# Navy Round 1 Wiki

## 1AC

### 1AC – Prices Adv

Contention 1 is Prices –

#### Best new studies prove that U.S. drug prices have skyrocketed in recent years because of lack of competition. That shuts off access to vital drugs and balloons debts.

Feldman 8/27 – Distinguished Professor of Law Chair & Director of the Center for Innovation, UC Hastings Law

Robin Feldman, Arthur J. Goldberg Distinguished Professor of Law, Albert Abramson ’54 Distinguished Professor of Law Chair, and Director of the Center for Innovation, The Price Tag of 'Pay-for-Delay', UC Hastings Research Paper Forthcoming, 27 Aug 2021, https://papers.ssrn.com/sol3/papers.cfm?abstract\_id=3846484

The skyrocketing price of prescription medication continues to plague the pharmaceutical industry. For example, an analysis of one million Medicare patients between 2010 and 2017 found that the average dosage-unit price of brand-name drugs increased by 313 percent even after accounting for rebates.2 [FN 2] 2 Robin Feldman, The Devil in the Tiers, J.L. & BIOSCI. 1, 19 (2021). The RAND Corporation found in 2021 that the price of brand-name prescription drugs in the U.S. is 256 percent of the prices in thirty-two OECD countries combined, ranging from 170 percent of prices in Mexico to 779 percent of prices in Turkey (ANDREW W. MULCAHY ET AL., RAND CORP., INTERNATIONAL PRESCRIPTION DRUG PRICE COMPARISONS: CURRENT EMPIRICAL ESTIMATES AND COMPARISONS WITH PREVIOUS STUDIES 26 (2021), <https://www.rand.org/content/dam/rand/pubs/research_reports/RR2900/RR2956/RAND_RR2956.pdf>). [End FN] Similarly, one in four Americans have difficulty affording their medications, and three in ten say costs have prohibited them from taking their medications as prescribed.3 With rising out-of-pocket costs and patients dangerously rationing medication, these prices are causing real pain for American patients. Diabetic patients, for example, paid nearly $6000 a year out of pocket for insulin in 2016, and patients with arthritis saw the price of Humira rise to $1552 a month in 2019.4 As difficult as the burdens are for any patient, the burden of paying high prices lands particularly hard on lower-income groups, threatening access to life-saving treatments and creating further gaps in equity across society.

Since the passage of legislation in the early 1980s, the nation has pinned its hopes on the disciplining effects of generic drugs. Generics are expected to enter the market rapidly when a drug’s patent protection expires, driving prices down to competitive levels.5 Something, however, is seriously amiss. Although generics continue to enter the market in record numbers, drug prices, out-of-of pocket costs, and real spending on drugs continue to soar unabated. The pharmaceutical industry is a complex and convoluted market, with significant distortions and inefficiencies.6 Among these problems, however, one cannot expect generic competitors to create a disciplining effect on prices, if brand companies are able to collude with their generic competitors.

In a landmark decision nearly a decade ago, the Supreme Court opened the door for antitrust suits against brand and generic pharmaceutical companies who engage in collusive settlements to delay the time for the generic to come to market. With these “pay-for-delay” agreements, brand-name companies offer prospective generic competitors cash in exchange for the generic’s promise not to enter the market until an agreed-upon date. Laying the groundwork for the lawsuit that would eventually lead to the Actavis decision, the Federal Trade Commission (FTC) published a study estimating that pay-for-delay agreements cost American consumers $3.5 billion annually, a figure that has been cited repeatedly by scholars and policy-makers alike.7 Similar concerns led Congress, in 2003, to require that brand and generic manufacturers file settlement agreements concerning the manufacture, marketing, or sale of generic drugs with the FTC and tasked the FTC with publishing an annual report on the state of pay-for-delay. 8

As this article will demonstrate, the $3.5 billion figure vastly understates the landscape. To understand the state of pay-for-delay agreements, this article leverages a range of methodologies to present an in-depth examination of the burden that pay-for-delay imposes, both on individual patients and society at large. Specifically, the analysis demonstrates the cost of unavailable generic options in drug markets that suffer pay-for-delay schemes. The findings are alarming, and far exceed the FTC estimate.

● Pay-for-delay settlements cost the U.S. population at least $6.4 billion annually: Calculations ranged from $6.4 billion to as high as $36.1 billion per year in total costs based on list prices, as the postponement of generic options required the continued usage of expensive brands.

● Pay-for-delay settlements saddled American patients with more than $600 million in annual out-of-pocket costs: Patients each year collectively paid between $610 million and $2.8 billion more out-of-pocket as a result of pay-for-delay.

● Pay-for-delay settlements cost the Medicare Part D program at least $2.3 billion annually: The government paid between $2.3 and $13.1 billion more each year to fund Part D because of pay-for-delay.

Moreover, although the Supreme Court’s landmark decision in Actavis opened the door for antitrust litigation, courts have failed to utilize the pathway provided. This article explores the modern legal landscape that has instead emerged since the Supreme Court’s historic pronouncement.

The article proceeds as follows. Part I describes pay-for-delay agreements, exploring the literature on the potential harm of such agreements among pharmaceutical competitors. Part II presents a new analysis demonstrating that the cost of pay-for-delay to American consumers is far greater than anyone has recognized, and well beyond the $3.5 billion figure cited by the FTC in 2010. We applied six different methodologies to provide as fair and broad a view as possible. The range of methodologies show that at a minimum, the cost of pay-for-delay settlements on the U.S. population between 2006 and 2017 is a minimum of $6.4 billion per year—almost double that of the FTC’s estimate. The methodology with the largest result suggests that the cost could be as high as $36 billion per year—10 times higher. Part III argues that courts are allowing this costly problem to flourish unchecked. This part reviews pay-for-delay decisions since Actavis, arguing that the courts have failed to properly analyze such cases from the perspective of all three notions inherent in the words “pay,” “for,” and “delay.” Finally, Part IV offers a path forward through the doctrinal haze.

#### Monopoly drug pricing is the primary driver of U.S. healthcare spending – doesn’t benefit R&D

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Ezekiel J. Emanuel, 3-23-2019, "Big Pharma’s Go-To Defense of Soaring Drug Prices Doesn’t Add Up," Atlantic, https://www.theatlantic.com/health/archive/2019/03/drug-prices-high-cost-research-and-development/585253/

How is it that pharmaceutical companies can charge patients $100,000, $200,000, or even $500,000 a year for drugs—many of which are not even curative?

Abiraterone, for instance, is a drug used to treat metastatic prostate cancer. The Food and Drug Administration initially approved it in 2011 to treat patients who failed to respond to previous chemotherapy. It does not cure anyone. The research suggests that in previously treated patients with metastatic prostate cancer, the drug extends life on average by four months. (Last year, the FDA approved giving abiraterone to men with prostate cancer who had not received previous treatment.) At its lowest price, it costs about $10,000 a month.

Abiraterone is manufactured under the brand name Zytiga by Johnson & Johnson. To justify the price, the company pointed me to its “2017 Janssen U.S. Transparency Report,” which states: “We have an obligation to ensure that the sale of our medicines provides us with the resources necessary to invest in future research and development.” In other words, the prices are necessary to fund expensive research projects to generate new drugs.

This explanation is common among industry executives. To many Americans, it can seem plausible and compelling. It’s easy to conjure images of scientific researchers in their protective gear and goggles carefully dropping precious liquids into an array of Erlenmeyer flasks, searching for a new cure for cancer or Alzheimer’s. But invoking high research costs to justify high drug prices is deceptive.

No matter the metric, drug prices in the United States are extreme. Many drugs cost more than $120,000 a year. A few are even closing in on $1 million. The Department of Health and Human Services estimates that Americans spent more than $460 billion on drugs—16.7 percent of total health-care spending—in 2016, the last year for which there are definitive data. On average, citizens of other rich countries spend 56 percent of what

Excessive drug prices are the single biggest category of health-care overspending in the United States compared with Europe, well beyond high administrative costs or excessive use of CT and MRI scans. And unlike almost every other product, drug prices continue to rapidly rise over time. HHS estimates that over the next decade, drug prices will rise 6.3 percent each year, while other health-care costs will rise 5.5 percent. Basic economic principles suggest that drug prices should be going down, not up: For most drugs, manufacturing volumes are increasing, and little new research is being conducted on those already on the market.

Reducing these high drug prices has become a major political concern—and a rare bipartisan cause for Democrats and Republicans to rally around, albeit with disagreement about how to actually get it done. In his State of the Union address last month, President Donald Trump called the price discrepancy between the United States and other countries “unacceptable” and “unfair,” and vowed to “stop it fast.” In a Senate Finance Committee hearing on drug pricing a few weeks later, Senator Ron Wyden of Oregon compared the way the drugmaker AbbVie protects the exclusivity of one of its drugs to the way Gollum protects his ring.

Yet every time Congress debates doing something about drug prices, the industry—and the advocacy groups it funds—vociferously returns to the point that lower prices will thwart innovative research. The fear of missing a cure for Alzheimer’s or Lou Gehrig’s disease or depression contributes to stalling reform. But there are many reasons to question the widely held notion that high drug prices and innovative research are inextricably linked.

The most telling data on a disconnect between drug prices and research costs has received almost no public attention. Peter Bach, a researcher at Memorial Sloan Kettering, and his colleagues compared prices of the top 20 best-selling drugs in the United States to the prices in Europe and Canada. They found that the cumulative revenue from the price difference on just these 20 drugs more than covers all the drug research and development costs conducted by the 15 drug companies that make those drugs—and then some.

To be more precise, after accounting for the costs of all research—about $80 billion a year—drug companies had $40 billion more from the top 20 drugs alone, all of which went straight to profits, not research. More excess profit comes from the next 100 or 200 brand-name drugs.

Drug companies tend to say they are unique in needing to spend a higher proportion of their capital on research than almost any other industry. But of all the companies in the world, the one that invests the most in research and development is not a drug company. It’s Amazon. The online retailer spends about $20 billion a year on R&D, despite being renowned for both low prices and low profits. Among the 25 worldwide companies that spend the most on research and development—all more than $5 billion a year—seven are pharmaceutical manufacturers, but eight are automobile or automobile-parts companies with profit margins under 10 percent. Amazon’s operating margin is under 5 percent. Meanwhile, the top 25 pharmaceutical companies reported a “healthy average operating margin of 22 percent” at the end of 2017, according to an analysis by GlobalData.

If you watch television, you know part of the answer to where this extra money is going: sales and advertising. Of the 10 largest pharmaceutical companies, only one spends more on research than on marketing its products. But it’s hard to figure out what it actually costs drug companies to conduct the research required to get FDA approval and bring a single drug to market. The pharmaceutical industry and its advocates tend to peg the cost of creating and bringing to market just one new drug at $2.6 billion. This figure comes from a cost report published in October 2016 by the Tufts Center for the Study of Drug Development.

There are several reasons to suspect that number is unreliable. According to the Tufts Center’s website, more than a quarter of its budget comes from “unrestricted grants” from pharmaceutical companies and their partners. And no one can verify Tufts’ analyses and claims: The authors say the data come from research spending on 106 drugs produced by 10 of the top 50 multinational pharmaceutical companies, but the underlying data are deemed proprietary and confidential.

Tufts also uses a cost-accounting methodology that appears to significantly inflate its estimate. About 45 percent of Tufts’ $2.6 billion figure is attributed to the amount companies would pay to lenders and shareholders for the capital they invest in research. Tufts uses an interest rate of 10.5 percent a year, but investment bankers tend to use just 6 percent in their economic models. That one change would reduce the Tufts estimate by about a quarter of its total figure. That’s not to mention other factors the Tufts team leaves out that reduce the cost of drug development, such as tax credits the federal government offers for research and development.

When asked about these issues, the report’s chief author, Joseph DiMasi, noted that one other study with public data, published in 2009, comes to similar results. He argues that even if we exclude the cost of capital, $1.4 billion per FDA-approved drug is a high price—and the cost has been growing at about 8.5 percent annually.

But in November 2017, a study published in JAMA Internal Medicine examined the costs of developing 10 cancer drugs approved by the FDA from 2006 to 2015 and provided a strong contrast to the Tufts study from a year before. Its authors, from Memorial Sloan Kettering and the Oregon Health and Science University, used annual financial disclosures from the Securities and Exchange Commission for companies that had only one cancer drug approved but had on average three or four other drugs in development. They found that companies took an average of 7.3 years to win FDA approval, at a median cost of $648 million. Only two drugs had research costs over $1 billion. Adding in the cost of capital at 7 percent increased the median research and development cost to $757 million—less than a third of the Tufts estimate.

Pharmaceutical companies often claim that the research costs of unsuccessful drugs also have to be taken into account. After all, 90 percent of all drugs that enter human testing fail. But most of these failures occur early and at relatively low costs. About 40 percent of drugs fail in preliminary Phase I studies, which assess a drug’s safety in humans and typically cost just $25 million a drug. Of the drugs that clear this first phase of testing, about 70 percent fail during Phase II studies, which assess whether a drug does what it is supposed to do. The research costs of these studies are still relatively low compared with overall R&D costs—on average, under $60 million a study.

The 2017 JAMA Internal Medicine study incorporated all research costs on drugs not yet on the market into its final calculations. The pharmaceutical companies it examined had an average drug success rate of 23 percent, which the Tufts researchers argue is too high to accurately represent the amount of money that failed drugs would usually add to a company’s research costs. But cancer drugs, specifically, do have a success rate of 20 to 25 percent—so the selection of only successful companies does not seem to be the difference.

Joaquin Duato, the vice chairman of Johnson & Johnson’s executive committee, argues that critics fail to deal with the realities of drug R&D. He told me that last year, Johnson & Johnson had $41 billion in prescription-drug sales, of which $8.4 billion went to R&D and $4.5 billion went to sales and marketing. Other costs included manufacturing, finance, IT, taxes, and more. This funds research on 100 candidate drugs, which result in one or two FDA approvals a year. “For drug companies, the return on capital is in the mid-teens, which is nowhere near tech-company returns,” Duato said.

Nevertheless, some former pharmaceutical-company executives say that research costs do not determine drug prices—and they explain how. In his book A Call to Action, Hank McKinnell, a past CEO of Pfizer, wrote under the heading “The Fallacy of Recapturing R&D Costs”:

How do we decide what to charge? It’s basically the same as pricing a car … A number of factors go into the mix. These factors consider cost of business, competition, patent status, anticipated volume, and, most important, our estimate of the income generated by sales of the product. It is the anticipated income stream, rather than repayment of sunk costs, that is the primary determinant of price.

Raymond Gilmartin, a former Merck CEO, once said to The Wall Street Journal: “The price of medicines is not determined by their research costs. Instead, it is determined by their value in preventing and treating disease.”

Exorbitant drug prices have two bad effects. First, high costs mean that lots of patients are unable to take their medications. A recent study in the Journal of Clinical Oncology assessed patients’ access to 38 different oral cancer drugs and found that 13 percent of cancer patients did not buy approved chemotherapy drugs if they had a co-payment of $10 a month, while 67 percent did not when they had to pay $2,000 or more. Another study showed that 25 percent of diabetic patient underuse their insulin because of cost.

Second, the high drug prices distort research priorities, emphasizing financial gains and not health gains. Cancer drugs are routinely priced at about $120,000 to $150,000 a year, and more than 600 cancer drugs are now being tested on humans. This can lead to great societal benefits: The United States is expected to face 1.76 million new cancer cases and more than 600,000 cancer deaths in 2019 alone. But many of the drugs that companies are pursuing have low promise, where the health gains are small—weeks of added life, not big cures. While even this short extra time can be valuable to individual families, too much investment in oncology means not enough in drugs for other illnesses whose treatments cannot be so highly priced.

Consider antibiotics. The Centers for Disease Control and Prevention ranks antibiotic-resistant infections as one of the nation’s top health threats. An estimated 2 million Americans become infected with such bacteria each year, and 23,000 die. A superbug that is resistant to all known antibiotics is an imminent threat. Yet because antibiotics are generally cheap, for most pharmaceutical and biotechnology companies they are not a primary focus. The Pew Charitable Trusts reports that only about 42 new antibiotics with the potential to treat serious bacterial infections were in clinical development for the U.S. market in December 2018. Six hundred drugs for cancer and only 42 for serious infections seems like profit maximization, not a case of sensible research priorities that reflects “value in preventing and treating disease.”

The simple explanation for excessive drug prices is monopoly pricing. Through patent protection and FDA marketing exclusivity, the U.S. government grants pharmaceutical companies a monopoly on brand-name drugs. But monopolies are a recipe for excessive prices. A company will raise prices until its profits start to drop.

To address the problem of high prices and reduced access to drugs, Johnson & Johnson advocates eliminating rebates to pharmacy benefit managers and insurers, which would increase price transparency and lower patient co-pays. But it would not necessarily lower total drug prices. The proposal avoids the standard economic response to monopoly pricing: price regulation. Every other developed country regulates drug prices, often through price negotiations pegged to cost-effectiveness analysis or some other measure of clinical benefit.

Will R&D go down if the United States follows this model? Not necessarily. Remember, the high drug prices fund R&D but also marketing, manufacturing, administrative expenses, and profits at the companies. Lower revenue from lower drug prices could reduce marketing, administration, and excessive profits before R&D costs have to be reduced.

Where cuts are made is up to drug companies. Their claims of lower R&D costs appear designed to generate fear, but as some former executives themselves have acknowledged, there is no necessary link between a decline in drug prices and a decline in R&D. Drug companies could make other choices that maximally improve the health of all Americans.

#### Specifically – Biologics account for 93% of the cost.

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Avik Roy, 3-8-2019, "Biologic Medicines: The Biggest Driver Of Rising Drug Prices," Forbes, https://www.forbes.com/sites/theapothecary/2019/03/08/biologic-medicines-the-biggest-driver-of-rising-drug-prices/?sh=16fb5a2618b0

The topic of high prescription drug prices is now the dominant policy issue on Capitol Hill. The new Congress has held a half-dozen hearings on the topic. But one issue that is at the heart of high prices has attracted little attention: the role of biologic drugs in rising drug costs.

In 2017, according to data from the IQVIA Institute, biologic drugs represented 2 percent of all U.S. prescriptions, but 37 percent of net drug spending. Since 2014, biologic drugs account for nearly all of the growth in net drug spending: 93 percent of it, in fact.

Why is that? And what are biologic drugs in the first place? I’ll try to explain.

The FDA regulates traditional and biologic drugs differently

In the old days, most FDA-approved drugs are what we call small molecules: traditional medicines with relatively simple chemical structures. For example, Lipitor (atorvastatin), a best-selling cholesterol-lowering drug, is comprised of 76 atoms, and is exceedingly cheap to manufacture. On the other hand, biologic drugs (or large molecules) like monoclonal antibodies are complex proteins, manufactured in living cells: a costlier process. Humira (adalimumab), the nation’s top drug by revenue, contains 20,067 atoms.

Biologic drugs are the wheelhouse of the biotechnology industry. Innovators in the 1970s and 1980s, like Genentech and Amgen, learned how to insert modified DNA sequences into harvested hamster cells, in order to make genetically engineered proteins that could treat diseases. For example, Epogen, Amgen’s first blockbuster drug, is a genetically engineered version of human erythropoietin: a protein that stimulates your bone marrow to produce more red blood cells. Because erythropoietin is normally produced in the kidney, people with kidney disease often have anemia that can be treated with Epogen.

Because biologic drugs are manufactured using different techniques than traditional, small molecule drugs, Congress and the FDA have chosen to regulate these two categories in different ways. Traditional drugs are governed by the Food, Drug, and Cosmetic Act: the law that originally created the Food and Drug Administration. Biologic medicines are governed by a different law, the Public Health Service Act.

In both cases, the FDA expects drugmakers to conduct clinical trials that demonstrate that a new drug is safe and effective. In both cases, the FDA scrutinizes manufacturing plants to ensure that medicines are consistently made from batch to batch.

Where things really change, in terms of FDA regulation, is after drugs have been on the market for a long time, with patents about to expire.

#### Budgetary overstretch driven by healthcare causes global instability.

Brown, PhD, Professor of Practice and Vice Chair, Public Administration and International Affairs at Syracuse, worked as an economist at the International Monetary Fund and as Chief Economist for Eastern Europe, Africa, and the Middle East at BNP Paribas, ‘13

(Stuart S., “Global Power: Key Issues,” in *The Future of US Global Power: Delusions of Decline*, Palgrave, p. 57-58)

In the first instance, structural26 budget deficits are more likely to be symptoms of incipient overstretch then prima facie evidence of national decline. Overstretch suggests a need to realign commitments and resources, hence spending and revenues. In principle, persistently large deficits demand adjustments that need not materially impact the underlying drivers of longer-term prosperity. In contrast, if fiscal imbalances prove sufficiently chronic, they can eventually trigger growth-inhibiting alterations in microeconomic incentives. In such cases, incipient overstretch can mutate into a more primary threat to the system's underlying dynamism.

In its classical formulation, “imperial overstretch” refers to unrestrained and exorbitant foreign military campaigns. The latter can be said to redound to the detriment of great powers by crowding out more productive capital investments. Yet in contrast to widespread impression, the US fiscal challenge does not primarily reflect out-of-control defense spending and the burden of foreign entanglements. If this were the case, then the feasibility of financing an ever-expanding global power projection would be brought into question. This neither minimizes the sizable resources the US commits to military-related spending nor denies that cutbacks in such spending can help facilitate overall fiscal adjustment. Rather, the point is that an endemic failure to rein in explosive economy-wide health care costs with the latter's implications for public sector health insurance programs – the real fiscal challenge – will do more to endanger macroeconomic stability and eventually erode the material foundation of US power (see chapter 8).

By viewing (health-care driven) fiscal deficits as a necessary manifestation of overstretch is misguided for a more basic reason. The root of the US fiscal problem involves unsustainable commitments – particularly in the area of health expenditure – made by government to its citizens. It is decidedly not a question of any dearth of national resources to adequately meet the health needs of the population at large. As the richest country in the world, the US possesses more than enough resources to achieve this goal. The relevant political and social question is whether the population’s basic health requirements are best met via ever-expanding entitlements requiring increasingly higher levels of taxation.

#### And – It’s a leading cause of death and suffering

WestHealth 20 – Citing new study

New Study Predicts More Than 1.1 Million Deaths Among Medicare Recipients Due to the Inability to Afford Their Medications: Beneficiaries skipping medications is causing early death and worsening medical conditions that will cost Medicare an extra $177.4 billion over the next 10 years, Nov. 19, 2020, https://www.westhealth.org/press-release/study-predicts-1-million-deaths-due-to-high-cost-prescription-drugs/

More than 1.1 million Medicare patients could die over the next decade because they cannot afford to pay for their prescription medications, according to a new study released today by the West Health Policy Center, a nonprofit and nonpartisan policy research group.

If current drug pricing trends and associated cost-sharing continue, researchers estimate cost-related non-adherence to drug therapy will result in the premature deaths of 112,000 beneficiaries a year, making it a leading cause of death in the U.S., ahead of diabetes, influenza, pneumonia, and kidney disease. Millions more will suffer worsening health conditions and run up medical expenses that will cost Medicare an additional $177.4 billion by 2030 or $18 billion a year for the next 10 years.

### 1AC – Innovation Adv

Contention 2 is Innovation –

#### Innovation is plummeting despite skyrocketing prices. Only competition rebalances patent incentives to solve both problems

Feldman 18 – Distinguished Professor of Law Chair & Director of the Center for Innovation, UC Hastings Law

Robin Feldman, Arthur J. Goldberg Distinguished Professor of Law, Albert Abramson ’54 Distinguished Professor of Law Chair, and Director of the Center for Innovation, May your drug price be evergreen, *Journal of Law and the Biosciences*, Volume 5, Issue 3, December 2018, pp. 590–647, https://doi.org/10.1093/jlb/lsy022

Out of the 106 top-selling drugs from between 2005 and 2014, more than 70% had their protection cliff extended at least once and more than 50% had their protection cliff extended more than once. The magnitude of the behavior highlights the extent to which stifling competition has become the norm in the pharmaceutical industry. When more than 70% of best-selling drugs had their protection extended, it is clearly the go-to approach for profitability.149

One can easily anticipate such maneuvering to continue going forward, particularly given the top-selling drugs going off patent. Between 2014 and 2020, an estimated $253 billion in worldwide drug sales is at risk due to expiration of patents on blockbuster drugs.150 Without societal action, the future is likely to look like more of the same.

