfizer failed to establish standing to appeal because, at the time the appeals were filed, Pfizer’s biosimilar of Ruxience® had not received FDA approval. As discussed below, later challenges to patents face a denser thicket that has been able to grow while a biosimilar is in development. SYSTEMIC PROBLEMS AT THE PATENT AND TRADEMARK OFFICE There are numerous reasons why originators are able to obtain excessive numbers of patents at the PTO. Procedures and incentives are two of the most important reasons. Procedures. The patentability rules used by the PTO make it easy to amass patents around a single invention. There is no limit to the number of “child patents” that can be filed from a single patent filing. And a loose approach to claim amendments allows patent owners to file child patents with only incrementally different claim wording. Objections to “double-patenting” (patenting the same invention twice) are relatively easy to circumvent. Moreover, even if a US patent examiner issues a final rejection against a patent application, a patent applicant can pay a fee and file a “request for continued examination” an unlimited number of times. Incentives. The PTO evaluates examiner performance based on a “count system.” Because examiners receive a higher count for a patent grant than for other actions, examiners have an incentive to work with applicants to obtain the higher count value. Experts and scholars have documented longstanding problems at the PTO that result in the issuance of invalid patents (see, for example, Lemley and Sampat (2012) and Ford (2013)). On reference biologics specifically, FY 2013–2018 data published by the PTAB on petitions challenging biologic patents show that fewer than a quarter of instituted claims were found to be patentable (Ankenbrand and Repko, 2019). FY 2013–2018 data published by the PTAB on petitions challenging biologic patents show that fewer than a quarter of instituted claims were found to be patentable. This is not to say that patent examiners are individually to blame for the rise of patent thickets. But the reality is that the PTO is an imperfect arbiter of intellectual property, and originators are able to capitalize on this, leaving biosimilar manufacturers — and consumers — to bear the burden. Consider reference biologic patents and related litigation in Germany and the UK compared to the United States. Germany and the UK are the two largest European biologics markets, and their patent litigation courts are among the most experienced in Europe. To date, there are 20 biosimilars that have received FDA approval that have also been submitted to the European Medicines Agency. Across these 20 biosimilars, 279 patents have been asserted in the United States, 16 patents in the UK, and only one patent in Germany (see Chart 1). Looking at specific products, manufacturers of biosimilars of Herceptin® that did not settle with the originator prior to litigation have been sued on an average of 35 patents in the United States, while only five Herceptin® patents were asserted in the UK and only one in Germany. In the case of Rituxan®, the originator asserted an average of 32 patents in the United States against biosimilar applicants who did not have a pre-litigation settlement. In the UK, the originator asserted an average of three patents. No Rituxan® patents were asserted in Germany. Several factors seem to contribute to the lower number of patents and the relative lack of patent litigation in Germany and the UK compared to the United States. First, some have argued that patent examination at the European Patent Office (EPO), and thus patents themselves, are of higher quality in Europe than in the United States For example, EPO President Benoît Battistelli has insisted that the EPO’s lower rate of granting patents is indicative of the better quality of review and greater soundness of patents in Europe compared to the United States (Chung, 2016). If this is true, it would make sense that better quality control at the EPO would weed out lower-quality secondary patents. US Patent Thickets in Context Patent thickets around reference biologics are a much more significant problem in the United States than they are in other countries. Comparing patent landscapes in other major markets has some limitations because the criteria and processes for granting and challenging patents can differ. But it is worth making some broad observations. Second, in Europe, patents can be challenged in the first nine months through opposition procedures at the EPO, or later through litigation (Moorkens et al., 2020). Opposition procedures are inexpensive, with a current fee of €815. This allows invalid patents that have been granted to be cleared quickly. In addition, in Europe, third parties can challenge the validity of patents at any stage during the development of their biosimilar. The equivalent tool in the United States is IPR, discussed above. However, compared to European patent oppositions, IPR is less accessible to third parties, in particular due to issues with standing. As noted earlier, biosimilar applicants in the United States may not be able to appeal a negative validity decision until their biosimilar application has been filed at the FDA, which can be 10 years or more following patent grant. Consider, for example, biosimilars of Herceptin®. Patents covering Herceptin® were filed in the United States and Europe in the early 1990s. The first EPO opposition was filed in 1996. Nine more European patents were opposed between 2000 and 2010, seven were opposed between 2011 and 2016, and six were opposed in 2017 and 2018. In the United States, the Herceptin® patent thicket was able to grow unchecked by thirdparty challenges until the first IPR was filed in 2015. Eight IPRs were filed in 2016, and 33 IPRs were filed in 2017. Despite these efforts, the first Herceptin® biosimilar applicant was sued under 40 US patents in January 2018, and three other applicants were sued under 40, 37, and 21 US patents, respectively. Impact of Patent Thickets on Domestic Manufacturing One consequence of patent thickets in the United States that is not well understood is the barrier they create to the domestic production of biosimilars. This is particularly important in light of the current interest among some policymakers, Democrats and Republicans alike, in encouraging more domestically produced prescription drugs. “Buy American” is only a viable option if manufacturers can produce in America without infringing US patents. At present, drug manufacturers are at legal risk if they manufacture or stockpile biosimilars for commercial launch in the United States before patents expire or patent litigation is resolved. Biosimilar manufacturer Hospira learned this the hard way in Amgen v. Hospira when Amgen was awarded $70 million in damages for Hospira’s infringement of an Epogen® process patent, despite Hospira not actually selling its biosimilar on the US market (Ainsworth and Bruns, 2020). Because manufacturing a biosimilar in preparation for market entry requires up to 12 months, a biosimilar firm needs to manufacture its product in a country where the patent situation is predictable. The vast majority of the time, this will not be the United States. Once manufacturing is up and running, a biosimilar firm is unlikely to move its operations to another country, as it can take years to transfer the technology, adding risks and costs. In other words, the jobs and economic activity associated with manufacturing US biosimilars will often be located outside the United States. The European Union, in an effort “to foster the competitiveness of EU producers of generic medicines and biosimilar products,” created an exception in 2019 that allows production and stockpiling of generic and biosimilar medicines before expiration of a supplementary protection certificate (a certificate that extends patent life in Europe) (European Council, 2019). Over 10 years, the new EU regulation is expected to result in net export sales of biosimilars and generic medicines of more than €1 billion annually, and potentially 20,000–25,000 jobs (Ibid.). As patent attorneys who called attention to this consequence of the US patent system said in 2018, “While there may be other reasons not to manufacture in the U.S., there is no reason why the U.S. patent system should effectively force companies to manufacture abroad” (Rein et al., 2018). Establishing an exception policy in the US like the one the EU recently instituted would reduce some of the barriers to manufacturing biosimilars in the United States but may be insufficient because of the layering and overlapping of patents in the United States described earlier. Despite the many advantages of manufacturing in the United States, uncertainty about a biosimilar manufacturer’s ability to avoid patent infringement in the United States will still drive manufacturing to foreign markets. While many reference biologics are manufactured domestically, market research expert Dawn Ecker predicts that, in the next few years, Europe will overtake the United States as the leader in biologic manufacturing (CPhI, 2019). This illustrates both the current success of US biologic manufacturing and a concerning trend for those interested in growing the US share of global biologic production. It also suggests that technical, regulatory, and manufacturing costs in the US are not insurmountable barriers and lends support to the view that domestic biosimilar manufacturing may be strongly deterred by patents.