V. SOLUTIONS

As described in the opening of this article, the intellectual property system in general and the patent system in particular are designed to provide an opportunity for innovators to garner a return. Competition may be held in abeyance for a limited time, but those who receive the benefit must pay for the privilege by disclosing sufficient information that competitors will be able to step in. This design reflects the deeply rooted notion that providing a period of exclusivity for inventors is intended to rebound to the benefit of society as a whole, not simply to the benefit of the inventors. The patent protection should end, returning the market to a competitive state.

This foundational structure of the patent system—one that delicately balances innovation and competition—is crumbling, whittled away across time as one good idea after another creates a special carve-out. Each carve-out, standing on its own, presents an appealing cause. Together, however, the result is a complete undermining of the system for pharmaceutical innovation as the repeated addition of protections, one after another, pushes competition further into the future, threatening innovation in the process. The behavior is not limited to a few bad apples. Our research reveals that it is endemic to the pharmaceutical industry.

In short, this is not an image of innovation and competitive entry. It is an image of a system that provides for repeated creation of competition-free zones, pushing a competitive market further and further out into the future. The problem is not only pervasive and persistent, but it is also growing across time.

The impact created by these repeated competition zones is not some abstract problem that our grandchildren may face. Rather, the nation's pharmaceutical system is in crisis today, with prices soaring to heights that distort both individual and government budgets.151 These dire circumstances bring calls for price controls, for government marching in to direct drug production, and for other strong measures.152 The US Government's history of directly managing pharmaceutical innovation, however, has been disappointing. In fact, prior to the Bayh-Dole Act of 1980, the federal government took responsibility for handing out licenses for innovation developed through government-funded research. Bayh-Dole shifted that responsibility from the federal government to universities, precisely because the government failed so miserably in this role. There is little reason to expect a different result this time.153

Competition is a powerful and effective tool, however, and paving the way for competition whenever it is possible remains the optimal approach. When the government itself bestows benefits that are stifling competition, society has both an obligation and an opportunity to act. One cannot, however, enter into such action lightly; it must be designed with thought and care. Pharmaceutical research and development are expensive, and companies must have sufficient incentive to travel down that risky road. Nevertheless, by incentivizing game-playing rather than innovation, society has clearly missed the mark.

#### Artificially shielding patents from scrutiny incentivizes pseudo-innovation – companies will develop the 50th version of Aspirin and not big breakthroughs

Elhauge and Krueger 12 – Petrie Professor of Law, Harvard Law School and Executive Director, Legal Economics

Einer Elhauge & Alex Krueger, “Solving the Patent Settlement Puzzle,” Texas Law Review, Vol. 91:283

Exceeding the optimal patent exclusion period is likewise inefficient for several reasons. First, the economic literature shows that patent profits that exceed the optimal level result in excessive investments in innovation that reduce social welfare compared to the optimal investments in innovation. Second, excessive patent protection can produce a net reduction in innovation by precluding subsequent innovations by others.

Third, settlements that over-reward the patent holder with a longer exclusion period than it deserves reduce the net reward for true innovation by increasing the reward more for less-deserving patents than for more deserving patents. As the proof below shows and the Second Circuit has already pointed out, settlements that exclude entry increase patent-holder profits more for weaker patents than for stronger patents. For example, the holder of a weak patent that is only 5% likely to be deemed a valid innovation could use such a settlement to secure exclusion throughout the entire patent term, even though its patent is 95% likely to be deemed a non-innovation, while the holder of an ironclad patent that is 100% likely to be deemed a true innovation could not increase its exclusion period through settlement because it would already expect 100% exclusion from litigation. Thus, settlements with an excessive exclusion period reduce the net reward for investing in a true innovation that leads to a stronger patent rather than in a pseudo-innovation that leads to a weaker patent. When a firm faces a choice between investing in true innovation or pseudo-innovation, this artificially reduced net reward for true innovation will distort its choice, and can reduce the rate of true innovation because it is generally harder, more costly, or less certain than pseudo-innovation.

#### Specifically – increasing competition is key to drive the revolution in biologics. Those are ground-breaking new treatments derived from living organisms, such as new vaccine tech and bacteriophages.

Carrier 20 – Michael A. Carrier is a leading authority in antitrust and intellectual property law with expertise in the pharmaceutical, high-technology, and music industries.

Carrier, Michael A. "Don't Die! How Biosimilar Disparagement Violates Antitrust Law." Northwestern University Law Review Online, 115, 2020-2021, p. 119-145. HeinOnline, <https://heinonline.org/HOL/P?h=hein.journals/nulro115&i=119>.

Competition is the key to low prices in the pharmaceutical industry. For decades, Americans have benefitted from affordable generic versions of brand-name drugs. But now, as biologics enter the market, we stand on the precipice of a revolution. In fact, biologics, which can cost patients hundreds of thousands of dollars per year, are predicted to be the "fastest growing segment of drug spending in the coming years."1

The hope, then, is that competition from follow-on products, known as biosimilars, will lower prices for patients. But pharmaceutical companies' campaign of biosimilar disparagement threatens to block this goal. Biologics are large, complex molecules derived from living organisms, most commonly proteins.2 According to the FDA, biologics "often represent the cutting-edge of biomedical research and, in time, may offer the most effective means to treat a variety of medical illnesses and conditions" that have "no other treatments available."3 Monoclonal antibodies, the most frequently developed type of biologic,4 include blockbuster products such as infection-reducing Neulasta, 5 as well as Humira and Remicade,7 both of which treat arthritis, colitis, and Crohn's disease. In targeting unhealthy cells without harming healthy cells, monoclonal antibodies have dramatically increased survival rates.9 Other types of biologics include vaccines, blood products, and gene therapies.10

#### Because they’re living, they are uniquely complex and expensive to synthesize, and no two are exactly alike

Carrier and Minniti 18 – Distinguished Professor, Rutgers Law School, Rutgers Law School, J.D. 2017

Michael A. Carrier and Carl J. Minniti III, BIOLOGICS: THE NEW ANTITRUST FRONTIER, UNIVERSITY OF ILLINOIS LAW REVIEW, 1/12/2018, <https://www.illinoislawreview.org/wp-content/uploads/2018/01/Carrier.pdf>

The science underlying biologics is profoundly different from that of small-molecule drugs. Small molecules are created through a series of chemical reactions known as chemical synthesis. This process is relatively predictable, allowing generics to imitate brand drugs at low cost. Put another way, brands and generics can put the same pieces of a puzzle together in the same way to create the same image. Biologics, in contrast, blow up that paradigm, emphasizing not the individual pieces of the puzzle but the way the puzzle is constructed. Because “the product is the process” and the use of living cells to create biologics is inherently sensitive, there is higher variability and follow-ons cannot precisely replicate the original product. Challenges in biologic development stem from not only the complexity of the molecule but also from changes during the product’s maturation. Unlike the “single and mono-molecular entity” making up small molecules, the final form of biologics is “a complex mix of the same protein molecule under various structurally close [protein-varying] isoforms.” The complicated nature of biologic development is revealed by the uncertainties in the structure of a protein, a typical biologic. A protein includes four structural levels: primary, secondary, tertiary, and quaternary. The primary structure consists of the amino acid sequence, which is essential for biologic activity. Even though drug developers can replicate an amino acid sequence, individualized production and purification methods result in unpredictable structural folding at the secondary, tertiary, and quaternary levels (each of which addresses larger three-dimensional structures). This unpredictability has dramatic effects, determining whether a drug confers therapeutic or toxic effects. Adding to the complexity, even if a biosimilar manufacturer could replicate the structure of the biologic, post-translational modifications to the structure could result in undetectable differences causing adverse patient reactions. Most therapeutic proteins induce a reflexive antibody response against the therapy introduced into the patient’s body. For that reason, immunogenicity—a triggered unwanted immune response—plays a critical role in biologic development. As a patient’s body attempts to fight off foreign proteins, certain product-related factors elicit particular responses, including molecule design, impurities, and post-translational modifications. The development of biologics is particularly difficult and unpredictable because the immunogenic response to proteins cannot be replicated in animal models to simulate an immune response in humans. If variability in biologic development and immunogenicity is a concern for the biologic manufacturer in making its own product, a follow-on maker will confront even higher hurdles. While these entities can rely on patent disclosures and other materials in the public domain, they will lack access to critical information the biologic manufacturer protects as a trade secret. Because biologics are “so closely defined by their manufacturing process,” this secrecy blocks competition. Finally, the effects of complexity and secrecy are exacerbated by the difficulty of even analyzing a protein’s structure. The ability to use analytic techniques to demonstrate clinical comparability is more limited than for small-molecule drugs, with a biosimilar manufacturer not able to show that its product is identical to the biologic product. Unlike generic versions of small-molecule drugs, which are chemically identical to brand versions, the structural variability and complexity inherent in biologic development cause follow-on versions to strive for, at most, similarity. These differences have direct effects on the relevant markets.

C. Markets

Biologics’ complexity is accompanied by their timeliness, with a follow-on biosimilars market poised to explode. This development is even more crucial given that many blockbuster small-molecule drugs are in the midst of losing patent protection, with nearly $200 billion in brand sales subject to generic competition by 2025. The end of a “golden age” for small-molecule block- busters has resulted in drug companies developing biologics, planning to receive as much as 50% of their revenues from the medications in the near future. Such a development will be profitable, with an average daily cost of $45 for a biologic vastly exceeding that of a $2 daily cost for a small-molecule drug. The biologic market, worth $46 billion in 2002, is expected to increase to $390 billion worldwide by 2020. The top-selling U.S. drug of 2015, immune system-treating biologic Humira, amassed more than $8 billion in sales. Other top-selling biologics include arthritis-treating Enbrel (nearly $6 billion) and arthritis-, Crohn’s disease-, and colitis-treating Remicade (more than $4 billion). The rise of biologics could be met with an onslaught of biosimilars, with biologics worth $67 billion in global sales witnessing the expiration of patents by 2020. But despite the clear market opportunity, biosimilar introduction has been relatively slow. One fundamental reason is that, unlike generics requiring expenditures of roughly $2 million, biosimilar development, involving more intensive and uncertain research and development, costs as much as $200 million. Congress enacted the Biologics Price Competition and Innovation Act of 2009 (“BPCIA”) in 2010, but it took until 2015 for the FDA to approve the first biosimilar: Zarxio, Sandoz’s follow-on version of Amgen’s billion-dollar neutropenia (anti-infection) therapy, Neupogen. As of the date of this Article, the FDA has approved only seven biosimilars. In addition to Zarxio, Mvasi received approval as a biosimilar to the $6.75 billion cancer therapy Avastin, and five biosimilars are follow-on versions of three blockbuster inflammatory disease treatments, each in the top ten drugs sold in the United States: (1) Amjevita and Cyltezo, biosimilars to the $8.3 billion Humira; (2) Erelzi, a biosimilar to the $5.9 billion Enbrel; and (3) Inflectra and Renflexis, biosimilars to the $4.6 billion Remicade. Early indications point to biosimilars lowering costs. For example, both Zarxio and Inflectra are sold at a 15% discount from the biologic price. And according to Renflexis sponsor Merck, the biosimilar product “will be introduced in the U.S. at a list price (wholesaler acquisition cost) of $753.39, representing a 35% discount off the current list price of Remicade.” In the small-molecule setting, the entry of a single generic modestly lowers price. As the previous paragraph showed, early returns from the biosimilars market are analogous. But while the entry of multiple small-molecule generics results in significant price erosion (50% with 2 generics and 75% with at least 6), we predict that the reductions may be more modest given attempts to recoup biosimilar development costs, which greatly exceed those incurred by generics. The market effects of biologics and biosimilars also will be shaped by the relevant laws and regulations.

#### Scenario A is Breakthroughs – COVID is only the first warning shot. Continued vaccine development is key to survival

EID = Emerging Infectious Disease

Excler et al. 21 – Jean-Louis Excler, International Vaccine Institute, Seoul, Republic of Korea; Melanie Saville, Coalition for Epidemic Preparedness Innovations (CEPI), London, UK; Seth Berkley, Gavi, the Vaccine Alliance, Geneva, Switzerland; Jerome H. Kim, International Vaccine Institute, Seoul, Republic of Korea

Jean-Louis Excler, Melanie Saville, Seth Berkley, and Jerome H. Kim, "Vaccine development for emerging infectious diseases," Nat Med 27, 591–600, 4-12-2021, <https://www.nature.com/articles/s41591-021-01301-0>

Newly emerging and reemerging infectious viral diseases have threatened humanity throughout history. Several interlaced and synergistic factors including demographic trends and high-density urbanization, modernization favoring high mobility of people by all modes of transportation, large gatherings, altered human behaviors, environmental changes with modification of ecosystems and inadequate global public health mechanisms have accelerated both the emergence and spread of animal viruses as existential human threats. In 1918, at the time of the ‘Spanish flu’, the world population was estimated at 1.8 billion. It is projected to reach 9.9 billion by 2050, an increase of more than 25% from the current 2020 population of 7.8 billion (https://www.worldometers.info). The novel severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) responsible for the coronavirus disease 2019 (COVID-19) pandemic1,2,3 engulfed the entire world in less than 6 months, with high mortality in the elderly and those with associated comorbidities. The pandemic has severely disrupted the world economy. Short of lockdowns, the only means of control have been limited to series of mitigation measures such as self-distancing, wearing masks, travel restrictions and avoiding gatherings, all imperfect and constraining. Now with more than 100 million people infected and more than 2 million deaths, it seems that the addition of vaccine(s) to existing countermeasures holds the best hope for pandemic control. Taken together, these reasons compel researchers and policymakers to be vigilant, reexamine the approach to surveillance and management of emerging infectious disease threats, and revisit global mechanisms for the control of pandemic disease4,5.

Emerging and reemerging infectious diseases

The appearance of new infectious diseases has been recognized for millennia, well before the discovery of causative infectious agents. Despite advances in development of countermeasures (diagnostics, therapeutics and vaccines), world travel and increased global interdependence have added layers of complexity to containing these infectious diseases. Emerging infectious diseases (EIDs) are threats to human health and global stability6,7. A review of emerging pandemic diseases throughout history offers a perspective on the emergence and characteristics of coronavirus epidemics, with emphasis on the SARS-CoV-2 pandemic8,9. As human societies grow in size and complexity, an endless variety of opportunities is created for infectious agents to emerge into the unfilled ecologic niches we continue to create. To illustrate this constant vulnerability of populations to emerging and reemerging pathogens and their respective risks to rapidly evolve into devastating outbreaks and pandemics, a partial list of emerging viral infectious diseases that occurred between 1900 and 2020 is shown in Table 1.

[[Figure Omitted]]

Although nonemerging infectious diseases (not listed in Table 1), two other major mosquito-borne viral infections are yellow fever and dengue. Yellow fever, known for centuries and an Aedes mosquito-borne disease, is endemic in more than 40 countries across Africa and South America. Since 2016, several yellow fever outbreaks have occurred in Angola, Democratic Republic of Congo, Nigeria and Brazil to cite a few10, raising major concerns about the adequacy of yellow fever vaccine supply. Four live attenuated vaccines derived from the live attenuated yellow fever strain (17D)11 and prequalified by the WHO (World Health Organization) are available12.

Dengue is an increasing global public health threat with the four dengue virus types (DENV1–4) now cocirculating in most dengue endemic areas. Population growth, an expansion of areas hospitable for Aedes mosquito species and the ease of travel have all contributed to a steady rise in dengue infections and disease. Dengue is common in more than 100 countries around the world. Each year, up to 400 million people acquire dengue. Approximately 100 million people get sick from infection, and 22,000 die from severe dengue. Most seriously affected by outbreaks are the Americas, South/Southeast Asia and the Western Pacific; Asia represents ~70% of the global burden of disease (https://www.cdc.gov/dengue). Several vaccines have been developed13. A single dengue vaccine, Sanofi Pasteur’s Dengvaxia based on the yellow fever 17D backbone, has been licensed in 20 countries, but uptake has been poor. A safety signal in dengue-seronegative vaccine recipients stimulated an international review of the vaccine performance profile, new WHO recommendations for use and controversy in the Philippines involving the government, regulatory agencies, Sanofi Pasteur, clinicians responsible for testing and administering the vaccine, and the parents of vaccinated children14.

Two bacterial diseases, old scourges of humanity, are endemic and responsible for recurrent outbreaks and are increasingly antimicrobial resistant. Cholera, caused by pathogenic strains of Vibrio cholerae, is currently in its seventh global pandemic since 1817; notably, the seventh pandemic started in 196115. Global mortality due to cholera infection remains high, mainly due to delay in rehydrating patients. The global burden of cholera is estimated to be between 1.4 and 4.3 million cases with about 21,000–143,000 deaths per year, mostly in Asia and Africa. Tragic outbreaks have occurred in Yemen and Haiti. Adding to rehydration therapy, antibiotics have been used in the treatment of cholera to shorten the duration of diarrhea and to limit bacterial spread. Over the years, antimicrobial resistance developed in Asia and Africa to many useful antibiotics including chloramphenicol, furazolidone, trimethoprim-sulfamethoxazole, nalidixic acid, tetracycline and fluoroquinolones. Several vaccines have been developed and WHO prequalified; these vaccines constitute a Gavi-supported global stockpile for rapid deployment during outbreaks16.

Typhoid fever is a severe disease caused by the Gram-negative bacterium Salmonella enterica subsp. enterica serovar Typhi (S. Typhi). Antimicrobial-resistant S. Typhi strains have become increasingly common. The first large-scale emergence and spread of a novel extensively drug-resistant (XDR) S. Typhi clone was first reported in Sindh, Pakistan17,18, and has subsequently been reported in India, Bangladesh, Nepal, the Philippines, Iraq and Guatemala19,20. The world is in a critical period as XDR S. Typhi has appeared in densely populated areas. The successful development of improved typhoid vaccines (conjugation of the Vi polysaccharide with a carrier protein) with increased immunogenicity and efficacy including in children less than 2 years of age will facilitate the control of typhoid, in particular in XDR areas by decreasing the incidence of typhoid fever cases needing antibiotic treatment21,22.

A model of vaccine development for emerging infectious diseases

The understanding of emerging infectious diseases has evolved over the past two decades. A look back at the SARS-CoV outbreak in 2002 shows that—despite a small number of deaths and infections—its high mortality and transmissibility caused significant global disruption (see Table 1). The epidemic ended as work on vaccines was initiated. Since then, the disease has not reappeared—wet markets were closed and transmission to humans from civets ceased. Consequently, work on vaccines against SARS-CoV ended and its funding was cut. Only a whole inactivated vaccine23 and a DNA vaccine24 were tested in phase 1 clinical trials.

Following a traditional research and development pipeline, it takes between 5 and 10 years to develop a vaccine for an infectious agent. This approach is not well suited for the needs imposed by the emergence of a new pathogen during an epidemic. Figure 1 shows a comparison of the epidemic curves and vaccine development timelines between the 2014 West African Ebola outbreak and COVID-19. The 2014 Ebola epidemic lasted more than 24 months with 11,325 deaths and was sufficiently prolonged to enable the development and testing of vaccines for Ebola, with efficacy being shown for one vaccine (of several) toward the end of the epidemic25,26. What makes the COVID-19 pandemic remarkable is that the whole research and development pipeline, from the first SARS-CoV-2 viral sequenced to interim analyses of vaccine efficacy trials, was accomplished in just under 300 days27. Amid increasing concerns about unmitigated transmission during the 2013–2016 Western African Ebola outbreak in mid-2014, WHO urged acceleration of the development and evaluation of candidate vaccines25. To ensure that manufacturers would take the Ebola vaccine to full development and deployment, Gavi, the Vaccine Alliance, publicly announced support of up to US$300 million for vaccine purchase and followed that announcement with an advance purchase agreement. Ironically, there had been Ebola vaccines previously developed and tested for biodefense purposes in nonhuman primates, but this previous work was neither ‘ready’ for clinical trials during the epidemic nor considered commercially attractive enough to finish development28.

[[Figure Omitted]]

From these perceived shortcomings in vaccine development during public health emergencies arose the Coalition for Epidemic Preparedness Innovations (CEPI), a not-for-profit organization dedicated to timely vaccine development capabilities in anticipation of epidemics29,30. CEPI initially focused on diseases chosen from a list of WHO priority pathogens for EIDs—Middle East respiratory syndrome (MERS), Lassa fever, Nipah, Rift Valley fever (RVF) and chikungunya. The goal of CEPI was to advance candidate vaccines through phase 2 and to prepare stockpiles of vaccine against eventual use/testing under epidemic circumstances. CEPI had also prepared for ‘disease X’ by investing in innovative rapid response platforms that could move from sequence to clinical trials in weeks rather than months or years, such as mRNA and DNA technology, platforms that were useful when COVID-19 was declared a global health emergency in January 2020, and a pandemic in March 202031,32.

CEPI has been able to fund several vaccine development efforts, among them product development by Moderna, Inovio, Oxford–AstraZeneca and Novavax. Providing upfront funding helped these groups to advance vaccine candidates to clinical trials and develop scaled manufacturing processes in parallel, minimizing financial risk to vaccine developers. The launch of the larger US-funded Operation Warp Speed33 further provided companies with funding—reducing risks associated with rapid vaccine development and securing initial commitments in vaccine doses.

Vaccine platforms and vaccines for emerging infectious diseases

Vaccines are the cornerstone of the management of infectious disease outbreaks and are the surest means to defuse pandemic and epidemic risk. The faster a vaccine is deployed, the faster an outbreak can be controlled. As discussed in the previous section, the standard vaccine development cycle is not suited to the needs of explosive pandemics. New vaccine platform technologies however may shorten that cycle and make it possible for multiple vaccines to be more rapidly developed, tested and produced34. Table 2 provides examples of the most important technical vaccine platforms for vaccines developed or under development for emerging viral infectious diseases. Two COVID-19 vaccines were developed using mRNA technology (Pfizer–BioNTech35 and Moderna36), both showing safety and high efficacy, and now with US Food and Drug Administration (FDA) emergency use authorization (EUA)37,38 and European Medicines Agency (EMA) conditional marketing authorization39,40. While innovative and encouraging for other EIDs, it is too early to assert that mRNA vaccines represent a universal vaccine approach that could be broadly applied to other EIDs (such as bacterial or enteric pathogens). While COVID-19 mRNA vaccines are a useful proof of concept, gathering lessons from their large-scale deployment and effectiveness studies still requires more work and time.

[[Figure Omitted]]

While several DNA vaccines are licensed for veterinary applications, and DNA vaccines have shown safety and immunogenicity in human clinical trials, no DNA vaccine has reached licensure for use in humans41. Recombinant proteins vary greatly in design for the same pathogen (for example, subunit, virus-like particles) and are often formulated with adjuvants but have longer development times. Virus-like particle-based vaccines used for hepatitis B and human papillomavirus are safe, highly immunogenic, efficacious and easy to manufacture in large quantity. The technology is also easily transferable. Whole inactivated pathogens (for example, SARS-CoV-2, polio, cholera) or live attenuated vaccines (for example, SARS-CoV-2, polio, chikungunya) are unique to each pathogen. Depending on the pathogen, these vaccines also may require biosafety level 3 manufacturing (at least for COVID-19 and polio), which may limit the possibility of technology transfer for increasing the global manufacturing capacity.

Other vaccines are based on recombinant vector platforms, subdivided into nonreplicating vectors (for example, adenovirus 5 (Ad5), Ad26, chimpanzee adenovirus-derived ChAdOx, highly attenuated vectors like modified vaccinia Ankara (MVA)) and live attenuated vectors such as the measles-based vector or the vesicular stomatitis virus (VSV) vector. Either each vector is designed with specific inserts for the pathogen targeted, or the same vector can be designed with different inserts for the same disease. The development of the Merck Ebola vaccine is an example. ERVEBO is a live attenuated, recombinant VSV-based, chimeric-vector vaccine, where the VSV envelope G protein was deleted and replaced by the envelope glycoprotein of Zaire ebolavirus. ERVEBO is safe and highly efficacious, now approved by the US FDA and the EMA, and WHO prequalified, making VSV an attractive ‘platform’ for COVID-19 and perhaps for other EID vaccines26 although the −70 °C ultracold chain storage requirement still presents a challenge.

Other equally important considerations are speed of development, ease of manufacture and scale-up, ease of logistics (presentation, storage conditions and administration), technology transfer to other manufacturers to ensure worldwide supply, and cost of goods. Viral vectors such as Ad5, Ad26 and MVA have been used in HIV as well as in Ebola vaccines42. Finally, regulatory authorities do not approve platforms but vaccines. Each vaccine is different. However, with each use of a specific technology, regulatory agencies may, over time, become more comfortable with underlying technology and the overall safety and efficacy of the vaccine platform, allowing expedited review and approvals in the context of a pandemic43. With COVID-19, it meant that the regulatory authorities could permit expedited review of ‘platform’ technologies, such as RNA and DNA, that had been used (for other conditions) and had safety profiles in hundreds of people.

#### It’s a constant arms race.

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David M. Morens and Anthony S. Fauci, "Emerging Infectious Diseases: Threats to Human Health and Global Stability," PLoS Pathog 9(7): e1003467, 7-4-2013, <https://journals.plos.org/plospathogens/article?id=10.1371/journal.ppat.1003467>

Will We Ever Eliminate Emerging Infectious Diseases?

While it has become possible to eradicate certain infectious diseases (smallpox and the veterinary disease rinderpest), and to significantly control many others (dracunculiasis, measles, and polio, among others), it seems unlikely that we will eliminate most emerging infectious diseases in the foreseeable future. Pathogenic microorganisms can undergo rapid genetic changes, leading to new phenotypic properties that take advantage of changing host and environmental opportunities. Influenza viruses serve as a good example of emerging and reemerging infectious agents in their ability to rapidly evolve in response to changing host and environmental circumstances via multiple genetic mechanisms. New “founder” influenza viruses [21] appear periodically, cause a pandemic, raise widespread population immunity, and then, in response to human immune pressures, evolve and persist for decades using multiple genetic evolutionary mechanisms to sustain continual immune escape. The 1918 influenza pandemic virus is one example: over the past 95 years, its descendants have evolved continually by antigenic drift, intra-subtypic reassortment, and antigenic shift, the latter producing new pandemics in 1957 and 1968 [14]. Even the genetically complex 2009 pandemic H1N1 influenza virus is a descendant of the 1918 virus [14]. Such continuous genetic hyper-evolution forces us to develop new influenza vaccines containing new antigens on an annual basis.

In the meantime, new human diseases keep emerging. As noted, in late 2012 the novel MERS coronavirus emerged in Saudi Arabia [13], and in early 2013 a new H7N9 avian influenza virus became epizootic in Eastern China, causing 132 spillover infections of humans (as of June 7, 2013), with 28 percent case fatality [10], [22]. Its pandemic potential, if any, remains to be determined. Whether or not such outbreaks become more widespread, they nonetheless attract global attention and require significant international effort to monitor and contain. Microbial advantages can be met and overcome only by aggressive vigilance, ongoing dedicated research, and rapid development and deployment of such countermeasures as surveillance tools, diagnostics, drugs, and vaccines.

We appear to be entering a new era in which several important emerging, reemerging, and stable infectious diseases are becoming better controlled (e.g., hepatitis B, rabies, Haemophilus influenzae type B, and even to some extent HIV/AIDS). However, our success in stopping the many new emerging diseases that will inevitably appear is not assured. We have many tools in our armamentarium, including preparedness plans and stockpiles of drugs and vaccines. But each new disease brings unique challenges, forcing us to continually adapt to ever-shifting threats [1]–[10], [23]. The battle against emerging infectious diseases is a continual process; winning does not mean stamping out every last disease, but rather getting out ahead of the next one.

#### The tempo and threat level are rising faster than ever – pandemics outweigh climate change and nuclear war

Dhillon 17 – former senior govt advisor on pandemic control; MD, Instructor-Harvard Med School, Physician-Brigham and Women’s Hospital in Boston

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In 2003 a doctor with SARS unknowingly infected several guests while staying at a Hong Kong hotel, and overnight the virus reached across the globe. China is currently battling a bird flu that kills nearly half of the people infected. If Ebola, which transmits through fluids, were spread by air, or if Zika, which has reached over 50 countries, were as deadly as Ebola, we would be facing an unprecedented catastrophe. An uncontrolled outbreak or bioterror attack could result in a contagion that kills over 30 million people.

We fear it is only a matter of time before we face a deadlier and more contagious pathogen, yet the threat of a deadly pandemic remains dangerously overlooked. Pandemics now occur with greater frequency, due to factors such as climate change, urbanization, and international travel. Other factors, such as a weak World Health Organization and potentially massive cuts to funding for U.S. scientific research and foreign aid, including funding for the United Nations, stand to deepen our vulnerability. We also face the specter of novel and mutated pathogens that could spread and kill faster than diseases we have seen before. With the advent of genome-editing technologies, bioterrorists could artificially engineer new plagues, a threat that Ashton Carter, the former U.S. secretary of defense, thinks could rival nuclear weapons in deadliness.

The two of us have advised the president of Guinea on stopping Ebola. In addition, we have worked on ways to contain the spread of Zika and have informally advised U.S. and international organizations on the matter. Our experiences tell us that the world is unprepared for these threats.

We urgently need to change this trajectory. We can start by learning four lessons from the gaps exposed by the Ebola and Zika pandemics.

Faster Vaccine Development

The most effective way to stop pandemics is with vaccines. However, with Ebola there was no vaccine, and only now, years later, has one proven effective. This has been the case with Zika, too. Though there has been rapid progress in developing and getting a vaccine to market, it is not fast enough, and Zika has already spread worldwide.

Many other diseases do not have vaccines, and developing them takes too long when a pandemic is already under way. We need faster pipelines, such as the one that the Coalition for Epidemic Preparedness Innovations is trying to create, to preemptively develop vaccines for diseases predicted to cause outbreaks in the near future.

Point-of-Care Diagnostics

Even with such efforts, vaccines will not be ready for many diseases and would not even be an option for novel or artificially engineered pathogens. With no vaccine for Ebola, our next best strategy was to identify who was infected as quickly as possible and isolate them before they infected others. Because Ebola’s symptoms were identical to common illnesses like malaria, diagnosis required laboratory testing that could not be easily scaled. As a result, many patients were only tested after several days of being contagious and infecting others. Some were never tested at all, and about 40% of patients in Ebola treatment centers did not actually have Ebola.

Many dangerous pathogens similarly require laboratory testing that is difficult to scale. Florida, for example, has not been able to expand testing for Zika, so pregnant women wait weeks to know if their babies might be affected. What’s needed are point-of-care diagnostics that, like pregnancy tests, can be used by frontline responders or patients themselves to detect infection right away, where they live. These tests already exist for many diseases, and the technology behind them is well-established. However, the process for their validation is slow and messy. Point-of-care diagnostics for Ebola, for example, were available but never used because of such bottlenecks.

Greater Global Coordination

We need stronger global coordination. The responsibility for controlling pandemics is fragmented, spread across too many players with no unifying authority. In Guinea we forged a response out of an amalgam of over 30 organizations, each of which had its own priorities. In Ebola’s aftermath, there have been calls for a mechanism for responding to pandemics similar to the advance planning and training that NATO has in place for its numerous members to respond to military threats in a quick, coordinated fashion.

This is the right thinking, but we are far from seeing it happen. The errors that allowed Ebola to become a crisis replayed with Zika, and the WHO, which should anchor global action, continues to suffer from a lack of credibility.

Stronger Local Health Systems

International actors are essential but cannot parachute into countries and navigate local dynamics quickly enough to contain outbreaks. In Guinea it took months to establish the ground game needed to stop the pandemic, with Ebola continuing to spread in the meantime. We need to help developing countries establish health systems that can provide routine care and, when needed, coordinate with international responders to contain new outbreaks.

Local health systems could be established for about half of the $3.6 billion ultimately spent on creating an Ebola response from scratch. Access to routine care is also essential for knowing when an outbreak is taking root and establishing trust. For months, Ebola spread before anyone knew it was happening, and then lingered because communities who had never had basic health care doubted the intentions of foreigners flooding into their villages. The turning point in the pandemic came when they began to trust what they were hearing about Ebola and understood what they needed to do to halt its spread: identify those exposed and safely bury the dead.

With Ebola and Zika, we lacked these four things — vaccines, diagnostics, global coordination, and local health systems — which are still urgently needed. However, prevailing political headwinds in the United States, which has played a key role in combatting pandemics around the world, threaten to make things worse. The Trump administration is seeking drastic budget cuts in funding for foreign aid and scientific research. The U.S. State Department and U.S. Agency for International Development may lose over one-third of their budgets, including half of the funding the U.S. usually provides to the UN. The National Institutes of Health, which has been on the vanguard of vaccines and diagnostics research, may also face cuts. The Centers for Disease Control and Prevention, which has been at the forefront of responding to outbreaks, remains without a director, and, if the Affordable Care Act is repealed, would lose $891 million, 12% of its overall budget, provided to it for immunization programs, monitoring and responding to outbreaks, and other public health initiatives.

Investing in our ability to prevent and contain pandemics through revitalized national and international institutions should be our shared goal. However, if U.S. agencies become less able to respond to pandemics, leading institutions from other nations, such as Institut Pasteur and the National Institute of Health and Medical Research in France, the Wellcome Trust and London School of Hygiene and Tropical Medicine in the UK, and nongovernmental organizations (NGOs have done instrumental research and response work in previous pandemics), would need to step in to fill the void.

There is no border wall against disease. Pandemics are an existential threat on par with climate change and nuclear conflict. We are at a critical crossroads, where we must either take the steps needed to prepare for this threat or become even more vulnerable. It is only a matter of time before we are hit by a deadlier, more contagious pandemic. Will we be ready?

#### Independently – Antibiotic resistance will cause extinction – boosting the innovation pipeline is necessary

Talkington 20 – oversees teams of policy experts, scientists, and advocates for Pew’s work on public health issues, including the rise of antibiotic-resistant bacteria,

Kathy Talkington, "The U.S. Is Not Prepared to Combat 'Existential Threat' of Antibiotic-Resistant Superbugs," The Pew Charitable Trusts, 7-27-2020, <https://www.pewtrusts.org/en/research-and-analysis/articles/2020/07/27/the-us-is-not-prepared-to-combat-existential-threat-of-antibiotic-resistant-superbugs>

At the July launch of the AMR Action Fund, Admiral Brett P. Giroir, U.S. assistant secretary for health, said the following:

"Antimicrobial resistance, I do believe, is the existential threat of this century."

Giroir’s warning is dire—but it’s not new. For years, leading public health and national security experts around the world have sounded the alarm about the growing threat posed by antibiotic-resistant bacteria. Commissions led by world-renowned economists, declarations from the United Nations General Assembly, urgent threat reports from the Centers for Disease Control and Prevention, and more have all come to the same conclusion: Antimicrobial resistance is a known and certain danger—and the global level of preparedness does not match the magnitude of the threat.

In June, The Pew Charitable Trusts sent a letter to the leaders of the Senate Committee on Health, Education, Labor, and Pensions, providing recommendations for how the U.S. can better prepare for future pandemics. The letter highlighted the urgent need for government incentives to help fix the broken antibiotic market. Pew recently reiterated this call to action in partnership with the World Health Organization.

There is widespread and longstanding consensus that such incentives are needed to revitalize and sustain the woefully inadequate antibiotic pipeline. Without them, antibiotic developers will continue to go bankrupt, and innovation will continue to stagnate. Now is the time for action. Policymakers must ensure that the U.S. is not caught flat-footed when the inevitable superbug outbreak hits. Some threats we cannot begin to anticipate, but when it comes to antibiotic-resistant bacteria, there’s no excuse for being unprepared.

#### Only new bacteriophage breakthroughs at-scale will solve ABR

Principi et al. 19 – Nicola Principi, Professor Emeritus of Pediatrics, Università degli Studi di Milano, Milan, Italy, Ettore Silvestri and Susanna Esposito, Department of Surgical and Biomedical Sciences, Pediatric Clinic, Università degli Studi di Perugia, Perugia, Italy

Nicola Principi, Ettore Silvestri, and Susanna Esposito, "Advantages and Limitations of Bacteriophages for the Treatment of Bacterial Infections," Front. Pharmacol. 10:513, 5-8-2019, <https://www.frontiersin.org/articles/10.3389/fphar.2019.00513/full#h4>

Potential Advantage of Bacteriophage (BP) Use to Treat Bacterial Infections

Theoretically, there are no bacteria that cannot be lysed by at least one BP. In this regard, BPs are significantly more effective than antibiotics, as, although some antimicrobial drugs have a very large spectrum of activity, an antibiotic able to kill all the bacterial species does not exist. However, the most attractive characteristic of BPs is their specificity of action, i.e., their ability to kill only the pathogen that they can recognize.

They have a very narrow spectrum of activity, which avoids the most important problem strictly related to the antibiotic administration, i.e., the influence on the entire microbiome with elimination of potentially beneficial bacteria, the overgrowth of secondary pathogens and the emergence of resistant bacteria (Domingo-Calap and Delgado-Martínez, 2018). Use of BPs without modification of the microbiota has been reported by several studies in both animals and humans. In mice, oral administration of four T4-like BPs effective against diarrhea-associated E. coli did not lead to any collateral damage of non-pathogenic bacteria of the same species (Chibani-Chennoufi et al., 2004). In humans, data confirming the specificity of BP action were shown in the study conducted by Sarker et al. (2012). These authors administered for 2 days an oral cocktail of nine T4-like E. coli BPs to 15 healthy adults. After a wash-out of 5 days, even though the given BPs could be detected in the feces of almost all treated subjects, no modification of gut microbiota composition was evidenced.

In comparison to antibiotics, BPs are supposed to have several other advantages. It is thought that BPs are significantly safer and better tolerated, as they replicate only in the target bacterium but cannot infect mammalian cells. This conclusion seems supported by all the experiences gathered in the past in Eastern Europe and all the studies carried out more recently in experimental animals and humans, which have not reported significant adverse events following BP administration (Kakasis and Panitsa, 2018). Moreover, administration is easier, as BPs do not need repeated administrations shortly after one another over several days, as is commonly required for antibiotics because they can remain in the human body for relatively prolonged periods of time, i.e., up to several days (Bogovazova et al., 1991, 1992). In general, very few doses are needed because of the increase in BP concentration in the site of infection after the initial administration. Contrarily to antibiotics, their effect is limited to the site of infection that can be reached, even when bacteria are situated in a body organ or system in which antimicrobials can hardly penetrate. A lytic phage, EC200(PP), active against S242, a fatal neonatal meningitis E. coli strain, was evaluated in models of meningitis with 100% fatality. Though low titres of the BP were detected in the central nervous system, treatment 1 and 7 h post-infection rescued 100% of pups (Pouillot et al., 2012).

Using the new cost-effective, large-scale DNA sequencing and DNA synthesis technologies, BPs can be engineered to be able to overcome some limitations of antibiotic treatment. A good example of this is given by the evidence that BPs can disperse biofilm, a structure that makes infections difficult to eradicate with standard antibiotic therapy even if bacteria are sensitive to the administered drug. In an in vitro study, Lu and Collins engineered a BP affective against an E. coli producing biofilm to express a biofilm-degrading enzyme (Lu and Collins, 2007). A simultaneous attack to the bacterial cells and the biofilm matrix was possible. The results were very encouraging, as the engineered BP reduced bacterial biofilm cell count by approximately 99.9%. Moreover, BP genetic modifications can help to fight bacterial resistance to antibiotics. Edgar et al. (2012) introduced in lysogenic phages the genes rpsL and gyrA, which confer sensitivity in a dominant fashion to two antibiotics, streptomycin and nalidixic acid, respectively. They found that, after engineering, the minimal inhibitory concentrations of bacterial strains previously defined resistant to these drugs were significantly reduced to levels usually found in sensitive pathogens.

Finally, the use of BPs might be less expensive than that of antibiotics whose targets are multidrug-resistant pathogens. In a small group of patients suffering from methicillin-resistant Staphylococcus aureus infection, Miedzybrodzki et al. (2007) found that use of BPs significantly reduced healthcare costs.

#### Scenario B is Leadership – the U.S. remains ahead of China in biotech now, BUT declining innovation will change that

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Scott Moore, author of *Rethinking China’s Rise: How to Compete and Cooperate on the Environment, Technology, and Beyond*, In Biotech, the Industry of the Future, the U.S. Is Way Ahead of China, February 17, 2021, <https://www.lawfareblog.com/biotech-industry-future-us-way-ahead-china>

A continuing refrain from Washington in recent years has been that the United States is falling behind China in the development of critical emerging technologies. In some fields, this may be true. But not in biotechnology. To be sure, China’s biotech sector is growing at a torrid pace, and some of its firms are becoming leaders in certain areas, such as cancer treatment. Yet the U.S. retains a dominant position in research, development and commercialization, accounting for almost half of all biotech patents filed from 1999 to 2013. The triumph of its biotechnology industry during the coronavirus pandemic, producing two highly effective vaccines using an entirely new approach based on messenger RNA, and in record time, shows that the U.S.’s competitive edge in biotechnology remains largely intact. And that has important implications as Washington gears up for a sustained period of geopolitical competition with Beijing.

Biotech is such a critical area for technological competition between the U.S. and China because it is transforming fields from medicine to military power. The great advances of the 19th century, like chemical fertilizers, resulted from mastering chemistry. In the 20th century, mastery of physics led to nuclear energy—and, more ominously, nuclear weapons. In the 21st century, biology offers a similar mix of peril and promise. This was illustrated dramatically by the award of the 2020 Nobel Prize for the discovery of an enzyme system known as CRISPR-Cas9, which allows an organism’s genomes to be edited with high precision. It is a transformational breakthrough. But while CRISPR shows great promise in the development of new cures for long-untreatable diseases, it could also lead to a whole new generation of deadly bioweapons.

That’s a prospect that increasingly alarms U.S. intelligence officials. In 2016, then-Director of National Intelligence James Clapper warned Congress that “[r]esearch in genome editing conducted by countries with different regulatory or ethical standards than those of western countries probably increases the risk of the creation of potentially harmful biological agents or products.” Although Clapper didn’t name specific countries, it soon became clear that he was referring mainly to China. Four years later, his successor, John Ratcliffe, issued a far more pointed warning that “China has even conducted human testing on members of the People’s Liberation Army in hope of developing soldiers with biologically enhanced capabilities. There are no ethical boundaries to Beijing’s pursuit of power.” Such capabilities are almost certainly only speculative—but they underscore why biotech leadership is so important for national security as well as economic competitiveness.

Beijing has long envied the United States’s dominant position in biotechnology and spent heavily to overtake it. Biotech has been a priority sector for state investment since the 1980s, and by one estimate Beijing had poured some $100 billion into the sector by 2018. Nowhere did it lavish more attention or invest more of its propaganda power than in developing a coronavirus vaccine. State media have spent months crowing that “China is working around the clock for breakthroughs in COVID-19 vaccines.” Yet despite this push, China’s vaccine program quickly took on a Potemkin air. In February 2020, barely two months after the onset of the pandemic and after a supposedly crash vaccine effort, a military doctor stood in front of a Chinese flag to receive what was billed as an experimental vaccine dose but was widely suspected to be a staged photo op. Now, having spent months talking up its two primary vaccine candidates to developing countries like Brazil and Indonesia, both of which have entered into purchase agreements with Chinese biotech firms, Chinese officials face severe mistrust among their nation’s overseas partners.

For China’s leaders, the disappointing returns on their big bet on biotechnology look likely to cause them more headaches at home as well as abroad—there are already signs that affluent Chinese place more trust in foreign-developed coronavirus vaccines than the homegrown ones produced at such great expense. For U.S. officials, though, China’s relative underperformance in vaccine development presents an opportunity to reassert the United States’s leadership in biotechnology and public health and bolster the nation’s depleted soft power in the process. The Biden administration has already signaled it will reengage in multilateral bodies such as the World Health Organization.

Yet the U.S. shouldn’t stop there. Washington should begin thinking now about how to emulate the success of the President’s Emergency Plan for AIDS Relief (PEPFAR)—which, though imperfect, is widely regarded as one of the most successful single public health interventions in history—to address growing disparities in access to coronavirus vaccines between countries. At the moment, vaccine supplies are controlled largely by rich countries, creating the risk of moral and public health failure if the gap persists. While COVID-19, the respiratory disease caused by the novel coronavirus, differs in many respects from AIDS, PEPFAR combined research, prevention, and access to therapeutics. Developing a comparable institutional structure to close the coronavirus vaccine access gap is the right thing to do—but it would also go a long way to restoring America’s battered global reputation.

At the same time, the United States can’t afford to rest on its laurels in biotechnology, or any other field. Aside from China, other nations like Singapore and Israel have also invested heavily to develop their biotechnology sectors, with Israel in particular giving rise to a thriving biotech industry. U.S. public investment in basic scientific research and development has meanwhile been on the decline for decades, and there are worrying signs that America’s once world-beating innovation ecosystem is less productive, and less entrepreneurial, than it once was. Despite strengths in translational research, moreover, the frontiers of biology increasingly sit at the intersection with other disciplines like computer science, meaning that funding agencies, universities and other organizations need to break down disciplinary silos. Boosting support for biotechnology research, while reforming how that money is used, will go a long way toward shoring up the United States’s leading position in the global biotech sector.

The U.S. biotechnology sector also faces other threats, not least growing espionage and intellectual property theft by foreign actors, especially those linked to China. Several high-profile cases brought by the U.S. Department of Justice’s China Initiative have involved biotechnology researchers, and American biotech firms have been top targets for cyber theft and intrusion. Sustained outreach to researchers and research institutions is critical to preventing such theft. But efforts to clamp down on the threats posed by espionage and intellectual property theft can easily go too far and must preserve the researcher mobility and data-sharing that is essential to doing cutting-edge science.

Beyond its shores, the United States should work with its partners and allies to enhance export controls on dual-use biotechnology—used for both peaceful and military gain—especially DNA templates. Many forms of genetic material and synthetic biology products are already subject to U.S. export controls, but gaps remain, and screening for genetic sequence orders relies primarily on voluntary regulation by biotech firms. Better coordinating export controls among major economies and U.S. allies can dramatically reduce the risk of sophisticated bioweapons development in the decades to come.

When it comes to biotechnology, the industry of the future, the U.S. remains well ahead of its rivals, including China. That’s something Americans can, and should, take pride in. But the U.S. must make proactive investments and undertake significant reforms now to ensure that things stay that way.

#### Biotech lead will be the key determinant

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Rob Carlson, also managing director at Bioeconomy Capital, an early-stage venture capital firm; and Chad Sbragia, also former director of the China Research Group for the U.S. Marine Corps and now a research staff member at the Institute for Defense Analyses; and Kate Sixt, also assistant director of the Strategy, Forces and Resources Division at the Institute for Defense Analyses, where she leads the Chemical, Biological, Radiological, and Nuclear Analysis group; BEYOND BIOLOGICAL DEFENSE: MAINTAINING THE U.S. BIOTECHNOLOGY ADVANTAGE, 14 September 2021, https://warontherocks.com/2021/09/beyond-biological-defense-maintaining-the-u-s-biotechnology-advantage/

From 2007 to 2008, tainted supplies of Chinese-manufactured heparin, a common blood thinner, led to 81 deaths across the United States. This should have been a wake-up call to the Department of Defense. Over the last two decades, biotechnology has become a key component of American supply chains, perhaps accounting for 20 percent of the chemicals the U.S. military uses. Those supply chains now span the globe and contain a significant amount of material produced in China. Remarkably, the full extent of the military’s dependence on Chinese biotechnology is unknown because the U.S. government is not assessing it. These dependencies extend beyond pharmaceuticals to fundamentals such as solvents and polymers. Just try and paint an aircraft without xylenes. If you’ve never thought about how difficult it would be, well that’s exactly the problem.

The Department of Defense has historically viewed biotechnology narrowly in relation to military medicine and biodefense. As a result, the vital role of biotechnology in military readiness and national security remains poorly understood. Biowarfare and bioterrorism are real risks, but approaching the nation’s biotechnology security needs only in these terms will leave the country ever more vulnerable.

China, by contrast, has been integrating biotechnology into its strategic development and elevating biotechnology to a key component of national security. China’s military-civil fusion development strategy makes biotechnology a core priority for the People’s Liberation Army. This strategy has one goal: to bring together China’s civilian and military industrial bases in order to better project power. To that end, China has cornered supply chains in multiple sectors, including pharmaceuticals ingredients and other important chemicals.