#### US has become heavily dependent on China for the production of generics.

Ferry **20.** [Jeff Ferry is chief economist at the Coalition for a Prosperous America (CPA).] 17 March 2020. Industry Week. “It’s Time To Rebuild Domestic Drug Production in the US, for Both Health and Economic Reasons” Accessed 12 September 2021. < <https://www.industryweek.com/the-economy/article/21126380/its-time-to-rebuild-domestic-drug-production-in-the-us-for-both-health-and-economic-reasons>> //MHES

With breathtaking speed, the coronavirus has revealed a previously overlooked vulnerability in the U.S. economy. The United States has become heavily dependent on China and other countries to supply many of the medicines used in everyday life. In the wake of the current pandemic, policymakers are exploring how to rebuild America’s domestic drug capability. A new analysis from our organization the Coalition for a Prosperous America (CPA) demonstrates that the economic benefits of rebuilding this domestic capability would be significant, including the creation of 804,000 high-paying manufacturing jobs. Over the past 20 years, U.S. pharmaceutical companies have progressively outsourced and offshored the manufacture of prescription medicines, generic drugs, and over-the-counter medications. Although Ireland has become a popular manufacturing location for some small-batch prescription medicines, China and India have taken the largest share of the production of generics and over-the-counter medications. Ironically, it is these low-cost medications that Americans now depend on when treating the coronavirus. Pharmaceutical expert Rosemary Gibson has authored a book, China RX, regarding the dangers of America’s dependence on China for key medications. Last week, Gibson—who is also a CPA member—testified in the Senate that three commonly used antibiotics—azithromycin, ciprofloxacin, and piperacillin/tazobactam—depend on ingredients manufactured only in China. Such reliance on China even extends to common household medicines; the U.S. imports 95% of its ibuprofen and 70% of its acetaminophen from China. China is well aware of the strategic importance of pharmaceutical manufacturing. In a speech last year, Chinese economist Li Daokiu bluntly explained China’s strategic options at a National People’s Conference event in Beijing: “We are at the mercy of others when it comes to computer chips, but we are the world’s largest exporter of raw materials for vitamins and antibiotics. Should we reduce the exports, the medical systems of some western countries will not run well.” The U.S. can and must bring home the manufacture of these vital pharmaceuticals. CPA’s economic modeling of the potential restoring of pharmaceutical production finds huge benefits for the U.S. economy. Last year, the United States imported $128 billion worth of pharmaceuticals. That makes it the third largest category of imports, even ahead of cellphones. Our trade deficit in pharmaceuticals was $74 billion. CPA’s economic modeling set a reasonable goal of increasing U.S. pharmaceutical production by $66 billion—the amount of annual production lost to pharmaceutical imports since 2010. We found that boosting U.S.-based pharmaceutical manufacturing to 2010 levels would increase U.S. jobs by 804,000 and raise U.S. gross domestic product (GDP) by $200 billion. In the pharmaceutical manufacturing industry specifically, reshoring would increase jobs by 62%. Federal data shows that, in 2018, there were 294,250 workers employed in pharmaceutical and medicine manufacturing, with a median income of $74,890. That’s 47% higher than the median for all private-sector employees. A boost to this sector would provide thousands of additional high-paying jobs at manufacturing plants across the country. The economic model is an illustrative exercise. We cannot bring back all of these jobs and factories overnight. The government should sit down with our leading pharmaceutical companies and develop a three-year plan to reshore production of vital medicines—beginning with those most crucial for fighting the coronavirus. It should do the same for ventilators, face masks, and other essential health care accessories. In the current Democratic presidential battle, Senator Bernie Sanders has repeatedly and correctly pointed out that pharmaceutical companies earn huge profits. As one example, Pfizer earned net income of $16.3 billion last year on revenue of $51.8 billion, a stunning net profit rate of 31.5%. There are very few billion-dollar companies in the world able to report such net profit rates. Sanders wants to increase taxes on corporations to redistribute some of those billions. But what he and many politicians in both parties fail to understand is that before the 1980s—before the rise of the “shareholder value” doctrine—there were two ways to redistribute excessive corporate profitability. One was via the tax system. The other was via a large manufacturing supply chain that paid workers well when the companies did well. That’s why the pharmaceutical sector pays its workers 47% more than the average worker. That’s why we had a greater sense of shared purpose in the U.S. between workers and employers 50 years ago. In 2007, Pfizer announced that it would outsource 30% of its manufacturing to Asia, lay off 10,000 employees, and deliver $2 billion in savings to its shareholders. That was a catastrophic decision. The senior managers at Pfizer are not bad people. Many of them are doctors and research chemists who have devoted their lives to finding cures for illnesses. But they are trapped in a system that rewards socially unproductive activity. That system is called shareholder value. Our first priority today must be reshoring production of the most vital medications. Our medium-term priority must be to begin rebuilding U.S. manufacturing for national security, patient safety, and economic reasons. And the fundamental change we need is to replace “shareholder value” with a national economic strategy that makes broadly shared prosperity, strategic security, and economic growth our top priorities.