Stephanie Rogers, the Defense Department’s acting principal director for biotechnology, recently declared that “the nation that leads the world in biotechnology will accrue enduring economic, societal, and defense gains.” Unfortunately, this awareness has yet to be reflected in government policy. Biotechnology security is national security — for the United States and for China. The Department of Defense should recognize biotechnology’s role as a foundational technology and make biotechnology development and supply chain security a priority.

Maintaining America’s Biotechnology Advantage

Biotechnology in the United States is a significant contributor to the economy. By one estimate, in 2017, U.S. biotechnology revenues exceeded $400 billion, or 2 percent of gross domestic product, substantially surpassing better-measured sectors such as mining. Bioeconomy revenues have grown at an average rate of 10 percent annually for two decades. Notably, U.S. biotechnology revenues alone were approximately equal to worldwide semiconductor revenues for 2017. Biotechnology now supplies critical medicines, and, as more than 90 percent of the corn and soy grown in the United States is genetically modified, biotechnology feeds the armed forces. Industrial biotechnology is responsible for upward of 20 percent of chemicals produced in the United States, suggesting a similar proportion of chemicals used in the military are also biologically derived. And these impressive figures may still be significant underestimates: Using a different methodology, the U.S. National Academy of Sciences recently concluded that the biotechnology industry contributes 5 to 7 percent of U.S. gross domestic product. Biotechnology, therefore, may already constitute an even larger share of the military supply chain.

As biotechnology continues to mature, its contribution to physical and economic security will become even more significant. Tools are now being deployed that enable the engineering and biomanufacturing of materials that will eventually not only displace petrochemicals but also surpass them in production scale and performance. Over the next ten to twenty years, biological production could soon supply up to 60 percent of physical inputs across the global economy, and biotechnology could have a “direct economic impact of up to $4 trillion a year.”

While the United States is arguably still leading in biotechnology, it risks losing this lead to China. In China, biotechnology is a national development and a security matter. China’s Innovation Driven Development Strategy emphasizes biotechnology’s essential role in the country’s economic development, while the Military-Civil Fusion Development Strategy seeks to ensure that biotechnology research is also oriented toward the country’s military and broader security goals. Chinese biotechnology revenues are reported to be of a similar size to those in the United States, although they are subject to even lesser clarity in reporting.

While China continues its licit and illicit acquisition efforts targeting the U.S. biotechnology sector, it is also shifting its attention to domestic innovation. In time, this will provide the People’s Liberation Army with new capabilities and increase both America’s and the Pentagon’s reliance on Chinese biotechnology products.

Recommendations As early as 1958, the Department of Commerce was tracking the economic contribution of semiconductors, even though they made up less than 0.1 percent of the gross domestic product. Yet, today, the U.S. government has made no equivalent effort to track the much more significant role of biotechnology. This illiteracy is a national security issue. American and Chinese bioeconomies are in competition, and Beijing asserts that it is investing with the intent to take, and to then maintain, the lead. To sustain America’s advantage, the U.S. Department of Defense should better understand its reliance on biotechnology and increase investment in it accordingly. The Pentagon’s recent investment in the BioIndustrial Manufacturing and Design Ecosystem is a notable step in the right direction. However, the seven-year budget for this project is approximately the cost of a single F-35A. For an investment that could impact the entire defense supply chain, this is inadequate. We recommend the following plan of action for the Department of Defense to take its place alongside the Departments of Commerce and State in the broader interagency effort to secure America’s biotechnology advantage. First, in close coordination with the Department of Commerce, the Department of Defense should make a systematic effort to better understand the role of biotechnology in the economy, supply chains, and manufacturing. This, in turn, should inform additional oversight and regulatory controls. The responsibility to understand, prepare for, and respond to biotechnology threats is balkanized, spread across at least nine departments and agencies. Vulnerabilities in the bioeconomy will affect the Department of Defense in terms of readiness, soldier health, and the ability to fulfill missions. Addressing those vulnerabilities begins with a sustained, comprehensive effort to understand the role of biotechnology in industry today, as well as how that industry contributes to defense supply chains, and how military acquisition policy shapes biotechnology. To that end, the Pentagon should work with the Department of Commerce to create domestic reporting codes for biotechnology revenues and employment for the quarterly and annual economic census, and further incorporate those codes into the North American Industrial Classification System. Institutionalizing the gathering of these data is the first step toward sustainable policymaking and rational spending. The Department of Commerce should then consider adding import/export controls on biotechnology, while avoiding overly broad restrictions that suffocate innovation. Protecting foundational technologies using the Foreign Investment Risk Review Modernization Act and Export Control Reform Act will be critical for securing biotechnology. However, biotechnology competition is not exclusive to commercial activities. The Pentagon should assess critical vulnerabilities and dependencies to assist the other agencies in bringing China’s foreign biotechnology access in line with standards in other major markets. The Department of Defense has been asked to document and secure supply chains critical to defense applications and to the overall U.S. economy. This should also apply to biotechnology. Current Pentagon efforts to expand domestic biological manufacturing capabilities are an important start, but a broader effort is needed. An empowered deputy national security adviser could help oversee the relationship between the Pentagon and the National Economic Council to promote and secure the military’s broader technology needs. Second, the Department of Defense should better study the accomplishments and intent of China, especially the Chinese military, in developing biotechnology as a strategic technology. Once the Department of Defense better understands critical U.S. biotechnology dependencies on China, it can begin the work of reducing them. This requires an interagency examination to identify cross-cutting resources, develop mitigation strategies, formulate best practices to bolster innovation, and expand outreach to allies and partners to reduce systemic gaps China could exploit. Partnership with industry and allies will allow the U.S. government to understand and counter Beijing’s efforts to distort commercial activity in its favor. To this end, the Department of Defense should mirror the National Security Council’s effort by creating an emerging technology portfolio within Office of the Under Secretary of Defense-Policy. While other technology offices in the Department of Defense are internally focused, an entity in this office that concentrates externally on foundational technology competition is required. Such an office may be able to address uncertainties in assessments of Chinese biotechnology revenues and capabilities. Finally, in coordination with the Department of State, the Department of Defense should identify opportunities for dialogue with the People’s Liberation Army about biotechnology-related security issues. It is time to include biotechnology in the dialogue mechanisms that compose bilateral U.S. defense relations with the People’s Liberation Army. This dialogue should prioritize the ethics of biotechnology in the context of future conflicts, the escalatory risks this technology creates, and the possibility of cooperation where the interests of the two nations intersect. Both sides should work toward a common understanding related to ethics, policies, and standards when operationalizing biotechnology. This will help avoid miscalculation and promote strategic stability. Unlike the U.S. government, Chinese leadership has a carefully considered position on the importance of biosafety and “biological problems” in national security. While these problems are understood to encompass traditional weapons concerns, they also extend to the health of the entire natural world in the context of ever-expanding applications of biotechnology. This position might provide an opportunity for constructive engagement at a time when tensions are rising. Conclusion The Pentagon needs to expand its approach to biotechnology beyond biodefense. If China maintains biological warfare aspirations, by all means address those. But defense planners should also address China’s broader approach to biotechnology and its integrated approach to civil-military fusion.

Securing biotechnology secures the nation. Maintaining the U.S. lead in biotechnology is critical to the nation’s economic and military resilience in war, peace, and the gray zone short of conflict. This requires better biotechnology collaboration — within the U.S. government, with allies and partners, and even, where possible, with competitors.

#### Retrenchment causes extinction

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Mira Rapp-Hooper, Stephen A. Schwarzman Fellow at the Council on Foreign Relations, 2020, Saving America’s Alliances: The United States Still Needs the System That Put It on Top, Foreign Affairs

The stakes of failing to reform the alliance system could scarcely be higher. If Washington does not act, it will miss the opportunity to protect its dearest interests on relatively favorable terms, before China’s growing power and Russia’s revanchism undermine the system’s proven guarantees. The reform agenda recommended here is vast, but it is far less burdensome than a U.S. foreign policy that cannot rely on allies. The United States can no more go it alone now than it could in the immediate postwar years. Whether the United States has alliances or not, American security and prosperity will still require an open and independent Asia and Europe. Even if Washington pulled back from both theaters, the United States would still face cyberattacks, financial and infrastructural disruptions, and assaults on its democratic institutions. And by retrenching, Washington would lose whatever readiness for conflict it currently has. If the country later joined a war abroad, it would have to do so only after significant time delays and without the allied cooperation that might have allowed it to prevail. Put simply, the United States might fall into a conflict that it could have instead deterred—one now waged with hypersonic speed and destruction.

#### Strong commercial innovation will be the key

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THE SINO-AMERICAN RACE FOR TECHNOLOGY LEADERSHIP, 2021, <https://warontherocks.com/2021/04/the-sino-american-race-for-technology-leadership/>

Setting the right foundation is crucial. Sound analytical judgments about China’s policies, plans, and prospects, along with a new framework for the relationship, are the starting point. Neither wholesale confrontation nor wholesale engagement are adequate to address U.S. concerns, but the relationship should be stable for this approach to have any chance of success. The view that economic competitiveness, innovation, and democratic norms are core components of national security should drive the development of a comprehensive strategy into which discrete policies of pressure, negotiation, multilateralism, high-level dialogue, and domestic measures fit. Industry should work closely with the government to ensure this perspective underpins U.S. policy, and the government should recognize that industry is central to the United States winning the technology race and therefore should get a vote on how to run it.

Out-competing and out-innovating China requires that America remain the world’s most attractive innovation hub, enticing the best talent, drawing in the most venture capital, and generating the largest revenues to support U.S. leadership of technology’s newest frontiers. It means continuing to “move fast and break things.” The ethos that made America a technology superpower can keep it so. It also means injecting some strategic realism into U.S. policy. As former Secretary of Defense William Cohen put it, China’s actions have caused the United States to say, “we can’t do business the way we’ve been doing business,” but, “we still have to do business.”

#### And, that will hinge on whether big pharma anticipates predictable and large net-revenues from pursuing innovative products

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James C. Robinson, the Leonard D. Schaeffer Professor, whose research and teaching focus on biotechnology and the healthcare delivery sectors, Competing With, And Learning From, China In The Global Pharmaceutical Innovation Race, 15 November 2021, https://www.healthaffairs.org/do/10.1377/forefront.20211110.463732/full/

The scale-up of pharmaceutical innovations generated by US biotechnology startups currently depends on product licensing by large pharmaceutical corporations. It works best for drugs eligible for the generous regulatory, tax, and subsidy provisions of the Orphan Drug Act of 1983, proving again the importance of public investment in ensuring commercial viability. Approximately half of the new drugs launched on the US market now are for orphan conditions. The ability of government to pick winners has been evident during the COVID-19 pandemic, as Operation Warp Speed financed vaccine product development, expansion of manufacturing capacity, and product distribution at a scale and speed exceeding the capacity of private investors. President Biden has proposed the creation of an Advanced Research Projects Agency for Health (ARPA-H) to fund cross-sectoral, high-risk research and R&D using the model of the Defense Advanced Research Projects Agency, the technology promoter responsible for the most fundamental innovations in defense in the past three decades, with $6.5 billion in dedicated funding. Yet, these proposals face adverse political headwinds.

For its part, the Chinese government provides direct subsidies for the scale-up of domestic firms that show the potential to become global leaders. Public funds account for 25 percent of total industry investment, and state development banks supplement these grants with low interest loans. Tax credits for business investment in applied product R&D, an effective policy instrument originally developed in the US, now are several times more generous in China.

Pricing And Product Demand

Innovation requires large-scale and predictable revenues to reward successful product launch. US pharmaceutical firms traditionally have enjoyed prices and revenues far in excess to those available in other nations. Congressional Democrats and the Biden administration have put forth proposals that would moderate drug prices, in turn, necessitating the expansion of other mechanisms for rewarding innovation. Some support would derive from initiatives to expand insurance coverage. High patent-protected drug prices would generate few revenues if manufacturers were to depend on patients for payment, as distinct from health insurers. Here again, the government already plays the decisive role. More than a third of the US population is covered by tax-financed public health insurance, and half has its private insurance subsidized through tax exclusions and premium subsidies. The Biden administration is committed to filling the remaining gaps in insurance coverage, which would support innovation by reducing the need for manufacturers to supply free drugs to the uninsured and finance copayment support programs for the underinsured. But further insurance expansion faces fierce opposition.

China favors domestic over foreign products in the design of its national drug formulary, with the intention of enabling its champions to achieve the economies of scale necessary to compete in global markets. For example, Chinese pharmaceutical firms have invested heavily in PD-1 oncology monoclonal antibodies. In 2020, the national formulary accepted four domestic PD-1 products and delisted foreign products in the therapeutic class. Access to the national formulary requires price discounts averaging 50 percent in the first year and further discounts in subsequent years. The low prices paid for foreign drugs in the domestic Chinese market will be accompanied by high prices charged for Chinese products launched in the US market. China interprets direct subsidies for product commercialization as an alternative to high prices as a reward for innovation, with the obvious advantage that governmental grants and loans are available only to Chinese firms. In contrast, the profits earned in the US market also accrue to foreign firms, which repatriate them to further develop their domestic innovation ecosystems.

China As Challenge And Opportunity

The challenge from China impacts each of the four pillars of pharmaceutical innovation, including the foundation in university research, the startup ecosystem, the scale-up of startups into global champions, and the assurance of predictable market demand. Unlike the imperative for rapid development of COVID-19 vaccines, the challenge from China cannot be dismissed as a once-in-a-century event. It is not going away.

Although the rise of China threatens the US life sciences industry, it also may indirectly support it. Fear of and competition with China may enable the US to overcome political gridlock and refurbish its science, revive its industry, and restore its erstwhile prominence.

### 1AC – Solvency

Contention 3 is solvency.

#### Pharma companies pay each other not to challenge weak patents, preventing drug competition. Antitrust law forbids some direct payments, but current standards create a perverse incentive to obfuscate deals

Feldman 8/27 – Distinguished Professor of Law Chair & Director of the Center for Innovation, UC Hastings Law

Robin Feldman, Arthur J. Goldberg Distinguished Professor of Law, Albert Abramson ’54 Distinguished Professor of Law Chair, and Director of the Center for Innovation, The Price Tag of 'Pay-for-Delay', UC Hastings Research Paper Forthcoming, 27 Aug 2021, https://papers.ssrn.com/sol3/papers.cfm?abstract\_id=3846484

Our empirical results highlight the fact that pay-for-delay is a far more costly problem than previously recognized. The Supreme Court opened the door to deal with these settlements in Actavis, but in applying the decision, lower courts, competition agencies, and relevant parties have struggled with each of the three aspects of the phrase: “pay,” “for,” and “delay.” Despite the opinion’s expectation that lower courts would be able to provide structure to the rule of reason in a pay-for-delay inquiry, 125 that structure has not materialized in a meaningful manner. The problem arises in part from the nature of the rule of reason inquiry and in part from the forms of deals that have emerged. Although it is possible that the Justices never intended to allow pay-for-delay cases to move forward, the tone of the opinion belies such a cynical interpretation.

A. What Constitutes “Pay”

One might imagine that the notion of “pay” would be simple. Nevertheless, some courts have struggled with the question of what might constitute an exchange of value and whether the notion of payment can extend beyond cash. Beyond the notion of what types of value might be included in the notion of pay, the way in which the inquiry unfolds has created obstacles for parties and competition authorities to actually measure value in a way that would be satisfactory under a rule of reason analysis.

In particular, some parties have asserted that cash is king. From this perspective, the only exchange of value that might matter would be dollars changing hands. In the immediate wake of Actavis, some courts initially failed to recognize non-cash forms of compensation—such as no-authorized-generic clauses—as unexplained payments from brands to generics.126 Although higher courts eventually rectified decisions in Lamictal and Loestrin, for example, expanding the Actavis precedent to include methods of payments other than cash,127 damage was done. Effectively permitting certain forms of pay-for-delay—even temporarily—serves to incentivize similarly designed anticompetitive deals, at great cost to patients and society. 128 Protracted court battles also present a significant drain on regulatory bandwidth, particularly when every instance of anticompetitive conduct must be demonstrated to the courts.

In the sophisticated world of modern commerce, however, there are many ways to provide value beyond simply handing over bags stuffed with bills. For example, one of the most valuable assets for an entering generic is the 180-day period in which the first filing generic can enter the market free of competition from other generics. Generic companies may earn a substantial portion of their profit during this period of time.129 Brand-name companies, however, found a way to make that period of time into an asset that can substitute for a cash payment.

[FN]

126 See, e.g., In re Loestrin 24 Fe Antitrust Litig., 45 F. Supp. 3d 180 (D.R.I. 2014), vacated and remanded, 814 F.3d 538 (1st Cir. 2016); In re Lamictal Direct Purchaser Antitrust Litig., 18 F. Supp. 3d 560 (D.N.J. 2014), vacated and remanded sub nom. King Drug Co. of Florence v. Smithkline Beecham Corp., 791 F.3d 388 (3d Cir. 2015). The payment in the settlement litigated in Actavis was a cash transfer from the brand to the generic; subsequent pay-for-delay settlements have featured payment forms that are less easily enumerated, such as no-authorized generic agreements. In this case, the brand company—in lieu of a cash payment—agrees to not launch an authorized generic during the first-filing generic company’s 180-day exclusivity period, thereby boosting the generic company’s revenues.

128 Evidence since Actavis suggests that pharmaceutical companies hew closely to guidelines implied by court decisions. According to the FTC 2017 report, only 3 of 20 agreements with explicit compensation exceeded the $7M allowed by Actavis for litigation fees; moreover, following a spate of court cases finding that a no-AG promise amounted to anticompetitive payment, 2017 saw no settlement agreements that included a no-AG clause. See Betsy Lordan, FTC Staf Issues FY 2017 Report on Branded Drug Firms' Patent Settlements with Generic Competitors, FTC (Dec. 3, 2020), https://www.ftc.gov/news-events/press-releases/2020/12/ftc-staff-issues-fy-2017-report-branded-drug-firms-patent

[End FN]

The scheme springs from the fact that although a generic must obtain FDA approval to enter the market, the brand-name company already has such an approval in its pocket. Thus, the brand-name company may market its own generic version of a drug—called an authorized generic or a branded generic—without the need for a lengthy approval process.130 Although the Hatch-Waxman system does not explicitly provide for authorized generics in its legislation, court rulings have affirmed that nothing prevents the innovator company from marketing an authorized generic version of their branded drug.131

The launch of an authorized generic has significant consequences for a first-filing generic. According to the FTC, competing with an authorized generic can cost a generic first-filer up to 45% of its revenue during the exclusivity period.132 The ability to remove that threat becomes an asset that the brand-name company can hand to the generic, in exchange for an agreement to stay off the market. A brand-name company can promise not to introduce an authorized generic, particularly during the valuable 180-day period. The deal is a little like old movies portraying protectionist rackets, in which the neighborhood shakedown artist says, “Nice front window you have there. Be a real shame if it got smashed in.” Here, a brand-name company can say the equivalent of, “Nice 180-day exclusivity period. Be a real shame if you lost half of it. Tell you what, just stay off the market for a while, and it is all yours.”

As courts and competition authorities have become suspicious of these “no-authorized-generic” agreements, companies have developed ever-more-complex variations on the theme. Rather than explicitly promise to not compete by producing an authorized generic, a brand-name company can promise not to license any third parties to make authorized generics, while reserving the right to make an authorized generic itself. If the brand manufacturer has a limited track record of launching authorized generics, this agreement can have the same effect as the no-authorized generic clause.133 In yet another variation, the brand and generic can enter into an agreement in which the generic is obligated to pay a royalty amount, but that royalty will decline if the brand-name company launches a competing authorized generic.134

In other complicated variants, brand-name companies may give the generic who agrees to stay off the market a license to make an authorized generic version of their brand drug, with the generic paying a royalty to the brand.135 Particularly if the royalty payment that the generic must pay is less than the market value of the benefit, that excess value may be camouflaging a “reverse” flow of payments in exchange for the generic’s agreement to stay off the market.136

Courts and competition authorities now generally recognize that no-authorized-generic agreements can constitute a form of payment for the purposes of pay-for-delay, although it took some time to reach that point.137 Nevertheless, the law has not fully absorbed the anticompetitive potential of the complex variations. These convoluted variants are difficult to tease out, let alone establish sufficient proof through the rule of reason standards, making obfuscation a successful strategy. For example, the most-recent FTC reports showed 226 agreements between brand and generic companies that year, 138 a significant increase from the 170 settlements just two years prior.

139 Ninety percent of those agreements included a transfer of patent rights that were not at issue in the lawsuit. Many of these could easily constitute a transfer of value.140 Challenging even a simple no-authorized-generic agreement is no easy task. For example, although the judicial definition of payment now includes “no-authorized-generic” agreements,141 private plaintiffs or the government bears the burden of evaluating and presenting the terms of a no-authorized-generic agreement in terms of cash value.142 The requirement follows the logic that in order to demonstrate the unreasonably large nature of a payment, as the Actavis decision specified, plaintiffs generally are required to translate that agreement into a specific, quantifiable value to the court’s satisfaction. Thus, a plaintiff who wishes to challenge even a simple no-authorized-generic agreement as anticompetitive must be prepared to engage in an expensive and lengthy court battle, with no consistent approach to valuation.143 Consider the Effexor case.

The district court in Effexor rejected the plaintiffs’ valuation of a no-authorized-generic agreement, which was based on an estimation of what an authorized generic cost the generic manufacturer of a different drug with nearly identical sales.144 Plaintiffs were able to obtain a reversal on appeal,145 but obtaining the appellate decision, however, took three years beyond the time that had already passed for the trial court ruling. The more a deal reaches behind the back and around the ears, the harder it is tease out the value transfer and pin down a specific dollar equivalent.

[FN 141]

141 See, e.g., United Food & Com. Workers Loc. 1776 & Participating Emps. Health & Welfare Fund v. Teikoku Pharma USA, Inc., 74 F. Supp. 3d 1052, 1070 (N.D. Cal. 2014) (“I agree with the bulk of the recent decisions holding that courts need not restrict the definition of “payments” under Actavis to cash. See, e.g., In re Nexium (Esomeprazole) Antitrust Litig., 968 F.Supp.2d 367, 382 (D.Mass.2013) (rejecting a motion to dismiss because a no-authorized-generic term could be a payment for the delay because a broader definition of payment “serves the purpose of aligning the law with modern-day realities.”)”); see also Time Ins. Co. v. Astrazeneca AB, 52 F. Supp. 3d 705, 710 (E.D. Pa. 2014) (“reverse payments deemed anti-competitive pursuant to Actavis may take forms other than cash payments” when considering a no-authorized-generic agreement); King Drug, 791 F.3d at 403 (“We do not believe Actavis 's holding can be limited to reverse payments of cash. For the following reasons, we think that a no-AG agreement, when it represents an unexplained large transfer of value from the patent holder to the alleged infringer, may be subject to antitrust scrutiny under the rule of reason.”).

142 See Feldman & Misra, Fatal Attraction, supra note 8, at 259-260 (explaining how the often-onerous burden of proving anticompetitive harm under rule of reason rests on the plaintiffs); see also Feldman, Defensive Leveraging, supra note 51 (describing the difficulty of successfully pleading a rule of reason case).

[End FN]

The 2003 Medicare Modernization Act requires generic-brand agreements to be submitted to the FTC for review, 146 and the reports the FTC publishes from these insights can point other investigators to possible anticompetitive conduct.147 However, the FTC is limited in its resources to investigate individual cases; reports are frequently beset by publishing delays, offer only annualized statistics, and may fail to adequately appreciate the nuanced, rapidly evolving techniques used by drug companies.148

For example, in December 2020 the FTC finally released its annual report covering the year 2017. The report lists as examples of “possible compensation” arrangements including: declining royalty structures,149 AG licensing to subsequent filers, and agreements to not license AGs to third parties.150 The FTC declines to assess the anticompetitive quality of these arrangements as “beyond the scope of this report.”151 The report also finds zero cases of the no-authorized-generic agreements so prevalent a decade earlier. 152

It would be naïve, however, to assume that the end of simple no-authorized-generic clauses marks the end of authorized generics in pay-for-delay. Rather, anecdotal evidence suggests that the character of brand-generic patent settlements is simply changing in response to the spate of court rulings finding that no-authorized-generic clauses constitute payment under Actavis. 153

B. What Constitutes “For”

Similar to the notion of what constitutes “pay,” courts and agencies have struggled over whether a transfer of value in an agreement constitutes a payment for staying off the market or simply a payment for legitimate value provided by the generic.

Side deals come in many shapes and sizes including: 1) arrangements to promote other drugs in the firms’ portfolios; 154 2) licensing deals that allow the brand or generic to manufacture the other party’s drug;155 3) agreements authorizing the generic to manufacture and/or sell a brand’s “authorized generic” without filing for generic approval; 4) research and development collaboration on future projects; and 5) deals to supply the brand company with raw materials for manufacturing.156 Such side deals are rarely found outside the settlement context. According to one prominent academic in the field, “many—such as an arrangement by which a brand relies on a generic for its marketing expertise—belie common sense.”157

The valuation of agreements featuring noncash provisions is further complicated by the fact that the details of these settlements are kept secret.158 This shroud of secrecy makes it difficult to identify and quantify the value of noncash settlements. Even if the presence of side deals is suspected, plaintiffs will rarely, if ever, have access to the terms of those agreements. Several district courts have already dismissed pay-for-delay litigation for failing to plausibly allege a large and unjustified payment.159 For example, the district court in Actos dismissed the indirect purchasers’ claims that Takeda engaged in anticompetitive conduct by entering into settlement agreements with generic manufacturers.160 While the court shared the majority view that Actavis was not limited to settlements dealing with pure cash, it also held that to find an unlawful reverse payment involving non-cash settlement terms, the court “must be able to estimate the value of the term, at least to the extent of determining whether it is “large” and “unjustified.””161 Because the plaintiffs could not explain the basis for their assertions nor offer any method of calculating the value of the licensing side deal, there was no factual basis for the court to reasonably estimate the value of the settlement terms and evaluate the settlements’ alleged anticompetitive effect.

The legality of settlements featuring side deals continues to be challenged. While the majority view is that side deals are not immune to antitrust scrutiny, plaintiffs still bear the burden of pleading information sufficient to estimate the value of these agreements. To describe the task of determining whether these terms are “large” and “unjustified” as difficult is an understatement.

It is interesting to note that although the FTC’s reports on pay-for-delay settlements for fiscal years 2015162 and 2016163 reported no side deals, the most recent report for fiscal year 2017 listed three settlements with side deals.164 These side deals included an agreement in which the brand manufacturer assigned the generic manufacturer five patents unrelated to the litigated product at no cost, another in which the generic sold intellectual property related to the litigated product to the brand manufacturer, and a third in which the brand manufacturer acquired the generic manufacturer's potentially competing 505(b)(2) product that was the subject of the patent litigation.165 These indicators suggest there is reason for concern that side deals can be used to hide payments for delay and that courts and agencies would be unable to ferret out any anticompetitive conduct.

C. What Constitutes “Delay”

Creating a full sweep, courts have also struggled with the question of what constitutes delay. The uncertainty centers on whether an agreement in which the generic enters before the patents expire should be considered delay. Supporters of pay-for-delay settlements routinely argue that such settlements can be procompetitive because they facilitate early entry of a generic before a branded drug’s patents have expired.166

In such instances, consumers would benefit from lower prices sooner than if the Paragraph IV challenge had never taken place. In Actavis, the Supreme Court recognized this procompetitive potential, commenting that early entry settlements, or settlements permitting the patent challenger to enter the market before the patent expires, could “bring about competition . . . to the consumer’s benefit.”167

That argument, however, assumes the patent is valid and infringed.168 Various studies suggest that assumption is unwarranted. For example, a 2002 Federal Trade Commission report found that considering all the patent infringement cases between generic and brand manufacturers between 1992 and 2000, generic applicants prevailed in a staggering 73 percent of cases.169 Similarly, an academic analysis of Federal Circuit decisions between 2002 and 2004 in which the court made a final ruling on the merits of a pharmaceutical patent claim found that generic challengers had a 70 percent success rate.170

In a more recent analysis, a study of patent lawsuits filed in a federal district court between 2008 and 2009 found that accused infringers won 74 percent of the definitive merits rulings while patentees won only 26 percent of the time.171

In fact, the FDA has gone so far as to provide a registry of disputed patent information in order to address inaccurate or extraneous patent listings on new drugs.172 As the author has previously written, “one can never assume that just because a company holds a patent that the patent is either valid or validly applied to the drug at issue.”173

A patent that is invalid or not infringed would have no power to stop entry. Thus, if the generic had pursued the litigation to conclusion, the result could easily have moved the patent barrier out of the way, allowing the generic to enter right away. As a result, it would be nonsensical to say that there is no delay if the parties agreed to stay out of the market until the expiration date of a noninfringed patent. Nevertheless, some courts have failed to contemplate that possibility in analyzing agreements.

Consider In re Humira. 174 Plaintiffs alleged that AbbVie’s settlement agreements with biosimilar manufacturers, in which the biologic company granted licenses for biosimilars to market the Humira biosimilar in Europe in 2018 while delaying entry into the U.S. market until 2023, constituted an unlawful pay-for-delay scheme.175

In dismissing the lawsuit, the district court found that the settlements were permissible because they allowed AbbVie’s rivals to enter the U.S. market before the patents on Humira (the latest of which expires in 2039) expired.176 The court failed to recognize, however, that the settlements eliminated the possibility that the biosimilars might have entered the U.S. market earlier than the stipulated date if they had pursued the litigation to conclusion and prevailed. As with many cases, the patents might not have been valid or validly applied.

#### So-called “pay for delay” deals in the biologics context specifically do not yet fall within the legal scope of antitrust

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January 12, 2018, “BIOLOGICS: THE NEW ANTITRUST FRONTIER,” https://www.illinoislawreview.org/wp-content/uploads/2018/01/Carrier.pdf

In determining the appropriate antitrust analysis of settlements, an initial question centers on the application of FTC v. Actavis. We believe that, in a broad holding of general applicability, Actavis confirmed antitrust law’s vital role in evaluating the legality of settlements involving payment and delayed entry. The Court relied on an array of previous cases to confirm that its precedents “make clearthat patent-related settlements can sometimes violate the antitrust laws.”

To be sure, the Court was not offering an antitrust assessment of biologic settlements. Nor could it have given that no court—even now, several years later—has considered settlements under the BPCIA. But we believe the settingof complex pharmaceutical regulation under the BPCIA easily offers sufficient similarities to the Hatch-Waxman Act to allow application of Actavis’s broad principles. In addition, payment to avoid the risk of biosimilar competition presents the same concerns highlighted in Actavis.

The linchpin in the antitrust analysis of settlements is whether a generic is excluded from the market based on a patent or payment. Exclusion based on a patent generally does not present antitrust concern because it is commonly understood that patent-term split agreements, by which brands and generics divide the remaining patent term by selecting a time for generic entry, do not violate the antitrust laws. The reason is that the parties’ compromise on the entry date reflects the odds of success in patent litigation. The greater the likelihood the patent is valid and infringed, the later in the period generic entry would be expected. The lower the likelihood, the earlier entry would be expected. A brand, however, is likely to gain additional exclusivity not explained by a patent by supplementing the parties’ entry-date agreement with a payment to the generic.

The same distinction between patent and payment should apply in the setting of biologics. The biologic manufacturer is entitled to rely on its patent to exclude a generic. But it should not be able to pay a biosimilar to gain additional delay. In determining whether there is payment, the court should consider, as one of us has explained before, whether the biologic manufacturer conveys “a type of consideration not available as a direct consequence of winning the lawsuit.” If the biosimilar manufacturer is able to obtain such consideration, “its exclusion from the market cannot be traced to the strength of the [biologic] patent.” In such a case, “the [biologic maker] is providing compensation beyond what even a valid and infringed patent would justify.”224 And, presenting antitrust concern, the biosimilar delays entering the market because of this payment.

One example of a form of payment that could arise in this setting involves a biosimilar’s access to a biologic’s distribution or reimbursement networks. In contrast to distribution through wholesalers and specialty distributors (each of which obtains a portion of revenues, reducing a biosimilar’s profitability), biologics could offer access to a “manufacturer direct” channel which, in selling directly to purchasers (e.g., specialty pharmacies and large hospitals), removes the “middleman.” Setting up an efficient supply chain is difficult and expensive, and not all biologics will be able to implement such a scheme. As a result, if a biologic has already set up direct distribution, one form of payment to a biosimilar could be access to, and integration into, the valuable network, which it would not be able to obtain through patent litigation.

Another type of payment could involve Group Purchasing Organizations (“GPOs”) or Pharmacy Benefit Managers (“PBMs”). GPOs are collections of providers that pool resources to maximize economies of scale in drug purchasing and sometimes function as distributors, gaining control over products offered to downstream purchasers.228 PBMs also manage prescription drug pro

[FOOTNOTES BEGIN]

221. HERBERT HOVENKAMP, MARK D. JANIS, MARK A. LEMLEY, CHRISTOPHER R. LESLIE, & MICHAEL A. CARRIER, IP AND ANTITRUST: AN ANALYSIS OF ANTITRUST PRINCIPLES APPLIED TO INTELLECTUAL PROPERTY LAW § 16.01[f] (3d ed. 2016). 222. Carrier, Payment After Actavis, supra note 219, at 9. 223. Id. 224. Id. 225. Id. 226. NIAZI, supra note 21, at 354–56; see also Jack McCain, Connecting Patients with Specialty Products, BIOTECHNOLOGY HEALTHCARE, Summer 2012, at 8, https://www.ncbi.nlm.nih.gov/pmc/articles/ PMC3411231/. 227. NIAZI, supra note 21, at 354–56. 228. Id. at 352, 353.

[FOOTNOTES END]

grams for downstream buyers and, in some cases, after negotiating rebates with manufacturers, limit the drugs sold under their plans. This latter role ensures that they “are very important” to a biosimilar manufacturer in controlling access to a biosimilar product.

We envision a scenario by which a settlement could include payment in the form of a biologic bringing a biosimilar under its umbrella, granting access to certain GPO and PBM agreements to which it would otherwise not have access.

Where there is payment, the court should consider its size. The Actavis Court compared the payment’s size to litigation costs. It stated that payments that “amount to no more than a rough approximation of the litigation expenses saved through the settlement” could be justified. Litigation costs in the biologics setting will generally be higher than in the small-molecule setting. In contrast to litigation in the Hatch-Waxman setting, with a generic in the initial stage only needing to review the Orange Book, law firms must conduct substantial pre-application investigations to identify patents that could be raised in the patent dance.

Finally, where there is at-risk entry, a settlement could include a “payment” from the biologic to the biosimilar, but that payment could constitute a legitimate forgiveness of damages. This presents a nuanced case that could be explained by the results of patent litigation. In other words, if the biologic wins, it is entitled to recover damages from the biosimilar. But if the biosimilar wins, it will not be required to pay anything. As a result, a biologic firm’s partial waiver of damages that the biosimilar could have owed falls within the range of what the latter could have obtained through successful litigation. In short, just like it has done in the Hatch-Waxman setting, the distinction between patent and payment can provide an appropriate framework for the antitrust analysis of settlements between biologics and biosimilars.

#### Plan: The United States federal government should increase prohibitions on anticompetitive reverse settlements of biologics

#### The plan solves – first, it establishes a rebuttable presumption of illegality for pay-for-delay deals. That incentivizes transparency instead of obfuscation

Feldman 8/27 – Distinguished Professor of Law Chair & Director of the Center for Innovation, UC Hastings Law

Robin Feldman, Arthur J. Goldberg Distinguished Professor of Law, Albert Abramson ’54 Distinguished Professor of Law Chair, and Director of the Center for Innovation, The Price Tag of 'Pay-for-Delay', UC Hastings Research Paper Forthcoming, 27 Aug 2021, https://papers.ssrn.com/sol3/papers.cfm?abstract\_id=3846484

There is an old saying in the field of psychology that insanity is doing the same thing over and over again while expecting to get a different result. After watching plaintiffs and competition authorities struggle to satisfy the rule of reason in order to establish a pay-for-delay case, it is clear that continuing down the same path is unlikely to be fruitful.

The rule of reason, untethered, is a meandering test that cannot even be described in a simple sentence. The formulation rises from the 1918 Board of Trade case:

“The true test of legality is whether the restraint imposed is such as merely regulates and perhaps thereby promotes competition or whether it is such as may suppress or even destroy competition. To determine that question the court must ordinarily consider the facts peculiar to the business to which the restraint is applied; its conditions before and after the restraint was imposed; the nature of the restraint and its effect, actual or probable. The history of the restraint, the evil believed to exist, the reason for adopting the particular remedy, the purpose or end sought to be attained, are all relevant facts. This is not because a good intention will save an otherwise objectionable regulation or the reverse; but because knowledge of intent may help the court to interpret facts and to predict consequences.”177

Application of the rule in practice is no less nebulous than its formulation, despite the fact that courts add numbers to each of the various steps. The Supreme Court itself has called the rule of reason complex and burdensome. The intricate requirements of the rule, not to mention the burden it places both on parties and the courts,178 make the rule of reason particularly ill-suited for examining the ever-increasing number of agreements between brand and generic competitors. Although some scholars have argued that the rule of reason should be shelved entirely, such a broad-scale change is unnecessary for these purposes.

Pinning pay-for-delay reform squarely on an outright ban may not prove tenable, and other commentators have proposed intriguing alternatives. By one policy, for instance, if companies are unable to prove that their patent infringement settlement value was less than the cost of litigation and other services, then all that the generic company can receive is what it would be entitled to by a court ruling that a brand patent is invalid or not infringed.179

In other words, all the brand company can promise is what the court would give the generic company if the parties proceeded with the patent infringement litigation, and the generic won. No-authorized-generic clauses, among other creative anticompetitive ploys, would be presumed illegal by this framework. At the same time, it would permit patent settlements to remain where they are potentially procompetitive, eliminating unnecessary litigation between drug companies. Other prospective solutions seek to improve upon the fines used currently to disincentivize pay-for-delay conduct. As our analysis demonstrates, even companies fined by the FTC for pay-for-delay may profit handsomely from the practice.180 Considering the failure of fines to sufficiently discourage pay-for-delay, some scholars have advanced alternative punishments for cited drug companies. For instance, a first-filing generic company that agreed to postpone production in exchange for a no-authorized-generic clause could be stripped of its 180-day exclusivity period.181 Additional legislation might stipulate that brand companies forfeit the chance to earn additional non-patent regulatory exclusivities for a drug whose monopoly period they paid off competitors to extend. This way, instead of simply reducing the profits of offending drug-makers, the repercussions of pay-for-delay redound as social benefit.

Despite potential remedy-related reforms, however, the most important change needed pertains to evaluating the anticompetitive nature of the agreement itself. The landmark decision in Actavis expressed optimism that courts would be able to manage the analysis in a more structured manner. That reality has not materialized. To resolve the problem, one should return to the basic notion that agreements between competitors are strongly disfavored under antitrust law.

Given that agreements between competitors are disfavored, the test for agreements between brands and generics in the context of Hatch-Waxman litigation should begin with a presumption that the agreement is anticompetitive. This approach respects the essential design of the Hatch-Waxman system to ensure rapid entry of generic drugs, in part, by providing an incentive for generic drug companies to challenge patents that are invalid or invalidly applied.182 Only when the public interest is clearly served should the presumption fall.

#### Second – settlements that either delay entry or are based on weak patents would be found anticompetitive. That effectively calibrates the patent system

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We propose several substantive changes to the antitrust approach to pay-for-delay settlements.

First, the key criterion in determining an unlawful agreement should be the existence of a restriction on generic entry—not the size or presence of a value transfer—considered in light of the strength of the category of patent in question. Arguably, the legitimacy of a pay-for-delay settlement is predicated on the strength of the underlying patent; in other words, pay-for-delay is only a problem insofar as the patent to which the deal relates is invalid or aimed at the wrong product, since the generic could enter the market immediately upon that determination. Much is at stake in these deals; several years of lost patent protection could translate into several billions of dollars of lost savings for the brand company. 57 Pay-for-delay agreements tend to settle litigation over a “secondary patent,” which is a patent on some feature of a drug other than the active pharmaceutical ingredient, such as a production process, a method of treatment, a salt or crystalline form, a new delivery mechanism, a new formulation, or even an ancillary aspect of a drug, such as the pill’s coating.58 Evidence shows that secondary patents form part of a deliberate strategy to prolong a drug’s effective period of patent protection.59 Though few patent cases reach a final decision on validity,60 secondary drug patents are frequently found invalid when challenged.61 Thus, secondary patents may over-reward a pharmaceutical drug’s actual innovative contribution with unwarranted extensions of effective patent protection, and both the brand and generic companies may have a good sense of the likelihood that a disputed secondary patent will survive a court challenge. For this reason, the category of the patent in question in a pay-for-delay agreement is highly germane to a meaningful examination of the potential illegality of the deal.

Next, the United States should move closer to a presumptive standard in evaluating pay-for-delay settlements in order to achieve more efficient and effective antitrust enforcement. The pay-for-delay bills introduced in Congress will help achieve that goal, as would adopting a standard similar to that of the European Union that places emphasis on an agreement’s aim to restrict competition rather than downstream effects on the marketplace.62 Although intent can be difficult to establish under U.S. law—particularly if plaintiffs must find smoking-gun evidence of subjective intent—those difficulties can be overcome by designing standards that use objective criteria as a means of inferring a company’s likely intent. The category of patent and the failure to sue on the core chemical or biological patent could be part of those objective criteria. The reluctance to call pay-for-delay presumptively illegal in the United States reflects a desire to preserve the freedom to settle and to avoid clogging the courts with costly and protracted patent litigation. However, the current approach to pay-for-delay favors industry over patients, and unless the approach is changed, drug prices will remain supra-competitive for periods longer than the HatchWaxman regulatory regime intended. In addition, deterring the litigation in the first place would reduce the burden on the courts, as well as the burden on society.

Finally, regulatory disincentives may be a more effective deterrent of payfor-delay deals than monetary penalties. For example, the FTC and FDA could jointly prohibit a generic company that is found to have participated in pay-fordelay from eligibility for the 180-day exclusivity period for any Abbreviated New Drug Application (ANDA) that it files in the ensuing five years. Without exclusive marketing rights as the first generic to file an ANDA, the generic company stands to lose the bulk of its profits on any generic drug launched in that five-year period. By enticing generic companies with profitable settlements, brand companies have co-opted the paragraph IV challenge, initially intended to enable generic companies to challenge weak or invalid patents.63 As a penalty for participation in pay-for-delay deals, the generic company could be prohibited from filing a paragraph IV certification on any ANDA for a certain number of years, effectively making the company ineligible for the 180-day exclusivity period and shutting them out of pay-for-delay settlements—at least those arising from patent litigation. Regulatory disincentives can counterbalance the “carrots” in the Hatch-Waxman Act, thereby rewarding innovation and hastening competition when the time is ripe.

CONCLUSION

Settlement agreements to end patent disputes are common and not in and of themselves indicative or suggestive of antitrust infringement. Often, settlements are a favored alternative to continuing costly litigation. However, pay-for-delay settlements come at a steep cost to patients by delaying the entry of less expensive generic alternatives to brand drugs. The ability to wield competition laws effectively against these settlements is of major importance to regulators, policymakers, and patients. Shifting the focus of antitrust scrutiny to restrictions on generic entry vis-à-vis the strength of the category of underlying patent, and creating disincentives for generic companies to acquiesce to pay-for-delay deals, will help grease the wheels of the Hatch-Waxman Act and accelerate the path to affordable drug prices for U.S. patients.

#### Third – the plan is a tailored remedy. Zero risk of doctrinal spillover

Hemphill 6 – Associate Professor of Law, Columbia

C. Scott Hemphill, JD & MA in Econ-Stanford, MSc in Econ-LSE, AB-Harvard, Paying For Delay: Pharmaceutical Patent Settlement As a Regulatory Design Problem, 81 N.Y.U. L. Rev. 1553 (Nov. 2006), <https://www.nyulawreview.org/wp-content/uploads/2018/08/NYULawReview-81-5-Hemphill.pdf>

The particular shape of congressional intervention in the balance between innovation and access, together with important industry-specific features of the pay-for-delay problem in pharmaceuticals, serve to undercut the Patent Act-based case for an exception to the ordinary operation of antitrust law. The argument applies in different ways to the innovator-focused and infringer-focused arguments for an exception.

With respect to innovators, the practice in question is a poor fit with Patent Act policy, because permitting pay-for-delay settlements is a highly innovation-inefficient means of increasing the incentive to innovate. To see this, consider as a benchmark a competitive practice that had the effect of increasing the length of the patent term at no incremental expense to the patentee. Arranging a longer term might be expected to increase producer profits and consumer allocative losses in equal measure (assuming, among other things, that the pro ducer faces the same demand curve in each period). If the social bene efits of innovation increase proportionately with profits, then the ratio between innovation and deadweight loss is unchanged with respect to term length.

If instead, as is frequently presumed, additional profits have a declining impact upon the social benefits of incremental innovation, then a longer term entails a lower ratio-that is, less innovation "bang" for the additional deadweight loss "buck." Such a practice is difficult to justify by reference to Patent Act policy, for the reason introduced in Part III.A. Congress's selection of a particular patent term length implements a choice about the balance between innova tion and acceptable deadweight loss. If Congress had chosen a longer term, it would have implemented a more innovation-protective policy with respect to patentees; but Congress did not do that. A "reason able effectuation" of the Patent Act's innovation protectiveness does not require permitting a practice that is less innovation-efficient than, but otherwise identical to, a major innovation-protective term of the Patent Act. Therefore, to the extent that a privately-arranged term lengthening is less innovation-efficient than the current period of exclusivity, it cannot be insulated from antitrust attack by reference to the policies of the Patent Act.217

Pay-for-delay settlements resemble an increase in effective term length, but in an important respect they are even less innovation-effi cient. In exchange for receiving a reprieve from competition, the pat entee must make a sizable payment. This payment reduces its profits and hence the incremental innovation incentive gained by arranging for the extension. 218 This deficit in innovation efficiency makes the agreements more difficult to justify as a reasonable effectuation of the Patent Act. In short, the Patent Act's general policy of innovation protectiveness has, at best, a weak claim to insulating pay-for-delay settlements from antitrust attack.

Moving from the general case of patents to the specific case of pharmaceuticals further weakens the argument for insulation. As already noted, antitrust is *in pari materia* not only with patent law, but with industry-specific regulation as well. Compared to the Patent Act, the Hatch-Waxman Act provides within its domain a more specific and hence more relevant account of the congressionally implemented balance between innovation and competition.

The balance set by the Hatch-Waxman Act is a deliberate effort to promote consumer access through litigated challenges. For most drugs, the Hatch-Waxman Act is less innovation-protective than the Patent Act; as noted previously, the tax on blockbusters is a conces sion to consumer access at the expense of innovation. For a few drugs, it is actually more innovation-protective, thanks to the innovation sub sidy provided by the industry-specific delays. In either case, the ordi nary operation of the Act sets a particular balance between innovation and competition. The balance set for a particular drug is disrupted by a settlement favoring somewhat more innovation at the further expense of consumer access.

The disruption to the congressional balance caused by settlement, moreover, is difficult to understand in a way consistent with the Hatch-Waxman scheme. With the Patent Act, a general norm in favor of innovation might at least be relied upon; by contrast, the Hatch Waxman Act provides a calibrated outcome for different types of drugs. The Patent Act is silent about the role of litigation and the extent to which litigation can be avoided in the interest of preserving profits. In the Hatch-Waxman Act, by contrast, the promotion and delay of litigation are central preoccupations of the regulatory regime. An open-ended permission for innovators to set innovation policy by self-help is less plausible, as Congress has taken explicit steps to fill those gaps. Since litigation is the instrument by which the regulatory arrangement accomplishes its ends, it is difficult to argue that an end run on the instrument is consistent with the scheme. And given that the regime explicitly provides for innovation protection in certain cases-an effective lengthening of the patent term for certain drugs, but a limited one-it is implausible to attribute to that regime a toler ance for an additional, highly innovation-inefficient means to accrue additional profits.

The infringer's argument against antitrust liability is also weaker in the pharmaceutical context, compared to the general case. First, the generic firm lacks an innovator's interest. The generic firms simply make use of the Hatch-Waxman scheme to offer a bio equivalent drug. Even if a Patent Act policy favoring innovation helps some infringers, it cannot be thought to apply here.