#### **Control over the US drug industry gives China a strategic advantage and risks nuclear war.**

Strom and Schell 19. [Holly Strom is a past president of the California State Pharmacy Board and the CEO of Strom and Associates LLC. Kenneth Schell is a past president of the California State Pharmacy Board and the COO of Strom and Associates LLC.] 1 October 2019. US News. “The Other U.S. Prescription Drug Problem.” Accessed 18 September 2021. < <https://www.usnews.com/news/best-countries/articles/2019-10-01/commentary-us-reliance-on-china-for-generic-drugs-is-a-security-threat>> //MHES

The biggest prescription drug crisis of recent years was the 2008 contamination of heparin, a widely used blood thinner. The FDA estimates that 149 Americans died and many hundreds more were seriously injured as a result. What's responsible for the repeated drug safety lapses? The offshoring of the American drug supply to China and, to a lesser extent, India during the past couple of decades. Lax safety standards and FDA oversight at plants in those two countries have allowed these drugs – and likely countless more we don't know about – to become contaminated and endanger patients. China and India now manufacture about 80% of the drugs consumed in the U.S. This figure understates China's dominance because many of the active ingredients in the Indian manufactured drugs come from China. The U.S. doesn't even manufacture vital drugs like antibiotics anymore, with the last penicillin factory closing in 2004. In 2017, FDA inspectors investigated a plant at China's Huahai Pharmaceuticals, which manufactured contaminated valsartan, and found rust, deteriorating equipment, ignored consumer complaints, testing anomalies and potential contamination. Two other Chinese plants were cited by the FDA last year for inadequate cleaning and maintenance procedures, unlocked and improper recording formulas, and inadequate testing, among other violations. FDA inspectors are unable or unwilling to provide appropriate oversight of Chinese manufacturing. In contrast to the robust testing required for approval for new prescription drugs, the FDA only requires that generic manufacturers prove that patients will absorb drugs at the same rate as the brand-name medications they copy. A 2016 Government Accountability Office report finds that some Chinese drug manufacturing plants are never investigated, while others are looked at infrequently. At the time of the report, the FDA only has 29 staff to inspect more than 3,000 foreign manufacturing facilities. And, the number of FDA investigators abroad dropped by 25% between 2016 and 2018, with two out of the three inspection offices in China closing in recent years. According to a Bloomberg analysis, the FDA checks less than 1% of drugs manufactured abroad for safety before allowing them into the country. And manufacturers are generally warned before inspections occur. Given the growing trade war and animosity between the two countries, the utter dependence on China for the U.S.'s basic medicines also poses a national security threat. China's drug manufacturing dominance gives it a nuclear option in the ongoing trade war. Millions of Americans could die without access to lifesaving medications if China decides to weaponize its drug-making. In order to ensure generic drug safety and protect against this national security threat, the U.S. must produce its most vital medications, such as antibiotics, insulin, and anesthesia, at home. In their 2018 book “China RX,” authors Rosemary Goodwin and Janardan Prasad Singh lay out 10 steps to achieve this goal. These include deeming medicines a strategic asset, providing incentives to bring manufacturing home, and increasing FDA testing of medications. Lawmakers plan to hold hearings soon about China's dominance in prescription drug manufacturing. These hearings should recommend that any forthcoming comprehensive prescription drug legislation include a reshoring element. If the status quo prevails, the country will continue experiencing dangerous and widespread drug contaminations – at best.

#### Nuclear war causes extinction.

**Starr 15.** Steven Starr, 8-14-2015, "Nuclear War, Nuclear Winter, and Human Extinction," Federation Of American Scientists, <https://fas.org/pir-pubs/nuclear-war-nuclear-winter-and-human-extinction/> ccajs

While it is impossible to precisely predict all the human impacts that would result from a nuclear winter, it is relatively simple to predict those which would be most profound. That is, a nuclear winter would cause most humans and large animals to die from nuclear famine in a mass extinction event similar to the one that wiped out the dinosaurs. Following the detonation (in conflict) of US and/or Russian launch-ready strategic nuclear weapons, nuclear firestorms would burn simultaneously over a total land surface area of many thousands or tens of thousands of square miles. These mass fires, many of which would rage over large cities and industrial areas, would release many tens of millions of tons of black carbon soot and smoke (up to 180 million tons, according to peer-reviewed studies), which would rise rapidly above cloud level and into the stratosphere. [For an explanation of the calculation of smoke emissions, see Atmospheric effects & societal consequences of regional scale nuclear conflicts.] The scientists who completed the most recent peer-reviewed studies on nuclear winter discovered that the sunlight would heat the smoke, producing a self-lofting effect that would not only aid the rise of the smoke into the stratosphere (above cloud level, where it could not be rained out), but act to keep the smoke in the stratosphere for 10 years or more. The longevity of the smoke layer would act to greatly increase the severity of its effects upon the biosphere. Once in the stratosphere, the smoke (predicted to be produced by a range of strategic nuclear wars) would rapidly engulf the Earth and form a dense stratospheric smoke layer. The smoke from a war fought with strategic nuclear weapons would quickly prevent up to 70% of sunlight from reaching the surface of the Northern Hemisphere and 35% of sunlight from reaching the surface of the Southern Hemisphere. Such an enormous loss of warming sunlight would produce Ice Age weather conditions on Earth in a matter of weeks. For a period of 1-3 years following the war, temperatures would fall below freezing every day in the central agricultural zones of North America and Eurasia. [For an explanation of nuclear winter, see Nuclear winter revisited with a modern climate model and current nuclear arsenals: Still catastrophic consequences.] Nuclear winter would cause average global surface temperatures to become colder than they were at the height of the last Ice Age. Such extreme cold would eliminate growing seasons for many years, probably for a decade or longer. Can you imagine a winter that lasts for ten years? The results of such a scenario are obvious. Temperatures would be much too cold to grow food, and they would remain this way long enough to cause most humans and animals to starve to death. Global nuclear famine would ensue in a setting in which the infrastructure of the combatant nations has been totally destroyed, resulting in massive amounts of chemical and radioactive toxins being released into the biosphere. We don’t need a sophisticated study to tell us that no food and Ice Age temperatures for a decade would kill most people and animals on the planet. Would the few remaining survivors be able to survive in a radioactive, toxic environment?

## Solvency

#### Plan: The member nations of the World Trade Organization ought to reduce intellectual property protections for medicines by providing drug innovators a single period of exclusivity for their drug.

#### **The aff solves patent thicketing via a one-and-done approach to IP protection for medicine.**

Feldman 19. [Robin Feldman is professor of law and director of the Institute for Innovation Law at UC Hastings College of the Law in San Francisco and author of “Drugs, Money, and Secret Handshakes” (Cambridge University Press, March 2019).] 11 February 2019. Stat News. “‘One-and-done’ for new drugs could cut patent thickets and boost generic competition” Accessed 5 September 2021. <https://www.statnews.com/2019/02/11/drug-patent-protection-one-done/> //re-cut MHES

Some experts believe the U.S. can rein in drug process with value-based pricing, which aims to tie the prices we pay for drugs to the benefits they provide, either in terms of longer life or better quality of life. Others call for dismantling pharmacy benefit managers. Still others want large groups like Medicare to negotiate with drug companies for better drug prices. While each of these might help, they cannot solve the problem alone. Why? Because they do not reach the heart of the problem. As I explain in my new book, “Drugs, Money, and Secret Handshakes,” the government itself is giving pharmaceutical companies the power they are wielding through overly generous drug patent protection. Effective solutions must address that problem. Drug companies have brought great innovations to market. Society rewards innovation with patents, or with non-patent exclusivities that can be obtained for activities such as testing drugs in children, undertaking new clinical studies, or developing orphan drugs. The rights provided by patents or non-patent exclusivities provide a defined time period of protection so companies can recoup their investments by charging monopoly prices. When patents end, lower-priced competitors should be able to jump into the market and drive down the price. But that’s not happening. Instead, drug companies build massive patent walls around their products, extending the protection over and over again. Some modern drugs have an avalanche of U.S. patents, with expiration dates staggered across time. For example, the rheumatoid arthritis drug Humira is protected by more than 100 patents. Walls like that are insurmountable. Rather than rewarding innovation, our patent system is now largely repurposing drugs. Between 2005 and 2015, more than three-quarters of the drugs associated with new patents were not new ones coming on the market but existing ones. In other words, we are mostly churning and recycling. Particularly troubling, new patents can be obtained on minor tweaks such as adjustments to dosage or delivery systems — a once-a-day pill instead of a twice-a-day one; a capsule rather than a tablet. Tinkering like this may have some value to some patients, but it nowhere near justifies the rewards we lavish on companies for doing it. From society’s standpoint, incentives should drive scientists back to the lab to look for new things, not to recycle existing drugs for minimal benefit. I believe that one period of protection should be enough. We should make the legal changes necessary to prevent companies from building patent walls and piling up mountains of rights. This could be accomplished by a “one-and-done” approach for patent protection. Under it, a drug would receive just one period of exclusivity, and no more. The choice of which “one” could be left entirely in the hands of the pharmaceutical company, with the election made when the FDA approves the drug. Perhaps development of the drug went swiftly and smoothly, so the remaining life of one of the drug’s patents is of greatest value. Perhaps development languished, so designation as an orphan drug or some other benefit would bring greater reward. The choice would be up to the company itself, based on its own calculation of the maximum benefit. The result, however, is that a pharmaceutical company chooses whether its period of exclusivity would be a patent, an orphan drug designation, a period of data exclusivity (in which no generic is allowed to use the original drug’s safety and effectiveness data), or something else — but not all of the above and more. Consider Suboxone, a combination of buprenorphine and naloxone for treating opioid addiction. The drug’s maker has extended its protection cliff eight times, including obtaining an orphan drug designation, which is intended for drugs that serve only a small number of patients. The drug’s first period of exclusivity ended in 2005, but with the additions its protection now lasts until 2024. That makes almost two additional decades in which the public has borne the burden of monopoly pricing, and access to the medicine may have been constrained. Implementing a one-and-done approach in conjunction with FDA approval underscores the fact that these problems and solutions are designed for pharmaceuticals, not for all types of technologies. That way, one-and-done could be implemented through legislative changes to the FDA’s drug approval system, and would apply to patents granted going forward. One-and-done would apply to both patents and exclusivities. A more limited approach, a baby step if you will, would be to invigorate the existing patent obviousness doctrine as a way to cut back on patent tinkering. Obviousness, one of the five standards for patent eligibility, says that inventions that are obvious to an expert or the general public can’t be patented.