Limiting the generic firm's ability to extract a benefit from unpromising litigation has some effect on an infringer's incentives, though not on its innovation incentives. To be clear, a limitation on settlement does not force the generic firm to see the litigation to com pletion-it can simply walk away from the suit.219 But a limitation on consumer-disregarding settlements does lower the value of the generic firm's abandonment option,220 an option that matters most when a party develops new information about its prospects during the course of litigation. The difference in reward implies that some marginal challenges will not be brought. There is little reason, however, to think that preserving the full value of this option is necessary to effec tuate a Hatch-Waxman Act policy of promoting challenges, not least because the incentive to challenge is already so large.

Second, and again unlike many infringers outside the pharmaceu tical context, the generic firm has deliberately stepped, not stumbled, into the infringement controversy. It does not move in uncertain ter rain filled with hidden patent dangers; the patents protecting pharma ceutical innovations are open and notorious, compiled in an FDA publication, Approved Drug Products with Therapeutic Equivalence, commonly known as the "Orange Book. ' '221 The generic firm volun teers for and seeks out the challenge by filing the Paragraph IV certifi cation, which invites a lawsuit by the innovator.222 Here, and unusually, Congress has recruited and offered to compensate generic firms to bring patent challenges. Far from being unwilling private attorneys general, generic firms have been deputized, in effect, to act on the public's behalf. The explicit use of litigation to achieve the balance undercuts the preference for settlement sometimes discerned in ordinary patent policy.

In summary, the analysis in this Part reinforces the conclusion from Part II that pay-for-delay settlements are properly accorded a presumption of illegality as unreasonable restraints of trade. It also undermines, in a domain-specific way, the patent policy arguments sometimes thought to justify a patent-based exception to antitrust as a general matter. Finally, the analysis offers industry-specific support for the proposition that pharmaceutical consumers do indeed have an entitlement to the average level of competition implied by litigation, a proposition more difficult to sustain as a general matter.

CONCLUSION

Examining pay-for-delay settlements from the perspective of regulatory design yields two main results. First, the industry-specific bounty renders feasible an allocatively harmful settlement in a surprisingly wide array of circumstances. Because only the first-filing generic firm has potential access to the exclusivity period, an innovator has an especially strong incentive to pay to neutralize that source of potential competition. Because a guaranteed bounty is a valuable source of compensation to a first-filing generic firm, settlements that divide the remaining patent term confer a noncash payment for delay. Allowing an innovator to make multimillion dollar payments up to the amount of saved litigation expense exacerbates the allocative harm.

Second, the Hatch-Waxman Act produces a specific pattern of encouragement to and limitations upon innovative activity. That industry-specific pattern, rather than the arguably innovation-protecttive policy of the Patent Act, provides the basis for an *in pari materia* analysis with antitrust law. The Hatch-Waxman Act's calibration between innovation and competition is disrupted if firms are free to engage in self-help. The resulting disruption is difficult to square with the policies that animate the Hatch-Waxman Act, particularly in light of the inefficiency of pay-for-delay settlements as a means to provide additional reward to innovators.

Beyond the analysis of pay-for-delay settlements and other competitive practices in the pharmaceutical industry, a careful engagement with regulatory facts and economic theory within a specific industry is a promising method of antitrust analysis. The approach advanced here requires a close look at the economic effects of the regulation and the legislative instrument by which it achieves those effects. The project entails two distinct though related inquiries: an inquiry into industry economics, including the technology of innovation and the dynamics of competition, and an inquiry into the effects of industry-specific regulation.

Such an economically aware and institutionally informed examination is particularly important in industries that are in a process of deregulation. Such industries are an area of renewed interest in antitrust, as exemplified by their inclusion in the work of the commission recently set up by Congress to consider alterations to existing antitrust aw. 223 Deregulation enlarges the domain of antitrust, as Herbert Hovenkamp has noted;224 it does so in part by altering the contours of liability. In some industries, the process of deregulation has occurred in an incomplete fashion, and partial deregulation may give rise to heightened antitrust concern.

Under partial deregulation, the regulatory regime manages the balance between innovation and competition by decentralized mechanisms, rather than by the central command of price regulation. Under full regulation, there may be little role for antitrust, given its redundancy upon a regulator actively managing the antitrust function. Under partial deregulation, however, redundancy is less likely. The use of a decentralized mechanism by Congress risks nullification by unilateral or concerted action by self-interested firms, with allocatively harmful effects. Where the mechanism is not well preserved by the industry-specific regulatory agency, there may be a heightened role for antitrust intervention.

One virtue of an industry-focused approach is the presence of built-in limiting principles. An antitrust decisionmaker can resolve one set of cases without having to reconsider an entire category of conduct. For example, a court can resolve pay-for-delay settlements in the pharmaceutical industry-a set of cases of great theoretical significance and practical importance-without reconsidering the relationship of antitrust and patent generally. Another consequence, of course, is that we therefore lack an answer to broader questions—here, whether consumer-disregarding settlements of patent litigation in other industries are actionable as antitrust violations. But in an area of legal and economic inquiry so complex, and in which we lack even basic information about the facts on the ground in other industries, including the prevalence and structure of such settlements, this limitation is a virtue rather than a vice.

#### Link is non-unique –A] subject matter – already taking an aggressive approach in HC

Cornell 9/16 – Head of the U.S. antitrust practice at global antitrust powerhouse Clifford Chance LLP

Tim Cornell, 20 years of antitrust experience, has advocated on behalf of dozens of clients before the US Federal Trade Commission, the US Department of Justice, and the federal courts, with Robert Houck, Peter Mucchetti, and Brian Yin, Antitrust Litigation 2021, Last Updated September 16, 2021, <https://practiceguides.chambers.com/practice-guides/antitrust-litigation-2021/usa/trends-and-developments>

After an eventful year of antitrust litigation related to healthcare in 2020, all indications are that 2021 will be just as action-packed.

In October 2020, subscriber plaintiffs and defendants in the Blue Cross Blue Shield (BCBS) multi-district litigation (MDL) in Alabama reached a preliminary agreement on a USD 2.67 billion settlement fund, along with sweeping reforms aimed at restoring competition in the healthcare insurance industry. The litigation is an amalgamation of claims going back to 2012 accusing dozens of local insurers (so-called "Blues") of using restrictive practices to suppress competition.

Then in January 2021, President Trump signed the Competitive Health Insurance Reform Act, eliminating certain antitrust exemptions health insurers had previously enjoyed under the McCarran Ferguson Act. While these exemptions were limited, commentators have suggested that the availability of the defense may have had a chilling effect on antitrust litigation in healthcare. The plaintiffs' success in the BCBS cases and the elimination of these antitrust protections for health insurers may result in more antitrust cases against health insurers in the next few years.

Meanwhile, the multitude of suits in the long-running generic drug price fixing matters has continued to progress. In July 2020, the federal judge overseeing the multidistrict litigation initially selected the complaint filed by a coalition of 44 state attorneys general against Teva to act as a "bellwether" case (a procedure whereby a representative action among many lawsuits proceeds first to trial to help shape subsequent litigation). But in August 2020, a grand jury indicted Teva on criminal price-fixing charges, as part of the DOJ's ongoing antitrust investigation of the generic drug industry. Concerned for the complications the civil and criminal matters could pose to one another, the court vacated its bellwether selection. In May 2021, the judge instead chose the states' complaint asserting a price fixing conspiracy affecting various dermatology treatments and other drugs. Meanwhile, the DOJ has continued to pursue its own generic drugs investigations, having criminally charged at least seven companies and a number of executives, while indicating that more indictments are expected.

The FTC also has continued to make healthcare a priority for antitrust enforcement. In the Spring of 2020, the FTC announced that it would increase resources it put towards the review of previously consummated healthcare deals, sending requests for information to a number of health insurers that had recently merged. Around the same time, the FTC initiated a challenge of Jefferson Health's proposed acquisition of Albert Einstein Healthcare Network in Philadelphia. In a rare defeat for the agency, a federal court rejected the challenge in December 2020. Seemingly undeterred, however, the FTC has continued to challenge hospital mergers, including in Memphis [In re: Methodist Le Bonheur Healthcare and Tenet Healthcare Corporation, FTC No. 9396] and New Jersey [In re: Hackensack Meridian Health, Inc. and Englewood Healthcare Foundation, FTC No. 9399].

In his 9 July 2021 Executive Order, President Biden continued his administration's focus on antitrust and healthcare issues. The order directs federal agencies to seek solutions to address anticompetitive conditions affecting the US economy, including the high cost of prescription medication and healthcare services, increasing hospital consolidation, and other areas related to healthcare.

#### B] Mechanism and internal link – recent court rulings, litigation, and reaffirmation of quick-look paradigm

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Tim Cornell, 20 years of antitrust experience, has advocated on behalf of dozens of clients before the US Federal Trade Commission, the US Department of Justice, and the federal courts, with Robert Houck, Peter Mucchetti, and Brian Yin, Antitrust Litigation 2021, Last Updated September 16, 2021, <https://practiceguides.chambers.com/practice-guides/antitrust-litigation-2021/usa/trends-and-developments>

NCAA: a Unanimous Decision for a Divided Court

On 21 June 2021, the Supreme Court unanimously held that restrictions imposed by the National Collegiate Athletic Association (NCAA) limiting the "education-related benefits" that member schools could provide to student athletes violated federal antitrust law, re-affirming the virtues of the Court's long-standing "rule of reason" analysis and making clear that the antitrust laws apply to anticompetitive agreements in labor markets. [Nat'l Collegiate Athletic Ass'n v. Alston, 141 S. Ct. 2141 (2021).] While the holding was a major blow to the NCAA, it has important implications beyond college sports—especially for its discussion of how courts could use a "quick look" form of the rule of reason analysis.

In NCAA v. Alston, former and current student-athletes sued the NCAA in class action litigation. They argued that the NCAA's rules restricting compensation were agreements between member schools that unreasonably restrained trade, in violation of Section 1 of the Sherman Act. [15 U.S.C. Section 1.]. The California district court applied a rule of reason analysis, considering:

whether the challenged restraints had substantial anticompetitive effects;

procompetitive rationales; and

whether these procompetitive effects could be achieved through less anticompetitive means.

After trial, the district court upheld the NCAA's restrictions capping undergraduate scholarships and compensation related to athletic performance, accepting that both improve consumer choice among sports enthusiasts by maintaining a distinction between amateur and professional sports. But the court held that the policy limiting "education-related benefits" did not fulfill that objective and violated the law. The Court of Appeals for the Ninth Circuit agreed.

The Supreme Court affirmed. The NCAA argued that the lower courts should have applied an "abbreviated deferential review" of its challenged restraints. Writing for a unanimous Court, Justice Gorsuch explained that the lower courts had properly applied the full rule of reason analysis, given the "complex questions" about the consumer benefits of the challenged policies. In doing so, Justice Gorsuch pointed out that the "market realities" had changed since 1984, when the Court assumed (without deciding) that different NCAA restrictions were justifiable. Justice Kavanaugh's concurrence went further, chastising the NCAA for holding themselves as "above the law" and potentially inviting future plaintiffs to again challenge the NCAA's remaining compensation restrictions (which the plaintiffs had not appealed to the Court).

The majority opinion notably recognised that the "quick look" rule of reason analysis can apply to determine that a challenged restraint is not anticompetitive. Historically, courts have used "quick look" analysis to condemn restraints, when “an observer with even a rudimentary understanding of economics could conclude that the arrangement in question would have an anticompetitive effect.” [Cal. Dental Ass'n v. Fed. Trade Comm'n, 526 U.S. 756, 770 (1999)]. The Court declined to apply the NCAA's requested quick look, but recognised that certain restraints may be "so obviously incapable of harming competition that they require little scrutiny."

While clearly a blow to the NCAA, the opinion will likely have ripple effects in other industries and contexts. It would not be surprising for more parties to advocate for "quick look" rule of reason analysis – particularly to absolve challenged restraints. And on the other end of the spectrum, the Department of Justice has already cited Justice Kavanaugh's concurrence to argue that price-fixing in labor markets should be per se unlawful. All this makes clear that attorneys and clients must be familiar with this case to be prepared when dealing with future antitrust issues.

#### C] Pay-for-delay – triggers the DA without solving our internal link

Kades 21 – Director of Markets and Competition Policy, Washington Center for Equitable Growth

Michael Kades, A Canary in the Coal Mine for the Failure of U.S. Competition Law: Competition Problems in Prescription Drug Market, Prescription for Change: Cracking Down on Anticompetitive Conduct in Prescription Drug Markets, Subcommittee on Competition Policy, Antitrust, and Consumer Rights, July 13, 2021, https://equitablegrowth.org/a-canary-in-the-coal-mine-for-the-failure-of-u-s-competition-law-competition-problems-in-prescription-drug-market/

In 2013, in the Androgel case (FTC v. Actavis), the Supreme Court rejected the lenient view that patent holders could simply pay potential infringers to stay off the market. According to the Supreme Court, an agreement in which the branded and generic companies eliminate potential competition and share the resulting monopoly profits likely violates the antitrust laws, absent some justification.28 The Supreme Court’s decision has limited pay-for-delay deals. In fiscal year 2017, the most recent year of reported data, the number of potential pay-for-delay deals with significant payments fell to three.29

That success has been incomplete, and it overlooks the cost of enforcement. The Supreme Court approach requires a case-by-case analysis of a practice that virtually always is anticompetitive. That allows companies to find new ways to hide compensation or offer a plethora of alternative justifications for their conduct. Based on the past mistakes and some open hostility to the Supreme Court’s decision, courts could accept one of these defenses and create a costly loophole.

Further, the approach is resource intensive. Indeed, the FTC resolved the Androgel case itself almost 6 years after the Supreme Court decision allowing the case to go forward and more than a decade after the case was filed. The FTC continues to litigate multiple cases against the same parties over the same product.30

## 2AC

### T Private Sector

#### We meet –

#### Counterinterp – “Private sector” is anything that isn’t the government

Law Insider N.D.

“Private sector definition,” *Law Insider*, <https://www.lawinsider.com/dictionary/private-sector>.

Private sector means not of a Federal, State or Local government owned nor controlled enterprise.

#### “The” can include specifics

Random House N.D.

“The,” Unabridged Dictionary, <https://www.dictionary.com/browse/the>.

1. (used, especially before a noun, with a specifying or particularizing effect, as opposed to the indefinite or generalizing force of the indefinite article a or an):

#### ‘By’ only requires anticompetitive practices resulting from private sector action.

Michigan Court of Appeals 10 (SAWYER, J. Opinion in DEQ. v. Worth Twp., 808 N.W.2d 260, 289 Mich. App. 414 (Ct. App. 2010). Google scholar caselaw. Date accessed 7/23/21).

Second, we look to the meaning of the phrase "by the municipality." This phrase is key because it answers plaintiffs' contention that MCL 324.3109(2) imposes responsibility for a discharge on a municipality without regard to the source of the discharge. That is, plaintiffs argue that any discharge of raw sewage within a municipality constitutes prima facie evidence of a violation by the municipality even if the municipality is not the source of the discharge. We disagree. The word "by" has many meanings. For its meaning as a nonlegal term, we look to a layman's dictionary rather than a legal one. Horace v. City of Pontiac, 456 Mich. 744, 756, 575 N.W.2d 762 (1998). We find these definitions from the Random House Webster's College Dictionary (1997) to be particularly helpful: "10. through the agency of" and "12. as a result or on the basis of[.]" Thus, MCL 324.3109(2) imposes responsibility on the municipality not when the violation merely occurs within the boundaries 264\*264 of the municipality, but when the violation occurs "through the agency of" the municipality or "as a result" of the municipality, that is to say, when it is the actions of the municipality that lead to the discharge.

#### Prefer – A] overlimiting – there’s only one aff under their interp, and it loses to states and the innovation DA

#### B] arbitrariness – limiting out plausible interps bc they don’t want to cut case negs to more than one aff is unfair and destroys prep/research incentives for both sides

#### Reasonability – competing interps causes substance crowdout

#### Functional limits solve – innovation DA, states CP, advantage CPs, and neolib K all limit viable affs

### CP Government Investment

#### Picking winners fails – government lacks the incentives and knowledge to pick the best firms

Thierer 8/18 – Adam Thierer is a Senior Research Fellow at the Mercatus Center at George Mason University. He specializes in innovation, entrepreneurialism, Internet, and free-speech issues, with a particular focus on the public policy concerns surrounding emerging technologies.  
Adam Thierer, August 18 2021, “Government Planning and Spending Won’t Replicate Silicon Valley,” Discourse, https://www.discoursemagazine.com/economics/2021/08/18/government-planning-and-spending-wont-replicate-silicon-valley/

Unfortunately, the “if you build it, they will come” mentality surrounding tech clusters and regional innovation hubs doesn’t take into account many economic, political, cultural and geographic challenges. Indeed, the history of previous efforts proves that these things cannot simply be willed into existence through top-down industrial policies, big bureaucracies and a lot of new spending programs. Clusters tend to grow more organically, and efforts by the government to force them are unlikely to meet with any more success than past experiments.

Wishful Thinking About Economic Development Subsidies

“Economic theory offers little reason to think that targeted economic development subsidies benefit the broader communities that ultimately pay for them,” concluded a recent Mercatus Center study on “[The Economics of a Targeted Economic Development Subsidy](https://www.mercatus.org/publications/government-spending/economics-targeted-economic-development-subsidy).” The authors highlighted the extensive economic literature that finds that “the net effect of targeted economic development subsidies is likely to be negative” because “the taxes funding the subsidies will discourage more economic activity than will be encouraged by the subsidies themselves.”

That points to the first problem with governments trying to pick winners: There is no free lunch. Economic development and industrial policy efforts always sound great in theory, but in the end they rely on government-granted privileges—discriminatory tax or regulatory relief, cash subsidies, loans and loan guarantees, in-kind donations and the provision of other valuable goods and services. The costs of these targeted privileges are passed along to those firms and economic sectors without the political clout to get the favors, or just borne by taxpayers more generally.

The second problem with policymakers trying to pick winners is that they’re just not very good at it. Forecasting future market trends and the evolution of technology has always been notoriously difficult, even in the private sector. Lacking a profit motive and business acumen, governments have a much worse track record than investors, regularly picking more losers than winners. This problem has grown more acute today due to “[the pacing problem](https://www.mercatus.org/bridge/commentary/pacing-problem-and-future-technology-regulation),” which refers to the inability of government policies and programs to keep up with the ever-quickening pace of modern technological innovation.

These realities have not stopped policymakers from repeatedly trying to use both direct and indirect subsidies to attract high-tech sectors and talent to specific destinations. But there is no precise recipe for growing tech clusters. And as economists [William R. Kerr](https://www.hbs.edu/competitiveness/faculty/Pages/faculty-profile-details.aspx?profile=wkerr) and [Frédéric Robert-Nicoud](https://www.unige.ch/gsem/en/research/faculty/all/frederic-robert-nicoud/) [note](https://www.aeaweb.org/articles?id=10.1257/jep.34.3.50), “developing even a semi-formal definition is tricky.” Typically, however, a tech cluster includes “an important overall scale of local activity, complemented by spatial density and linkages amongst local firms.”

This is not easily replicated. Indeed, in the U.S. a huge amount of the nation’s high-tech startup activity and venture capital funding is concentrated only in Silicon Valley and eight other big-city areas: New York City, Boston, Los Angeles, Seattle, Washington, D.C., San Diego, Austin and Chicago. Of course, large cities have long possessed many advantages for attracting skilled labor and investors, and they often tend to have a high concentration of universities and research labs, making it far easier for tech clusters to develop in these large urban centers than in rural areas. Fine. But much of the nation is dotted with other large cities. Why can’t they become thriving tech clusters?

This kind of thinking is driving the latest push to create the next great innovation hub. “With federal support, the U.S. can recreate Silicon Valley success nationwide,” [says Steve Case](https://thehill.com/opinion/technology/550262-with-federal-support-the-us-can-recreate-silicon-valley-success-nationwide?rl=1), former head of America Online. [Others argue](https://www.brookings.edu/events/leveraging-regional-tech-hubs-to-advance-racial-equity/) regional tech hubs can help advance economic inclusion and racial equity.

#### Iterative innovation is key – money alone doesn’t solve because innovation happens in interaction between companies

Kotlikoff 08 – Professor of Economics Boston University

Laurence J. Kotlikoff, “Stimulating Innovation in the Biologics Industry: A Balanced Approach to Marketing Exclusivity,” September 2008, http://people.bu.edu/kotlikof/New%20Kotlikoff%20Web%20Page/Kotlikoff\_Innovation\_in\_Biologics21.pdf

Limiting Monopoly Protection to Stimulate Innovation

The importance of successive rounds of innovation — of each innovation building on, but also undermining the monopoly position of the prior round — was dubbed creative destruction by the father of growth theory, Joseph Schumpeter. According to Schumpeter, innovation is the engine of growth, and it’s not pretty. Entrepreneurs must be able to compete and destroy or they will not create. In Schumpeter’s words, “Economic progress, in capitalist society, means turmoil. [What counts is] competition from the new commodity, the new technology, the new source of supply, the new type of organization... competition which... strikes not at the margins of the profits and the outputs of the existing firms, but at their foundations and their very lives.” Paul Romer, today’s leading theorist of economic growth, emphasizes the self-propelled nature of growth — that growth feeds upon itself. “We consistently fail to grasp how many ideas remain to be discovered. Possibilities do not add up. They multiply.”45 Sandwiched between Schumpeter and Romer is the past century’s third great student of economic growth, Nobel laureate Robert Solow. Solow developed growth accounting and showed that innovation (better technology) is a major source of U.S. economic growth. In fact, each innovation is part of a chain. Today’s innovation cannot proceed if yesterday’s is not accessible. And tomorrow’s innovation must wait until today’s innovation is available for use. Moreover, if the current length of monopoly protection suffices to incentivize today’s innovation, extending the length of protection will do nothing to increase current innovation. Instead, it will simply delay future innovation with the economy, over time, falling further and further behind with respect to the level of technology it would otherwise have available. Economists have modeled this process, conceptualizing innovation in a number of different ways. Andrew Horowitz and Edwin Lia wrote a classic paper in 1996, for example, in which they view innovation as moving up a product quality ladder. Higher rungs on the ladder entail better technology and higher quality products. The innovator in their model, which need not be the same person or company through time, can be viewed as holding the top position on the ladder with generics moving up from below. The closer the generics get, the more competition the current innovator faces. This gives the current innovator an incentive to move to yet a higher position on the ladder. Moving up the ladder is innovation, and the more rungs the innovator (or replacement innovator) climbs over a given period of time, the higher the rate of innovation. Patent length in the model corresponds to the amount of time the government keeps the generics from using the latest technology — moving up the ladder to where the prior innovators have been. Once the current patent expires, the generic can move up. But when he does, he finds that the top-rung innovator has innovated to an even higher rung, the position of which is temporarily protected by a new patent. This is not a model of evergreening. Each time the top-rung innovator company innovates, it represents a true improvement in technology — one that comes at a real cost to the company. But it’s only the threat of competition that keeps the top-rung innovator (the near monopolist) innovating. And setting the patent length correctly is critical. As the authors point out, “Patent length either too short, or too long, will weaken innovative incentives.” In particular, patent length that’s too long will lead to more innovation when innovation occurs (the top-rung company will move up more rungs when it realizes it has to innovate to stay ahead because its patent is expiring), but to less frequent innovation. In the extreme, making the patent indefinite kills off innovation entirely; in this case, the top-rung company faces no competitive pressure and would compete only against itself by incurring the cost of inventing a better product. Another classic paper on patent policy is Nancy Gallini’s (1992) Rand Journal article.48 Gallini’s model lets competitors invent around incumbents, but at a cost. If patent length is set too long, competitors realize that they’ll not be able to use existing knowledge in a timely manner and that the only way they can compete is to come up with their own invention. Under these circumstances, this makes private sense, but it also makes social nonsense for the same reason that it makes no sense to re-invent the wheel. Knowledge that’s been acquired at a cost and that can be conveyed at zero cost is knowledge that should be used. Gallini’s paper, in its own way, gets at the cost of patent races alluded to above. Invention that can be monopolized even for a finite period of time represents a prize worth fighting for. But if only one party can win or, in Gallini’s case, if multiple parties can win, but not fully, there can be too much effort put into invention. Again, what’s privately optimal can be socially undesirable.

### K Neolib

#### Perm do both – plan lowers drug prices and stops ppl from dying bc they can’t afford medicine – key to actualize the alt’s politics

Feldman 8/27 – Distinguished Professor of Law Chair & Director of the Center for Innovation, UC Hastings Law

Robin Feldman, Arthur J. Goldberg Distinguished Professor of Law, Albert Abramson ’54 Distinguished Professor of Law Chair, and Director of the Center for Innovation, The Price Tag of 'Pay-for-Delay', UC Hastings Research Paper Forthcoming, 27 Aug 2021, https://papers.ssrn.com/sol3/papers.cfm?abstract\_id=3846484

The skyrocketing price of prescription medication continues to plague the pharmaceutical industry. For example, an analysis of one million Medicare patients between 2010 and 2017 found that the average dosage-unit price of brand-name drugs increased by 313 percent even after accounting for rebates.2 [FN 2] 2 Robin Feldman, The Devil in the Tiers, J.L. & BIOSCI. 1, 19 (2021). The RAND Corporation found in 2021 that the price of brand-name prescription drugs in the U.S. is 256 percent of the prices in thirty-two OECD countries combined, ranging from 170 percent of prices in Mexico to 779 percent of prices in Turkey (ANDREW W. MULCAHY ET AL., RAND CORP., INTERNATIONAL PRESCRIPTION DRUG PRICE COMPARISONS: CURRENT EMPIRICAL ESTIMATES AND COMPARISONS WITH PREVIOUS STUDIES 26 (2021), <https://www.rand.org/content/dam/rand/pubs/research_reports/RR2900/RR2956/RAND_RR2956.pdf>). [End FN] Similarly, one in four Americans have difficulty affording their medications, and three in ten say costs have prohibited them from taking their medications as prescribed.3 With rising out-of-pocket costs and patients dangerously rationing medication, these prices are causing real pain for American patients. Diabetic patients, for example, paid nearly $6000 a year out of pocket for insulin in 2016, and patients with arthritis saw the price of Humira rise to $1552 a month in 2019.4 As difficult as the burdens are for any patient, the burden of paying high prices lands particularly hard on lower-income groups, threatening access to life-saving treatments and creating further gaps in equity across society.

#### Plan’s nuanced use of competition policy is good – thinking that using competition policy to incentivize drug development is the equivalent of mass deregulation is totalizing – both state planning and complete decentralization are disasters

Coniglio, antitrust attorney in the Washington, DC office of Sidley Austin LLP, ‘20

(Joseph V., “Economizing the Totalitarian Temptation: A Risk-Averse Liberal Realism for Political Economy and Competition Policy in a Post-Neoliberal Society,” 59 Santa Clara L. Rev. 703)

The implication of the foregoing is that the most pressing task for competition policymakers may not involve a rethinking of first principles. The principles of neoliberal competition policy may have ultimately been proven justified by an unprecedented period of economic growth, technological progress and reductions in poverty, and should presumably remain operative as long as they remain the best framework for bringing about these ends. Neither, as we have suggested, must the capitalist entrepreneur be lost in the process. The totalitarian temptation to submit to general state control of the economy-whether it be in the form of communism from below or fascism from above should be resisted so as to preserve and build upon the great prosperity Western Civilization has managed to achieve.

This statement will no doubt be highly unsatisfactory to many critics of neoliberalism who seek more fundamental and revolutionary changes. Surely, they suggest, there must be some principled basis for critiquing the neoliberal status quo with which so many are frustrated. Indeed, there very well may be, and none of the arguments in this article should be understood to the contrary. The goal of this article has been limited to a tailored defense of neoliberal principles only as they relate to competition policy, broadly understood. It does not suggest that neoliberal monetary, trade, and fiscal policies are also sound-let alone a neoliberal social order, where all the core institutions within society are organized according to the neoliberal principles of wealthmaximization, empiricism, and the rest.129 This is to say that even if neoliberalism is a sound theory as applied to the area of competition policy, neoliberal monetary policy, for example, may be problematic and a just target for contemporary critics. Similarly, claiming that competition policy should be enforced using a consumer welfare standard does not mean that all the organs of law and civil society should be oriented to maximize wealth or consumer welfare, even if this economic inquiry is nonetheless informative. 30 It is well known that several prominent neoliberals have expanded the neoliberal policy apparatus beyond the regulation of market capitalism with which antitrust is concerned to domains typically understood to be beyond a purely utilitarian purview.' 3 ' However, whatever the merits of these broader neoliberal policy programs, the competition policy baby, so to speak, should not be thrown out with the bathwater.

Consider the charge that neoliberal policies have increased wealth inequality in the United States. Some commentators attempt to link this increased inequality with a decline in competition'3 2 and, by implication, consumer welfare competition policy. Notwithstanding the interest such theories appeared to have garnered from highly distinguished economists and policymakers, such as Nobel Laureate Joe Stiglitz,133 one might alternatively consider whether increasing wealth inequality and the resultant social strife are far more a result of policies in other areas, such as monetary policy. 134 At the same time as Chicago School antitrust policy took root, the American economy began to undergo sustained expansions in the money supply and reductions in interest rates that, at least in theory, disproportionately reward the owners of financial assets, who are more likely to be wealthy. 135

#### Only market incentives produce truly innovative technology – state planning can give you a lab but it cannot fiat the formula for new biologics

Janeway, board of directors of the U.S. Social Science Research Council and co-founder of the Institute for New Economic Thinking, ‘12

(William, Doing Capitalism in the Innovation Economy, pg. 273-277)

All of the stages of development are dependent to some degree on speculative forays into the unknown. None lends itself to optimal management in accord with a strict accounting of expected returns relative to costs incurred, whether conducted by a central planner or an established, profit-making enterprise. When scientific advance was funded by the profits of the great corporations through the first half of the twentieth century, the costs of the central research labs could no more be rationalized by the calculus of prospective financial returns than could the costs of the National Science Foundation (NSF) or the Defense Advanced Research Projects Agency (DARPA) or the National Institutes of Health (NIH) – which is why they were all required to shift resources toward explicitly applied research and development when profits came under pressure. Thus, the prime and critical constituent elements of the Innovation Economy are sources of funding decoupled from concern for economic return. This is clearly so with respect to the unfettered pursuit of scientific curiosity, but support for such research may be fully available from the state only during transient moments of national self-confidence when economic competition seems least threatening. Perversely, investment in scientific research is likely to be challenged as the nation’s competitive position weakens. So the Haldane principle, invoked in Britain to defend the autonomy of scientific research from political pressures, dates back to the First World War, when the sun still did not set on the British Empire. It was radically revised by the Rothschild Report in post-Empire 1971 to draw a bright line between pure and applied research and to subject the latter to the test of a customer–contractor relationship.3 In the United States, Vannevar Bush’s vision of public investment in science transcended near-term considerations of return, economic or political. Two generations later, the NIH and NSF are collaborating under the tortuous acronym STAR METRICS – “Science and Technology for America’s Reinvestment: Measuring the Effects of Research on Innovation, Competitiveness and Science” – in response to “increasing pressure to document the results of … research investments in a scientific manner and to quantify how much of the work is linked to innovation.”4 The attempt to manage scientific research in narrow pursuit of “value for money” can be expected to reduce its potential for creative exploration of the unknown. As I learned from my engagement with computing, the state has directly and indirectly accelerated construction of technology platforms to support the speculative exploits of entrepreneurs and the capitalists who finance them. Financial bubbles, in which returns are decoupled from the economic fundamentals, are the complementary engine of Schumpeterian waste. There are some examples of efficient deployment of new technological infrastructure: the construction of the French railroad system under state direction *was a model* of engineering efficiency and proceeded pari passu with the railroad systems in Britain and the United States, but without their duplicative waste. But, regardless of how potentially revolutionary networks have been planned, their financing has exploited the essential and inevitable herding behavior of investors. And, for the final phase of the Innovation Economy, there is no substitute for the speculative wastefulness of financial markets and the proliferation of hosts of hopeful commercial monsters funded thereby to explore the new economic space. When the great technology corporations were still funding basic research in their central labs, their monopoly positions in the markets they served inhibited their ability to exploit the technologies derived therefrom. Three times I directly observed signal examples of such failure. During the 1980s, I witnessed repeated instances of “fumbling the future” at Xerox when none of the innovations delivered by PARC could measure up to the profits of the entrenched, patent-protected copier business.5 Like all investors in the birth of client–server computing, I was an indirect beneficiary of AT&T’s failure to capitalize on the extraordinary information technologies created within its Unix Systems Laboratory. And at BEA, I was both the direct beneficiary of AT&T’s invention of Tuxedo and, in equal measure, of IBM’s inability to sacrifice the profits from its proprietary products to compete directly in the new world of open and distributed computing. Joseph Schumpeter expressed the view that large firms have an inherent advantage in innovation relative to smaller enterprises.6 But, as Josh Lerner summarizes the experience of the biotech and internet revolutions: “The enabling technologies were developed with government funds at academic institutions and research laboratories. It was the small entrants … who first seized upon the commercial opportunities.”7 In defiance of Schumpeter’s expectation, economic innovation has not been effectively bureaucratized by the great corporations. Rather, it tends to be delivered by new companies. But funding those new companies depends on access to financiers who have access to financial markets prone to speculative excess. This is the lesson both of my professional life as a practitioner and of my research into the sources of venture capital returns. And it is a lesson drawn not only from the most recent iteration of the Innovation Economy or from the long-term development of the British and American economies. Even in the bank-based industrial economies of Germany and Japan, the stock exchange played a critical role in funding aggressive investment in frontier technologies during their initial high-growth decades of the late nineteenth and early twentieth centuries.8 The vast expansion of the German and Japanese banking systems took place to finance post-Second World War recovery, precisely when innovation was a distraction from the defined task of literally reconstructing the physical assets of the economy. The most recent new economy – the digital economy in whose development I have passed my professional career – was built through the combined forces of state funding of research and speculative financing of the companies created to transform the fruits of research into commercial goods and services. But the discrediting of LBJ’s Great Society in the context of Vietnam, followed by the stagflation of the 1970s, opened the door to the return of market fundamentalism as a constraint on state initiatives.

#### Being pro-free-market doesn’t tell you what the purpose of markets is – we can code the market to maximize social welfare, but central planning is computationally impossible

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Eric A. Posner and E. Glen Weyl, “Epilogue: After Markets?” *Radical Markets: Uprooting Capitalism and Democracy for a Just Society*, Princeton University Press 2018, Epub (email [arg5180@gmail.com](mailto:arg5180@gmail.com) for relevant text).

Markets as Miracles

As we saw in chapter 1, many economists who were committed to the market economy also considered themselves “socialists.” Yet in the early twentieth century, socialism became identified with central planning, thanks to the role of Marxism and the French Revolution in inspiring and justifying the economic policies of the Soviet Union. Central planning also received a boost from World War I, where national control of the economy for the purpose of war production was more successful than advocates of laissez-faire could ever have imagined. This led to a heated debate about whether central planning should be used in peacetime as well.

In the popular imagination, central planning could not succeed because it provided individuals with no incentives to work. People needed the prospect of riches, or at least wages, to get them out of bed in the morning. Yet incentives were quite strong in the Soviet Union, stronger, in many ways, than they are in capitalist countries. While there was less chance under Communism to grow rich, any prisoner of the Gulag knew the fate of those who “malingered.”

Another popular argument against central planning was advanced by Nobel Laureate Friedrich Hayek in 1945. Hayek argued that no central planner could obtain information about people’s tastes and productivity necessary to allocate resources efficiently.1 The genius of the market was the way that the price system could, in disaggregated fashion, collect this information from everyone and supply it to those who needed to know it, without the involvement of a government planning board.

A related version of this argument, less well-known than Hayek’s but actually more compelling, was made a few decades earlier. The brilliant economist Ludwig von Mises argued that the fundamental problem facing socialism was not incentives or knowledge in the abstract but communication and computation.2 To see what Mises meant, consider an illustrative parable proposed by Leonard Read in his 1958 essay, “I, Pencil.” 3

Read tells the “life story” of a pencil. Such a simple thing, one would at first think. And yet as you begin to reflect, you realize the enormously complex layers of thought and planning it would require to make a pencil from scratch. The wood must be chopped, cut, shaped, polished, and honed. The graphite must be mined, chiseled, and shaped. The ferrule—the collar that connects the wood shaft and the eraser—is an alloy of dozens of metals, each of which must be mined, melted, combined, and reformed. And so forth.

Yet what is most remarkable about the pencil is not its complexity but the complete lack of understanding that anyone involved in the manufacture of the eventual pencil has about any of these steps in the process. The lumberjack knows only that there is a market for his wood and some price that induces her to buy the needed tools, cut down trees, and sell lumber down the line of production. The lumberjack may never even know that the wood is used for a pencil. The pencil factory owner knows only where to purchase the needed intermediate materials and how to run a line assembling them. The knowledge and planning of the pencil’s creation emerge organically from the process of market relations.

Now suppose that we were to try to replicate the market relationships with a central planning board. The board would determine how much wood to chop and when, the number of workers to employ at each stage of production, the correct places and times to produce, ship, and build. Yet, to do this effectively the board would have to understand a great many things. It would have to learn from each of these specialized producers the unique knowledge of her domain of expertise that allows her to earn a living—for example, whether the lumber would have a more valuable use elsewhere in the economy (to build houses or ships or children’s toys) than as an input for pencils. Absorbing all this information and constantly receiving and processing the necessary updates to keep abreast of evolving conditions in each of these steps of the process, would overwhelm the capacity of even the most skilled managers.

And even if the board somehow had an unlimited capacity to absorb this information, it would still have the unmanageable problem of trying to act on this sea of data. Prices, supply and demand, and production relations in markets arise through a complex interplay of individuals each helping to optimize a tiny part of a broad social process. If, instead, a single board had to plan this entire dance, it would force a small number of individuals to contemplate an endless sequence of choices and plans. Such elaborate calculations are beyond the capacity of even the most brilliant group of engineers.

Mises wrote decades before the rise of the fields of computer science and information theory and lacked any way to formalize these intuitive ideas. Many of Mises’s arguments were dismissed by mainstream economists, whose increasingly narrow mathematical approach to the field Mises disdained. Mises’s critics, including Oskar Lange, Fred Taylor, and Abba Lerner, argued that the market mechanism was but one of many ways (and far from the most efficient way) to organize an economy. They viewed the economy purely mathematically, rather than computationally, and saw no difficulty in principle with solving a (very large) system of equations relating the supply and demand of various goods, resources, and services.

In a simplified picture of the economy, ordinary people perform dual functions as producers (workers, suppliers of capital, etc.) and consumers. As consumers, people have preferences regarding different goods and services. Some people like chocolate, others like vanilla. As producers, they have different talents and capacities. Some people are good at doing math, others at mollifying angry customers. In principle, all we need to do is figure out people’s preferences and their talents, and assign jobs to people who do them best, while distributing the value created by production in the form of goods and services that people really want. Rewards and penalties need to be determined to give people incentives to reveal their preferences and talents, and to ensure that they actually do what they are supposed to do. All of this can be represented mathematically and solved. That’s why socialist economists viewed the economy as a math problem the solution of which only required a computer.

Yet the later development of the theory of computational and communication complexity vindicated Mises’s insights. What computational scientists later realized is that even if managing the economy were “merely” a problem of solving a large system of equations, finding such solutions is far from the easy task that socialist economists believed. In an incisive computational analysis of central planning, statistician and computer scientist Cosma Shalizi illustrates how utterly impossible “solving” a modern economy would be for a central planning board. As Shalizi notes in his essay, “In the Soviet Union, Optimization Problem Solves You,” the computer power it takes to solve an economic allocation problem increases more than proportionately in the number of commodities in the economy.4 In practical terms, this means that in any large economy, central planning by a single computer is impossible.

To make these abstract mathematical relationships concrete, Shalizi considers an estimate by Soviet planners that, at the height of Soviet economic power in the 1950s, there were about 12 million commodities tracked in Soviet economic plans. To make matters worse, this figure does not even account for the fact that a ripe banana in Moscow is not the same as a ripe banana in Leningrad, and moving it from one place to the other must also be part of the plan. But even were there “merely” 12 million commodities, the most efficient known algorithms for optimization, running on the most efficient computers available today, would take roughly a thousand years to solve such a problem exactly once. It can even be proven that a modern computer could not achieve even a reasonably “approximate” solution—and, of course, today there are far more goods, services, transport choices, and other factors that would go into the problem than there were in the Soviet Union in the 1950s. Yet somehow the market miraculously cuts through this computational nightmare.

Markets as Parallel Processors

But all of this raises a question. If the problem is so hard to solve, how is it possible for the market to solve it? Consider Lange’s quote from our epigraph.5 The market is just a set of rules enforced by the government—not much different from a computer algorithm, although a very complex one. It’s true that no single person invented the market. Yet the rules of the market are well understood, and economists are constantly telling people to implement them. Imagine that a new country is created, and its leaders ask a western economist how best to create an economy. The economist will tell them how to set up a market—the rules of contract and property law, for example. (Indeed, economists have been running around the halls of government of developing countries and the floors of start-ups for decades doing just this.) Aren’t the economists just supplying a kind of computer program to the leaders, who by implementing it are engaging in a style of centralized planning?

To understand how the market solves the “very large system of equations,” you need to know the key ideas of distributed computing and parallel processing. In these systems, complicated calculations that no one computer could perform are divided into small parts that can be performed in parallel by a large number of computers distributed across different geographic locations. Distributed computing and parallel processing are best known for their role in the development of “cloud computing,” but their greatest application has gone unnoticed: the market economy itself.

While the human brain is wired differently from a computer, computational scientists estimate that a single human mind has a computational capacity roughly ten times greater than the most powerful single supercomputer at the time of this writing.6 The combined capacity of all human minds is therefore tens of billions of times greater than this most powerful present-day computer. The “market” is then in some sense a giant computer composed of these smaller but still very powerful computers. If it allocates resources efficiently, it does so by harnessing and combining their separate capacities.

Adopting this perspective, we must ask how the market is “programmed” to achieve this outcome. The economy consists of a variety of resources and human capacities at a range of locations, along with a system for transmitting data about these resources among individual human beings. A standard approach in parallel processing is to take information local to one location in, say, a picture or puzzle and assign this to one processor, integrating these inputs on still other processors in a hierarchical fashion. Now apply this image to the economy. In every place, we take one of the computers (humans) available to us and assign it to collect information about that location’s needs and resources and report some parsimonious “compressed” summary of all that data to other computers. For example, there might be a hierarchical arrangement of computers, with those responsible for particular locations on the ground reporting to a higher “layer” that integrates local areas and then upward from there.

Consider the following example. A person works on a farm and is in charge of ensuring that the farm is productive and that her family is happy. This person sends information about the farm and her family, not in its full richness and complexity, but in broad strokes, to district managers. One manager specializes in understanding the resources that farms need to operate—seeds, fertilizer— while another understands the resources that people living on farms need in order to be happy, including food and clothing. These managers would then aggregate these data and convey them to the next layer, perhaps a national wheat distributor or a regional supplier of products for use on farms. At every level of this chain, some information would need to be lost for the parallel processing to remain parallel and tractable: the farm manager could not detail every way in which a slightly better paved road would help in conveying goods to market or how slightly cleaner water would protect her crops. But at least she could report the largest and most important needs and hope that the loss of information only slightly reduces the efficiency of the resulting solution.

This arrangement has a flavor of central planning but also resembles a market economy. People specialize in different parts of the production chain and operate under limited information, yet are able to coordinate their behavior because the information takes a certain form. While people are experts on local conditions, they know little about economic conditions elsewhere. They know that grain prices are high and tractor prices are low, but not why this is the case. When they buy a tractor or sell grain, they don’t tell the vendor or purchaser their life story, all the conditions on their farm, and so forth. They just place an order or offer so much grain at the going price.

This “price system” thus greatly simplifies communication between different parts of the economy. In fact, economists have shown that prices are the minimum information that a farmer needs to plan her operations effectively. So long as every important way that the farm could benefit or draw down resources from the outside world has a price attached to it, this is all the information the farmer needs to make economic decisions. Any greater information would be a waste, from a purely economic efficiency perspective, though it might be interesting from time to time to develop personal relationships. Conversely, if these prices were not available, there would be no way for a farmer to know whether it pays to use new tractors or rely instead on more labor, nor would she know how many seeds to plant for next season. The farmer without such prices could easily produce too little or waste resources on a tractor that could be better used for more labor, seed, or even consumption.

In this sense, prices are the “minimum” information necessary for rational economic decision-making.7 No other system of distributed computing can be equally productive and yet require less communication.

Markets elegantly exploit distributed human computational capacity. In doing so they allocate resources in ways that no present computer could match. Von Mises was right that central planning by a group of experts cannot replace the market system. But his argument was mistakenly taken as implying that the market is “natural” rather than a human-created program for managing economic resources. In fact, there is nothing natural about market institutions. Human beings create markets—in their capacity as judges, legislators, administrators, and even private business people who frequently set up organizations that create and manage markets.

Markets are powerful computers, but whether they produce the greatest good or not depends on how they are programmed. We advocate “Radical Markets” because we believe that in the present stage of technological and economic development, when cooperation has grown too large to be managed by moral economies, the market is the appropriate computer to achieve the greatest good for the greatest number. If we see it as such, we can fix the bugs in the market’s code and enable it to generate more wealth that is distributed more fairly.

By sharpening our understanding of the role and value of markets, the computational analogy clarifies our claim that the solutions we propose are based on extending the reach of markets. The COST on wealth radicalizes markets as it puts greater responsibility on individuals to articulate their values and gives them greater ability to claim things they value highly. QV does the same in the political sphere. Our ideas on migration give individuals more scope for determining the best path for where they live and work. Our proposals on antitrust and data valuation break up centralized power and place greater responsibility on individuals and small firms to compete, innovate, and make rational economic choices to allow for the distributed computation of optimal economic allocations. But all these proposals raise the question: if the market is just a computer program that harnesses the power of individual human intellects, will it still be necessary as computer power increases?

#### The “imminent collapse unless alt” narrative is wrong—enough time to address existential risk without discarding capitalism

Wade, Professor of Global Political Economy at the Department of International Development, London School of Economics, ‘21

(Robert H., “What is the Harm in Forecasting Catastrophe due to Man-Made Global Warming?” July 22, <https://www.globalpolicyjournal.com/blog/22/07/2021/what-harm-forecasting-catastrophe-due-man-made-global-warming>)

When parts of western Germany, Belgium and Netherlands have just experienced catastrophic floods and the Pacific northwest has recently broken heat records, it is counter-intuitive to challenge the prevailing pessimism about global warming – captured for example by the Financial Times columnist Martin Wolf who says, “Given this signal failure [to vaccinate against Covid in line with the global interest], it is impossible to imagine we will do much more than fiddle while the planet burns.”

The danger of this mindset is that it encourages inflation of the threat-language far beyond the credible science, so that the future cannot be discussed except in terms of a choice between “disaster”, “catastrophe”, “planetary extinction” on the one hand or impossibly fast reforms to how humanity lives, works and governs, on the other.

Every sensible person agrees that (1) global warming has been happening over most of the second half of the twentieth century and on into the twenty first, and (2) most of it to date is due to greenhouse gas emissions. What could be called the “mainstream view” of climate change goes much further, onto uncertain epistemological ground: (3) man-made global warming is the main cause of all kinds of disagreeable events – including extreme weather, rising seas, and much more; (4) humanity faces impending catastrophe unless we undertake far-reaching changes to how we live, work and govern in order to cut CO2 emissions and dematerialize economies (“net zero by 2050”).

This essay identifies some of the weaknesses in the evidence presented in support of the mainstream view, including weaknesses in the claim that 97% of climate scientists believe in anthropogenic global warming, in the claim that global temperatures will rise much faster than they have been rising, and in the (implicit) claim that the horrifying worst-case scenario presented by the Intergovernmental Panel on Climate Change represents the likely scenario to 2100 in the absence of radical actions starting now. It identifies the incentive mechanisms that produce the exaggerations and sustain wide credence in them. At the end it considers the question: does highlighting the doomsday exaggerations serve to reduce the political and public pressures for necessary ameliorative action, in a world where powerful fossil lobbies seek to block or delay such action for reasons independent of “evidence”? To what extent must mass publics be “panicked” in order to induce enough collective political, business and family action to substantially slow the growth of greenhouse gas emissions?