#### **Reshoring manufacturing operations is key to US job creation and ensuring national security.**

Ferry **2.** [Jeff Ferry is chief economist at the Coalition for a Prosperous America (CPA).] 17 March 2020. Industry Week. “It’s Time To Rebuild Domestic Drug Production in the US, for Both Health and Economic Reasons” Accessed 12 September 2021. < <https://www.industryweek.com/the-economy/article/21126380/its-time-to-rebuild-domestic-drug-production-in-the-us-for-both-health-and-economic-reasons>> //MHES

With breathtaking speed, the coronavirus has revealed a previously overlooked vulnerability in the U.S. economy. The United States has become heavily dependent on China and other countries to supply many of the medicines used in everyday life. In the wake of the current pandemic, policymakers are exploring how to rebuild America’s domestic drug capability. A new analysis from our organization the Coalition for a Prosperous America (CPA) demonstrates that the economic benefits of rebuilding this domestic capability would be significant, including the creation of 804,000 high-paying manufacturing jobs. Over the past 20 years, U.S. pharmaceutical companies have progressively outsourced and offshored the manufacture of prescription medicines, generic drugs, and over-the-counter medications. Although Ireland has become a popular manufacturing location for some small-batch prescription medicines, China and India have taken the largest share of the production of generics and over-the-counter medications. Ironically, it is these low-cost medications that Americans now depend on when treating the coronavirus. Pharmaceutical expert Rosemary Gibson has authored a book, China RX, regarding the dangers of America’s dependence on China for key medications. Last week, Gibson—who is also a CPA member—testified in the Senate that three commonly used antibiotics—azithromycin, ciprofloxacin, and piperacillin/tazobactam—depend on ingredients manufactured only in China. Such reliance on China even extends to common household medicines; the U.S. imports 95% of its ibuprofen and 70% of its acetaminophen from China. China is well aware of the strategic importance of pharmaceutical manufacturing. In a speech last year, Chinese economist Li Daokiu bluntly explained China’s strategic options at a National People’s Conference event in Beijing: “We are at the mercy of others when it comes to computer chips, but we are the world’s largest exporter of raw materials for vitamins and antibiotics. Should we reduce the exports, the medical systems of some western countries will not run well.” The U.S. can and must bring home the manufacture of these vital pharmaceuticals. CPA’s economic modeling of the potential restoring of pharmaceutical production finds huge benefits for the U.S. economy. Last year, the United States imported $128 billion worth of pharmaceuticals. That makes it the third largest category of imports, even ahead of cellphones. Our trade deficit in pharmaceuticals was $74 billion. CPA’s economic modeling set a reasonable goal of increasing U.S. pharmaceutical production by $66 billion—the amount of annual production lost to pharmaceutical imports since 2010. 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And the fundamental change we need is to replace “shareholder value” with a national economic strategy that makes broadly shared prosperity, strategic security, and economic growth our top priorities.

## Framing

**The standard is maximizing expected well-being.**

#### [1] The connection between pain and pleasure and phenomenal conceptions of intrinsic value and disvalue is irrefutable – everything else regresses – robust neuroscience proves.

Blum et al. 18 Kenneth Blum, 1Department of Psychiatry, Boonshoft School of Medicine, Dayton VA Medical Center, Wright State University, Dayton, OH, USA 2Department of Psychiatry, McKnight Brain Institute, University of Florida College of Medicine, Gainesville, FL, USA 3Department of Psychiatry and Behavioral Sciences, Keck Medicine University of Southern California, Los Angeles, CA, USA 4Division of Applied Clinical Research & Education, Dominion Diagnostics, LLC, North Kingstown, RI, USA 5Department of Precision Medicine, Geneus Health LLC, San Antonio, TX, USA 6Department of Addiction Research & Therapy, Nupathways Inc., Innsbrook, MO, USA 7Department of Clinical Neurology, Path Foundation, New York, NY, USA 8Division of Neuroscience-Based Addiction Therapy, The Shores Treatment & Recovery Center, Port Saint Lucie, FL, USA 9Institute of Psychology, Eötvös Loránd University, Budapest, Hungary 10Division of Addiction Research, Dominion Diagnostics, LLC. North Kingston, RI, USA 11Victory Nutrition International, Lederach, PA., USA 12National Human Genome Center at Howard University, Washington, DC., USA, Marjorie Gondré-Lewis, 12National Human Genome Center at Howard University, Washington, DC., USA 13Departments of Anatomy and Psychiatry, Howard University College of Medicine, Washington, DC US, Bruce Steinberg, 4Division of Applied Clinical Research & Education, Dominion Diagnostics, LLC, North Kingstown, RI, USA, Igor Elman, 15Department Psychiatry, Cooper University School of Medicine, Camden, NJ, USA, David Baron, 3Department of Psychiatry and Behavioral Sciences, Keck Medicine University of Southern California, Los Angeles, CA, USA, Edward J Modestino, 14Department of Psychology, Curry College, Milton, MA, USA, Rajendra D Badgaiyan, 15Department Psychiatry, Cooper University School of Medicine, Camden, NJ, USA, Mark S Gold 16Department of Psychiatry, Washington University, St. Louis, MO, USA, “Our evolved unique pleasure circuit makes humans different from apes: Reconsideration of data derived from animal studies”, U.S. Department of Veterans Affairs, 28 February 2018, accessed: 19 August 2020, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6446569/>, R.S.

**Pleasure** is not only one of the three primary reward functions but it also **defines reward.** As homeostasis explains the functions of only a limited number of rewards, the principal reason why particular stimuli, objects, events, situations, and activities are rewarding may be due to pleasure. This applies first of all to sex and to the primary homeostatic rewards of food and liquid and extends to money, taste, beauty, social encounters and nonmaterial, internally set, and intrinsic rewards. Pleasure, as the primary effect of rewards, drives the prime reward functions of learning, approach behavior, and decision making and provides the **basis for hedonic theories** of reward function. We are attracted by most rewards and exert intense efforts to obtain them, just because they are enjoyable [10]. Pleasure is a passive reaction that derives from the experience or prediction of reward and may lead to a long-lasting state of happiness. The word happiness is difficult to define. In fact, just obtaining physical pleasure may not be enough. One key to happiness involves a network of good friends. However, it is not obvious how the higher forms of satisfaction and pleasure are related to an ice cream cone, or to your team winning a sporting event. Recent multidisciplinary research, using both humans and detailed invasive brain analysis of animals has discovered some critical ways that the brain processes pleasure [14]. Pleasure as a hallmark of reward is sufficient for defining a reward, but it may not be necessary. A reward may generate positive learning and approach behavior simply because it contains substances that are essential for body function. When we are hungry, we may eat bad and unpleasant meals. A monkey who receives hundreds of small drops of water every morning in the laboratory is unlikely to feel a rush of pleasure every time it gets the 0.1 ml. Nevertheless, with these precautions in mind, we may define any stimulus, object, event, activity, or situation that has the potential to produce pleasure as a reward. In the context of reward deficiency or for disorders of addiction, homeostasis pursues pharmacological treatments: drugs to treat drug addiction, obesity, and other compulsive behaviors. The theory of allostasis suggests broader approaches - such as re-expanding the range of possible pleasures and providing opportunities to expend effort in their pursuit. [15]. It is noteworthy, the first animal studies eliciting approach behavior by electrical brain stimulation interpreted their findings as a discovery of the brain’s pleasure centers [16] which were later partly associated with midbrain dopamine neurons [17–19] despite the notorious difficulties of identifying emotions in animals. Evolutionary theories of pleasure: The love connection BO:D Charles Darwin and other biological scientists that have examined the biological evolution and its basic principles found various mechanisms that steer behavior and biological development. Besides their theory on natural selection, it was particularly the sexual selection process that gained significance in the latter context over the last century, especially when it comes to the question of what makes us “what we are,” i.e., human. However, the capacity to sexually select and evolve is not at all a human accomplishment alone or a sign of our uniqueness; yet, we humans, as it seems, are ingenious in fooling ourselves and others–when we are in love or desperately search for it. It is well established that modern biological theory conjectures that **organisms are** the **result of evolutionary competition.** In fact, Richard Dawkins stresses gene survival and propagation as the basic mechanism of life [20]. Only genes that lead to the fittest phenotype will make it. It is noteworthy that the phenotype is selected based on behavior that maximizes gene propagation. To do so, the phenotype must survive and generate offspring, and be better at it than its competitors. Thus, the ultimate, distal function of rewards is to increase evolutionary fitness by ensuring the survival of the organism and reproduction. It is agreed that learning, approach, economic decisions, and positive emotions are the proximal functions through which phenotypes obtain other necessary nutrients for survival, mating, and care for offspring. Behavioral reward functions have evolved to help individuals to survive and propagate their genes. Apparently, people need to live well and long enough to reproduce. Most would agree that homo-sapiens do so by ingesting the substances that make their bodies function properly. For this reason, foods and drinks are rewards. Additional rewards, including those used for economic exchanges, ensure sufficient palatable food and drink supply. Mating and gene propagation is supported by powerful sexual attraction. Additional properties, like body form, augment the chance to mate and nourish and defend offspring and are therefore also rewards. Care for offspring until they can reproduce themselves helps gene propagation and is rewarding; otherwise, many believe mating is useless. According to David E Comings, as any small edge will ultimately result in evolutionary advantage [21], additional reward mechanisms like novelty seeking and exploration widen the spectrum of available rewards and thus enhance the chance for survival, reproduction, and ultimate gene propagation. These functions may help us to obtain the benefits of distant rewards that are determined by our own interests and not immediately available in the environment. Thus the distal reward function in gene propagation and evolutionary fitness defines the proximal reward functions that we see in everyday behavior. That is why foods, drinks, mates, and offspring are rewarding. There have been theories linking pleasure as a required component of health benefits salutogenesis, (salugenesis). In essence, under these terms, pleasure is described as a state or feeling of happiness and satisfaction resulting from an experience that one enjoys. Regarding pleasure, it is a double-edged sword, on the one hand, it promotes positive feelings (like mindfulness) and even better cognition, possibly through the release of dopamine [22]. But on the other hand, pleasure simultaneously encourages addiction and other negative behaviors, i.e., motivational toxicity. It is a complex neurobiological phenomenon, relying on reward circuitry or limbic activity. It is important to realize that through the “Brain Reward Cascade” (BRC) endorphin and endogenous morphinergic mechanisms may play a role [23]. While natural rewards are essential for survival and appetitive motivation leading to beneficial biological behaviors like eating, sex, and reproduction, crucial social interactions seem to further facilitate the positive effects exerted by pleasurable experiences. Indeed, experimentation with addictive drugs is capable of directly acting on reward pathways and causing deterioration of these systems promoting hypodopaminergia [24]. Most would agree that pleasurable activities can stimulate personal growth and may help to induce healthy behavioral changes, including stress management [25]. The work of Esch and Stefano [26] concerning the link between compassion and love implicate the brain reward system, and pleasure induction suggests that social contact in general, i.e., love, attachment, and compassion, can be highly effective in stress reduction, survival, and overall health. Understanding the role of neurotransmission and pleasurable states both positive and negative have been adequately studied over many decades [26–37], but comparative anatomical and neurobiological function between animals and homo sapiens appear to be required and seem to be in an infancy stage. Finding happiness is different between apes and humans As stated earlier in this expert opinion one key to happiness involves a network of good friends [38]. However, it is not entirely clear exactly how the higher forms of satisfaction and pleasure are related to a sugar rush, winning a sports event or even sky diving, all of which augment dopamine release at the reward brain site. Recent multidisciplinary research, using both humans and detailed invasive brain analysis of animals has discovered some critical ways that the brain processes pleasure. Remarkably, there are pathways for ordinary liking and pleasure, which are limited in scope as described above in this commentary. However, there are **many brain regions**, often termed hot and cold spots, that significantly **modulate** (increase or decrease) our **pleasure or** even produce **the opposite** of pleasure— that is disgust and fear [39]. One specific region of the nucleus accumbens is organized like a computer keyboard, with particular stimulus triggers in rows— producing an increase and decrease of pleasure and disgust. Moreover, the cortex has unique roles in the cognitive evaluation of our feelings of pleasure [40]. Importantly, the interplay of these multiple triggers and the higher brain centers in the prefrontal cortex are very intricate and are just being uncovered. Desire and reward centers It is surprising that many different sources of pleasure activate the same circuits between the mesocorticolimbic regions (Figure 1). Reward and desire are two aspects pleasure induction and have a very widespread, large circuit. Some part of this circuit distinguishes between desire and dread. The so-called pleasure circuitry called “REWARD” involves a well-known dopamine pathway in the mesolimbic system that can influence both pleasure and motivation. In simplest terms, the well-established mesolimbic system is a dopamine circuit for reward. It starts in the ventral tegmental area (VTA) of the midbrain and travels to the nucleus accumbens (Figure 2). It is the cornerstone target to all addictions. The VTA is encompassed with neurons using glutamate, GABA, and dopamine. The nucleus accumbens (NAc) is located within the ventral striatum and is divided into two sub-regions—the motor and limbic regions associated with its core and shell, respectively. The NAc has spiny neurons that receive dopamine from the VTA and glutamate (a dopamine driver) from the hippocampus, amygdala and medial prefrontal cortex. Subsequently, the NAc projects GABA signals to an area termed the ventral pallidum (VP). The region is a relay station in the limbic loop of the basal ganglia, critical for motivation, behavior, emotions and the “Feel Good” response. This defined system of the brain is involved in all addictions –substance, and non –substance related. In 1995, our laboratory coined the term “Reward Deficiency Syndrome” (RDS) to describe genetic and epigenetic induced hypodopaminergia in the “Brain Reward Cascade” that contribute to addiction and compulsive behaviors [3,6,41]. Furthermore, ordinary “liking” of something, or pure pleasure, is represented by small regions mainly in the limbic system (old reptilian part of the brain). These may be part of larger neural circuits. In Latin, hedus is the term for “sweet”; and in Greek, hodone is the term for “pleasure.” Thus, the word Hedonic is now referring to various subcomponents of pleasure: some associated with purely sensory and others with more complex emotions involving morals, aesthetics, and social interactions. The capacity to have pleasure is part of being healthy and may even extend life, especially if linked to optimism as a dopaminergic response [42]. Psychiatric illness often includes symptoms of an abnormal inability to experience pleasure, referred to as anhedonia. A negative feeling state is called dysphoria, which can consist of many emotions such as pain, depression, anxiety, fear, and disgust. Previously many scientists used animal research to uncover the complex mechanisms of pleasure, liking, motivation and even emotions like panic and fear, as discussed above [43]. However, as a significant amount of related research about the specific brain regions of pleasure/reward circuitry has been derived from invasive studies of animals, these cannot be directly compared with subjective states experienced by humans. In an attempt to resolve the controversy regarding the causal contributions of mesolimbic dopamine systems to reward, we have previously evaluated the three-main competing explanatory categories: “liking,” “learning,” and “wanting” [3]. That is, dopamine may mediate (a) liking: the hedonic impact of reward, (b) learning: learned predictions about rewarding effects, or (c) wanting: the pursuit of rewards by attributing incentive salience to reward-related stimuli [44]. We have evaluated these hypotheses, especially as they relate to the RDS, and we find that the incentive salience or “wanting” hypothesis of dopaminergic functioning is supported by a majority of the scientific evidence. Various neuroimaging studies have shown that anticipated behaviors such as sex and gaming, delicious foods and drugs of abuse all affect brain regions associated with reward networks, and may not be unidirectional. Drugs of abuse enhance dopamine signaling which sensitizes mesolimbic brain mechanisms that apparently evolved explicitly to attribute incentive salience to various rewards [45]. Addictive substances are voluntarily self-administered, and they enhance (directly or indirectly) dopaminergic synaptic function in the NAc. This activation of the brain reward networks (producing the ecstatic “high” that users seek). Although these circuits were initially thought to encode a set point of hedonic tone, it is now being considered to be far more complicated in function, also encoding attention, reward expectancy, disconfirmation of reward expectancy, and incentive motivation [46]. The argument about addiction as a disease may be confused with a predisposition to substance and nonsubstance rewards relative to the extreme effect of drugs of abuse on brain neurochemistry. The former sets up an individual to be at high risk through both genetic polymorphisms in reward genes as well as harmful epigenetic insult. Some Psychologists, even with all the data, still infer that addiction is not a disease [47]. Elevated stress levels, together with polymorphisms (genetic variations) of various dopaminergic genes and the genes related to other neurotransmitters (and their genetic variants), and may have an additive effect on vulnerability to various addictions [48]. In this regard, Vanyukov, et al. [48] suggested based on review that whereas the gateway hypothesis does not specify mechanistic connections between “stages,” and does not extend to the risks for addictions the concept of common liability to addictions may be more parsimonious. The latter theory is grounded in genetic theory and supported by data identifying common sources of variation in the risk for specific addictions (e.g., RDS). This commonality has identifiable neurobiological substrate and plausible evolutionary explanations. Over many years the controversy of dopamine involvement in especially “pleasure” has led to confusion concerning separating motivation from actual pleasure (wanting versus liking) [49]. We take the position that animal studies cannot provide real clinical information as described by self-reports in humans. As mentioned earlier and in the abstract, on November 23rd, 2017, evidence for our concerns was discovered [50] In essence, although nonhuman primate brains are similar to our own, the disparity between other primates and those of human cognitive abilities tells us that surface similarity is not the whole story. Sousa et al. [50] small case found various differentially expressed genes, to associate with pleasure related systems. Furthermore, the dopaminergic interneurons located in the human neocortex were absent from the neocortex of nonhuman African apes. Such differences in neuronal transcriptional programs may underlie a variety of neurodevelopmental disorders. In simpler terms, the system controls the production of dopamine, a chemical messenger that plays a significant role in pleasure and rewards. The senior author, Dr. Nenad Sestan from Yale, stated: “Humans have evolved a dopamine system that is different than the one in chimpanzees.” This may explain why the behavior of humans is so unique from that of non-human primates, even though our brains are so surprisingly similar, Sestan said: “It might also shed light on why people are vulnerable to mental disorders such as autism (possibly even addiction).” Remarkably, this research finding emerged from an extensive, multicenter collaboration to compare the brains across several species. These researchers examined 247 specimens of neural tissue from six humans, five chimpanzees, and five macaque monkeys. Moreover, these investigators analyzed which genes were turned on or off in 16 regions of the brain. While the differences among species were subtle, **there was** a **remarkable contrast in** the **neocortices**, specifically in an area of the brain that is much more developed in humans than in chimpanzees. In fact, these researchers found that a gene called tyrosine hydroxylase (TH) for the enzyme, responsible for the production of dopamine, was expressed in the neocortex of humans, but not chimpanzees. As discussed earlier, dopamine is best known for its essential role within the brain’s reward system; the very system that responds to everything from sex, to gambling, to food, and to addictive drugs. However, dopamine also assists in regulating emotional responses, memory, and movement. Notably, abnormal dopamine levels have been linked to disorders including Parkinson’s, schizophrenia and spectrum disorders such as autism and addiction or RDS. Nora Volkow, the director of NIDA, pointed out that one alluring possibility is that the neurotransmitter dopamine plays a substantial role in humans’ ability to pursue various rewards that are perhaps months or even years away in the future. This same idea has been suggested by Dr. Robert Sapolsky, a professor of biology and neurology at Stanford University. Dr. Sapolsky cited evidence that dopamine levels rise dramatically in humans when we anticipate potential rewards that are uncertain and even far off in our futures, such as retirement or even the possible alterlife. This may explain what often motivates people to work for things that have no apparent short-term benefit [51]. In similar work, Volkow and Bale [52] proposed a model in which dopamine can favor NOW processes through phasic signaling in reward circuits or LATER processes through tonic signaling in control circuits. Specifically, they suggest that through its modulation of the orbitofrontal cortex, which processes salience attribution, dopamine also enables shilting from NOW to LATER, while its modulation of the insula, which processes interoceptive information, influences the probability of selecting NOW versus LATER actions based on an individual’s physiological state. This hypothesis further supports the concept that disruptions along these circuits contribute to diverse pathologies, including obesity and addiction or RDS.

#### [2] Moral uncertainty means preventing extinction should be our highest priority. **Bostrom** **12** [Nick Bostrom. Faculty of Philosophy & Oxford Martin School University of Oxford. “Existential Risk Prevention as Global Priority.” Global Policy (2012)] <https://www.existential-risk.org/concept.html#:~:text=Existential%20Risk%20Prevention%20as%20Global%20Priority%20ABSTRACT%3A%20Existential,in%20net%20existential%20risk%20have%20enormous%20expected%20value.> These reflections on moral uncertainty suggest an alternative, complementary way of looking at existential risk; they also suggest a new way of thinking about the ideal of sustainability. Let me elaborate.¶ Our present understanding of axiology might well be confused. We may not now know — at least not in concrete detail — what outcomes would count as a big win for humanity; we might not even yet be able to imagine the best ends of our journey. If we are indeed profoundly uncertain about our ultimate aims, then we should recognize that there is a great option value in preserving — and ideally improving — our ability to recognize value and to steer the future accordingly. Ensuring that there will be a future version of humanity with great powers and a propensity to use them wisely is plausibly the best way available to us to increase the probability that the future will contain a lot of value. To do this, we must prevent any existential catastrophe.

#### [3] Actor specificity: A] governments have side constraints - they don’t have infinite resources - and therefore must consider tradeoffs. All policies will benefit some and harm others. B] No intent-foresight distinction for governments – deliberating over an action requires analysis of foreseen consequences which could be prevented which makes them intrinsic to state action

#### C] Governments aren’t singular rational agents which makes theories about individuals irrelevant – only consequentialism solves by analyzing ends divorced from an actor

## Underview

#### [1] 1AR Theory – a) AFF gets it because otherwise the neg can engage in infinite harm, making debate impossible, b) drop the debater – the 1AR is too short for theory and substance so ballot implications are key to check, c) no RVIs – they can stick me with 6min of answers to a short arg and make the 2AR impossible, d) competing interps – 1AR interps aren’t bidirectional and the neg should have to defend their norm since they have more time. e) Aff theory comes first - it’s a much larger strategic loss because 1min is ¼ of the 1AR vs 1/7 of the 1NC which means there’s more harm if I’m devoting a larger fraction of time.

#### [2] Aff RVIs – a) Skew – no 2AC for carded offense which means that they invest more time into substance and theory. The crowded 1AR can’t cover both sufficiently making rounds structurally neg skewed. Give aff RVI to make up for time with ballot access

## Method

#### [1] Pluralism is good.

**Bleiker 14** – (6/17, Roland, Professor of International Relations at the University of Queensland, “International Theory Between Reification and Self-Reflective Critique,” International Studies Review, Volume 16, Issue 2, pages 325–327)

Methodological pluralism lies at the heart of Levine's sustainable critique. He borrows from what Adorno calls a “constellation”: an attempt to juxtapose, rather than integrate, different perspectives. It is in this spirit that Levine advocates multiple methods to understand the same event or phenomena. He writes of the need to validate “multiple and mutually incompatible ways of seeing” (p. 63, see also pp. 101–102). In this model, a scholar oscillates back and forth between different methods and paradigms, trying to understand the event in question from multiple perspectives. No single method can ever adequately represent the event or should gain the upper hand. But each should, in a way, recognize and capture details or perspectives that the others cannot (p. 102). In practical terms, this means combining a range of methods even when—or, rather, precisely when—they are deemed incompatible. They can range from poststructual deconstruction to the tools pioneered and championed by positivist social sciences. The benefit of such a methodological polyphony is not just the opportunity to bring out nuances and new perspectives. Once the false hope of a smooth synthesis has been abandoned, the very incompatibility of the respective perspectives can then be used to identify the reifying tendencies in each of them. For Levine, this is how reification may be “checked at the source” and this is how a “critically reflexive moment might thus be rendered sustainable” (p. 103). It is in this sense that Levine's approach is not really post-foundational but, rather, an attempt to “balance foundationalisms against one another” (p. 14). There are strong parallels here with arguments advanced by assemblage thinking and complexity theory—links that could have been explored in more detail.