Policy Recommendations

Every sensible person agrees that (1) global warming has been happening over most of the second half of the twentieth century and on into the twenty first, and (2) most of it to date is due to greenhouse gas emissions.

But too much policy discussion about global warming is polarized and locked into a “syndrome of exaggeration”. The mainstream view talks of coming disaster, catastrophe, even extinction, short of urgent and massive action on a global scale. But it is easy to question the empirical basis of this forecast – not least the long history of repeated wild exaggerations of disaster relative to what later transpired. In response an active but small “sceptical” community exaggerates its scepticism. The two sides make a syndrome in that the behaviour of each confirms the negative expectations of the other.

What is now strangely urgent is to calm down the present climate hysteria so that safety-first resource allocation and consumption decisions can be made without “climate” being the touchstone of the very future of humanity, the current idol of the ancient human longing for Salvation in anxious times, the pathway for all the ingredients of a better world.

The essay suggests changes in the budget and mandate of the Intergovernmental Panel on Climate Change; more action by learned societies in calling to account the wild exaggerators; beefing up the Loss and Damage pillar of the Paris Agreement; boosting investment in “clean coal” technologies as well as renewables, and linking coal-power retirement to the coming on stream of attractive alternatives; creating central planning capacity at national and international levels (eg in multilateral development banks) to integrate investment decisions in energy, transport, buildings, industry and agriculture; and last but not least, respecting the principle of free speech while maintaining the standards of civil discourse.

Every sensible person agrees that (1) global warming has been happening over most of the second half of the twentieth century and on into the twenty first, and (2) most of it to date is due to greenhouse gas emissions. Many go on to say that (3) global warming is the cause of all kinds of disagreeable events – including extreme weather, rising seas, and much more; and that (4) humanity faces impending catastrophe short of far-reaching changes to how we live, work and govern in order to cut CO2 emissions and dematerialize economies. This could now be described – with only a little exaggeration – as the mainstream view.

The Impending Catastrophe

Here are examples of people and organizations claiming that catastrophe for humanity and the biosphere lies ahead if the people of developed and developing countries alike do not make radical changes soon.

The New York Times reported after the G7 Summit in June 2021 that “Mr Biden was once again part of a unanimous consensus that the world needs to take drastic action to prevent a climate disaster”. The report explains that “… the world needs to urgently cut emissions if it has any chance of keeping average global temperatures from rising above 1.5C compared with preindustrial levels. That’s the threshold beyond which experts say the planet will experience catastrophic, irreversible damage.”

US climate envoy John Kerry delivered a dire warning on 12 May 2021 on “the mounting costs … of global warming and of a more volatile climate”. 2020’s tally of “22 hurricanes, floods, droughts and wildfires shattered the previous annual record of 16 such events, and that was set only 4 years ago…. You don’t have to be a scientist to begin to feel that we’re looking at a trend line.”

Christiana Figueres, former executive secretary of the UN Framework Convention on Climate Change and pivotal figure in the Paris Agreement, declared in 2020, “It is only over the next 10 years from here to 2030 that we can influence what is going to happen. The scary thing is that after 2030 it basically doesn’t really matter what humans do. We will be in danger of those tipping points having a domino effect on each other and we will lose total control.” (1)

Some more examples:

Kevin Drun, 2019: “[The Green New Deal] would only change the dates for planetary suicide by a decade or so. It’s nowhere near enough even if we do it ”.

Professor Frank Fenner, microbiologist, ANU, 2010: “We’re going to become extinct. Whatever we do now is too late”

John Davies, geophysicist, senior researcher at the Cold Climate Housing Research Center, 2014: “With business as usual life on earth is largely doomed”.

James Hansen, former Director, NASA Goddard Institute for Space Studies, testifying at a Congressional hearing on global warming in 2008: “We’re toast if we don’t get on to a very different path. This is the last chance” to avoid mass extinctions, ecosystem collapse and dramatic sea level rises. “We [scientists] see a tipping point occurring right before our eyes. The Arctic is the first tipping point and it’s occurring exactly the way we said it would.” In five to 10 years [by 2013-2018], the Arctic will be free of ice in the summer.

James Hansen, testimony at Congressional hearing, 1988: “world's leading climate expert [Hansen] predicts lower Manhattan underwater by 2018”

Dr Michael Mann, Penn State: “We’re talking about literally giving up on our coastal cities of the world and moving inland”

United Nations Environment Programme, 2005: “Fifty million climate refugees by 2010.” (2)

United Nations Environment Programme, 2011: “60 million environmental refugees by 2020”

The Guardian carried a front-page story in 2004 headlined, “Now the Pentagon tells Bush: climate change will destroy us”. The by-line reads: “Secret report warns of rioting and nuclear war. Britain will be ‘Siberian’ in less than 20 years. Threat to the world is greater than terrorism”. The text continues, “A secret report, suppressed by US defence chiefs…, warns that major European cities will be sunk beneath rising seas as Britain is plunged into a ‘Siberian’ climate by 2020. Nuclear conflict, mega-droughts, famine and widespread rioting will erupt across the world.” (Emphases added).

Remember that in the 1960s and 1970s many experts forecast an immanent Ice Age. For example, 1970: “Ice age by 2000”. 1971: “New Ice Age coming by 2020 or 2030.” 1976: “Scientific consensus planet cooling famines imminent”. 1978: “No end in sight to 30 year cooling trend”.

The Climate Change Consensus

The diagnoses and prescriptions in the above statements express an underlying consensus.

Human actions (mainly burning fossil fuels and changing land use) are causing rising concentration of atmospheric CO2 (and other greenhouse gases, GHG),

Rises in man-made GHG are causing rising global temperatures in atmosphere and seas, and

This temperature rise poses not just a serious threat to humanity and the whole biosphere, but an existential threat.

In other words, the existence of humans and many other species is at stake if we do not succeed in drastically cutting CO2 emissions as the way to reduce the atmospheric concentration of GHG and thereby slow or reverse the rise in global temperature. In the oft used phrase, humanity faces an “existential crisis” induced by climate change caused by human actions. Implied but not normally stated, there are no benefits from higher concentrations of CO2 or higher temperature to be weighed against costs. Also implied but not normally stated, we must act to stop climate change regardless of cost, because the costs might include deep disruption of human civilization or even extinction.

We have to think of avoiding climate change as the global equivalent of avoiding explosions at nuclear power plants (Chernobyl, Fukushima). We invest heavily in safety-first measures in order to reduce the probability of a nuclear explosion to a very low level because the costs of a nuclear explosion are so huge. The same logic applies at the level of climate, in terms of the costs of average temperature rising by more than ~ 1.5 C from “pre-industrial”.

This is the Anthropogenic Global Warming Consensus, or Climate Change Consensus (CCC) for short. I use “consensus” in the same sense as “the Washington Consensus” about best policy for developing countries, the phrase coined by John Williamson in 1990.

The CCC is now well anchored into international agreements (such as the Paris Declaration), national policy, and increasingly corporate strategy too. The periodic Assessment Reports of the Intergovernmental Panel on Climate Change (IPCC) reaffirm it, particularly in the Summary for Policymakers. Financial Times journalist Pilita Clark observed, “The world has rarely seen any environmental idea take off like the push to cut greenhouse gas emissions to net zero. A fringe concept six years ago, it has gone mainstream so quickly that more than 60 percent of countries now have some sort of net zero goal, along with investors managing nearly $37tn and at least 20 percent of the 2,000 largest publicly listed companies. The International Energy Agency [IEA] warns in a striking net zero report today that all new oil, gas and coal projects and exploration must stop if global warming is to stay below 1.5C.”

Scientific support comes from the fact that 97% of climate scientists agree that man-made greenhouse gases have been responsible for “most” of the warming of the Earth’s average temperature over the second half of the twentieth century. The 3% who are sceptical are not highly regarded scientists and some are in the pay of fossil fuel interests.

In the face of this scientific, interstate, and corporate agreement about the necessity of a global Big Push to cut CO2 emissions fast, developing countries and China carry a heavy responsibility, because they are the major source of global CO2 emissions, mainly from their consumption of fossil fuels. They must quickly follow the developed countries in investing on a massive scale in sources of renewable energy, whose prices are falling fast. Developed countries will offer large-scale financing and technical assistance for them to make the switch – in the developed countries’ self-interest.

It is true that developed countries put up most of the stock of greenhouse gases now in the atmosphere as they used fossil fuels to power their ascent to the top of the global hierarchy of income and wealth over the past two centuries. But that gives developing countries, even though they remain well down the income hierarchy, no justification for saying that they therefore have the right to carbon space for powering their economic development – because continuing to use relatively accessible, cheap and reliable fossil-fuel energy to power their growth pushes all humanity and the biosphere towards ruin.

Do Virtually all Climate Scientists Agree with the CCC?

It is widely cited that “97% of climate scientists agree warming is man-made”; or more exactly, “97% of science papers taking a position on climate change say it is man-made”. The conclusion is frequently amped up to “a 97% consensus that ‘humans are causing a global warming crisis’”.

Note that this last statement – with “crisis” – is not the same as the previous two, but all three statements tend to be conflated, so that people agreeing with “most recent warming is man-made” tend to be scored as agreeing that global warming is a crisis, which commonly gets inflated into agreeing that it is an existential crisis or the existential crisis.

Note that these statements of “consensus” do not specify the time period.

Note also that “high consensus” in science is only a weak criterion of “truth” in science – but the 97% figure is often deployed as evidence of the “truth” that warming is man-made. Of course, it is worth knowing to what extent there are “widely accepted truths” in any field. But problems come when the “fact” of consensus is established in a clearly tendentious way.

A standard source of the claim that 97% of climate scientists agree that global warming is man-made is the study by John Cook et al. (2013). The study rated about 12,000 abstracts of peer-reviewed papers published between 1991 and 2011. The rating was done by 12 volunteers, each abstract was rated by two people, making 24,000 ratings. The ratings were in three categories: (1) implicit or explicit endorsement of human-caused global warming; (2) no opinion; (3) implicit or explicit rejection or minimization of the human influence. About 4,000 abstracts took a position on the cause of global warming, 97.1% of which endorsed human-caused global warming.

Notice that this should not be, but commonly is translated as “97% of climate scientists endorse …”. Notice too that the abstracts were not rated as to whether they stressed greenhouse gases or man-made changes in land use and land cover; the implicit assumption is, man-made greenhouse gases are the cause of warming. Finally, notice that the abstracts were not rated as to whether they endorsed the idea of a global warming crisis or catastrophe; only as to whether they endorsed the idea of human causes of global warming.

A Wikipedia essay describes the study as “a landmark climate research paper [which] found that 97.1% of climate scientists supported the hypothesis of anthropogenic global warming (AGW). As of March 2021, the paper has received at least 1,270,076 downloads.”

There is an obvious question. Does “endorsement of human-caused global warming” mean warming caused 100% by human actions, or 75%, or 50%, or 25%? Any of these may be consistent with “climate change is man-made”. By leaving the degree of causation by humans open, thumbs can be put on the scales to yield the conclusion that virtually all well-qualified scientists believe that global warming of the past several decades is caused almost entirely by human action (would not be occurring in the absence of that action).

Professor Mike Hulme, professor of Human Geography at the University of Cambridge, concludes: “The ‘97% consensus’ article is poorly conceived, poorly designed and poorly executed.” Analysis by David Legates et al (2015) found that only 0.3% of the sampled papers “endorsed the standard definition of consensus: that most warming since 1950 is anthropogenic”. Research physicist Nicola Scafetta: “Cook et al (2013) is based on a straw man argument because it does not correctly define the IPCC AGW [anthropogenic global warming ] theory, which is NOT that human emissions have contributed 50%+ of the global warming since 1900 but that almost 90-100% of the observed global warming was induced by human emission”. (3)

It is testimony to the apocalyptic emotion behind people’s response to “climate change” and “global warming” that the Cook et al. paper, and others with similar methods, have commanded such credence in the face of evident flaws – notably (1) in fudging the distinction between agreeing that human actions have some role in global warming and agreeing that human actions explain most global warming; (2) in not asking whether – extent to which -- the scientists’ papers identified global warming as a problem, a crisis, an existential crisis, over what time period. (4)

By keeping it vague what the “consensus” agrees on, authors and users of the studies have given the impression that endorsement of “humans are causing global warming” means endorsement that “humans’ enhancement of the greenhouse effect will be dangerous enough to be ‘catastrophic’”, and therefore also means endorsement of the imperative for urgent, radical action on a global scale by governments, firms and families.

It is testimony to the pervasive anxiety of the zeitgeist that such surveys are routinely cited as demonstrating a near-unanimous scientific consensus in favor of radical, far-reaching climate policy (including for energy, food and materials), when the surveys do not even ask the question as to whether the respondent considers that (a) the anthropogenic component of recent warming is dangerous, and (b) dangerous enough to require a global climate policy. The surveys are almost valueless scientifically, but valuable politically.

Upward Bias in Temperature Forecasting Models

The prospect of a coming catastrophe for humanity and the biosphere rests heavily on outputs of climate forecasting models. But as David Legates and co-authors argue, these models “exhibit a strong exaggeration in their results even when narrowly adopting atmospheric carbon dioxide as the sole driver of climate responses…. [General circulation models, such as those of the IPCC, the Intergovernmental Panel on Climate Change] have consistently overestimated the climate sensitivity to rising atmospheric carbon dioxide.”

Ross McKitrick (2020) begins his assessment, “Two new peer-reviewed papers from independent teams confirm that climate models overstate atmospheric warming, and the problem [of overstatement] has gotten worse over time, not better”. One of the papers (by McKitrick and John Christy) examined 38 models, the other, 48 models, used by the Intergovernmental Panel on Climate Change (IPCC), the various US “National Assessments”, the EPA’s “Endangerment Finding”, and more.

McKitrick continues, “Both papers looked at ‘hindcasts’, which are reconstructions of recent historical temperatures in response to observed greenhouse gas emissions and other changes (eg aerosols and solar forcing). Across the two papers it emerges that the models overshoot historical warming from the near-surface through the upper troposphere, in the tropics and globally.” The study based on 48 models for 1998 to 2014 found that they warm on average 4 to 5 times faster than the observations.

McKitrick concludes, “modelling the climate is incredibly difficult, and no one faults the scientific community for finding it a tough problem to solve. But we are all living with the consequences of climate modelers stubbornly using generation after generation of models that exhibit too much surface and tropospheric warming, in addition to running grossly exaggerated forcing scenarios (eg RCP8.5).

“[W]hen the models get the tropical troposphere wrong, it drives potential errors in many other features of the model atmosphere. Even if the original problem was confined to excess warming in the tropical mid-troposphere, it has now expanded into a more pervasive warm bias throughout the global troposphere.

“If the discrepancies in the troposphere were evenly split across models between excess warming and cooling we could chalk it up to noise and uncertainty. But that is not the case: it’s all excess warming…. That’s bias, not uncertainty, and until the modelling community finds a way to fix it, the economics and policy making community are justified in assuming future warming projects are overstated, potentially by a great deal….”

The strong upward bias in temperature forecasts relative to observations compromise the models’ forecasting impacts on ecosystems, including agriculture, by exaggerating the probability of catastrophic effects.

The IPCC makes projections of future global temperatures to the end of century based on various models. They range from a low of 1.4 C to a high of 5.6 C over pre-industrial temperature (roughly 1900). The wide range makes them almost meaningless. The IPCC explains that the wide range results from uncertainty about the magnitude of the feedback between warming and increased rates of evaporation – and David Seckler adds, also about the effects of evaporation on clouds and precipitation. (5)

It is astonishing to learn that the climate models miss a critical component of the climate system -- the hydrological cycle, and specifically clouds, which the IPCC calls the “wild card” in the climate system.

The IPCC’s Worst Case Scenario is commonly used as the Business as Usual without a Radical Policy Action’ Scenario

The IPCC’s Assessment Report 5 (AR5), published in 2014, presented a range of forecasts of global climate out to 2050 and 2100, based on different assumptions about radiative forcing (a measure of how much of the sun’s energy the atmosphere traps). The most extreme – the worst case – was called Representative Concentration Pathway (RCP) 8.5. It assumes ominous reversals in several basic, long-standing trends, all heading in the extremely wrong direction to 2100:

high population growth to reach more than 12 billion people

slow technology development

coal consumption increases by 500 % between 2005 and 2100 (no account taken of supply constraints)

slow GDP growth

fast rise in world poverty

high energy use

high GHG emissions.

temperature forecast: 5 C rise between 2005 and 2100.

RCP 8.5’s vision is horrifying, as worst-case scenarios should be.

A whole wave of literature, in peer-reviewed journals as well as in media, even by IPCC authors, has since presented this worst-case as either “the most likely case” or “the baseline case – business as usual without policy action”. This misleading assumption provoked a recent paper in Nature subtitled: “Stop using the worst-case scenario for climate warming as the most likely outcome” (see also, Chrobak, 2020).

The Politics: How has the CCC become so Dominant

How can we understand the present dominance of the CCC in public and political opinion around the world, despite repeated evidence -- over decades -- of wildly exaggerated forecasts of doom when compared against measured outcomes, and despite the real uncertainties (“known unknowns”) in knowledge about basic mechanisms?

We can identify several mutually reinforcing reasons.

1. The public demand for negatively-inflected news, especially on climate

News that fits the CCC plays into a more general logic of “If it bleeds, it leads”, meaning that the media tend to deliver negativity – about climate, health, almost anything – because readers and viewers want negatively-inflected stories. Recent research finds that across all types of articles the most popular stories have high negative content. Surprisingly, politics matters little: there is no difference between conservative and liberal outlets in propensity to deliver negativity. Rather, the difference is between media outlets by size and influence: the bigger and more influential the media brand, the stronger the bias towards the negative – showing how good they are at delivering what people want. According to Matthew Yglesias, several recent research studies find that “the kind of stories people like to consume are compulsive rather than satisfying …. You’re clicking and sharing stories about terrible things and raising alarms and listening to the alarms that are being raised by others, and it all feels very compelling precisely because it’s gloomy and alarming …. People like to get mad, then share the content so that peers can share their outrage.”

Climate lends itself well to this negativity bias. Richard Betts, then the head of climate impacts at the Met Office, explained the demand for negative climate stories (BBC News Channel, 11 January 2010, emphasis added ):

“The focus on climate change is now so huge that everybody seems to need to have some link to climate change if they are to attract attention and funding. Hence the increasing tendency to link everything to climate change – whether scientifically proven or not …. I have quite literally had journalists phone me up during an unusually warm spell of weather and ask ‘is this a result of global warming?’ When I say ‘no, not really, it is just weather’, they’ve thanked me very much and then phoned somebody else, and kept trying until they got someone to say yes it was. Talking up of the problem then gives easy ammunition to those who wish to discredit the science.”

Holman Jenkins, in The Wall St Journal (2018), describes the other side of the exaggeration incentive: “Over the past 15 or 20 years the climate beat has been handed over to reporter-activists who’ve decided that climate science is impenetrable but at least nobody ever got fired for exaggerating the risks of climate change.”

Climate scientist Judith Curry identifies a similar logic in the frequent conflation of extreme weather events and “global warming”. “In 2005 [following Hurricane Katrina] the public found it very hard to care about 1 degree or even 4 degrees of warming – heck, the temperatures varied by that much on a day-to-day basis.… However, arguments that a relatively small amount of global warming (order 1 C) could result in more intense hurricanes, well that got their attention…. The activists now had a new weapon in their arsenal – attributing extreme weather events to manmade climate change. The ‘will to act’ seemed tied to alarmism about extreme weather events. Which provides a key political role for unsupported ‘storylines’ about extreme weather events.” The “heat dome” over the Pacific northwest of the US and Canada in June 2021 was generally treated as yet more evidence of “climate change. You would not know it from the coverage, but in Washington and Oregon, the number of days per decade with temperature above 99 F shows no upward trend from 1911-20 to 2011-20. For example, the number of days above 99 F in 1971-80 was more than in 2011-20. Across the US the 1930s was arguably the hottest decade on record; the time of the deadly “Dust Bowl”, summer 1936, was the hottest summer on record between 1895 and 2020.

An attempt to push the distinction between “weather” and “climate” is unwelcome in this context, because it weakens the motivating, mobilising force of “climate” as the boundless enemy that could destroy humanity, like the Biblical Flood. The Climate Apocalypse is imminent, is the motivational message (also see Adler, 2019).

This is the deeper story behind the wild exaggerations of the forecasts and the continued high credibility of those who make them. The exaggerations express the apocalyptic thinking about climate now sweeping the world, including the financial and corporate world. They express a story of humans damaging Nature, and Nature destroying humans in return. These stories themselves express ancient de-creation stories of humans misbehaving in the eyes of God, and God punishing them. The Biblical flood occurred because God decided the people had become wicked, had stopped respecting God and Nature, so He resolved to wipe life off the face of the earth, saving only a breeding pair of each species in order to recreate the world in His image. Much the same story appeared in Sumerian culture long before the Bible, and later in the Quran, expressing a desperate human wish for Salvation.

In our more secular age, apocalyptic theology can rely on Nature in place of God -- Nature invested with God-like powers of punishment and reward.

2. The “political” science of the IPCC

The IPCC was established to provide a properly scientific center of gravity for discussions about climate, and issue regular balanced assessments of the state of scientific climate knowledge. But there are at least two basic problems with the IPCC process. One is that the mandate of the IPCC says that it is “to assess … the scientific, technical and socio-economic information relevant to understanding the scientific basis of risk of human-induced climate change, its potential impacts and options for adaptation and mitigation” (emphasis added). (6) The mandate does not mention to assess the interaction between human and natural causes. It is as though natural causes do not exist. The IPCC’s whole body of work consequently is slanted towards exaggerating human causes of given climate changes, marginalizing the role of natural causes interacting with human causes. Which among other effects leads it to give undue weight to “mitigating” climate change (by changing human actions) relative to “adapting” to climate changes partly induced by natural forces.

The common justification given by IPCC defenders is: natural causes operate only very slowly; the climate is changing fast; therefore the climate changes must be driven by humans, and humans can change their behaviour fast – when forced and sufficiently motivated to do so ( using all the techniques of Machiavelli). This justification underplays the point that some natural causes – eg the Atlantic Multidecadal Oscillation – do change fairly quickly, over decades, with far reaching effects (eg Atlantic Multidecadal Oscillation and its impacts on the Greenland ice sheet).

The second IPCC problem is that this bias to doomsday forecasts – therefore to urgent and far-reaching action -- is intensified in the process of translating from the technical reports to the summaries for policy makers. The translation – done mostly by non-scientists -- tends to downplay uncertainties and up-play certainties in an alarming, even catastrophizing direction. Hence the tendency to treat worst-case scenarios as likely scenarios. Recall the subtitle to the Nature paper, “Stop using the worst-case scenario for climate warming as the most likely outcome” (2020).

3. Logic of decision-making and logic of mobilization

The tendency to treat worst-case scenarios as likely scenarios “in the absence of radical changes to how we live, work and govern” can be understood in terms of the distinction between the logic of decision-making and the logic of mobilization or action. To make the best decision about what to do, one needs to explore a range of possible alternative courses of action, weigh up the pros and cons of each, then decide which is best. But having exposed many people to a range of options, there may be action-sapping disagreement as to which is best. To get a great mass of people to move all in one direction one needs to present them with only two alternatives, one of which is crazy, and pretend to be entirely confident of the two outcomes. (7) If they can be convinced that there are only two alternatives and one is crazy, they will follow.

The Climate Change Consensus expresses the logic of mobilization. It presents two alternatives. “Do nothing (or little)”, which leads to catastrophe, extinction, the planet becomes ungovernable, coastal cities must be abandoned, lower Manhattan will be underwater by 2018. Or else, quickly decarbonize the world economy and push towards a broader dematerialization of lifeways. No prizes for guessing which wins. This is how you mobilize people on a vast scale to do what you think must be done. Or as a US senator from the West once put it, “Managing politicians is like herding wild horses. To get them running in the same direction you have to stampede them.” (8)

4. Left and right politics

While the demand for negatively-inflected news cuts across the political spectrum, political ideology certainly shapes people’s beliefs about climate. Climate change “scepticism” is almost a talisman of the center-right and right, and is strongly promoted by fossil fuel interests. Climate “alarmism” is more pronounced on the center-left and left of the ideological spectrum. It is promoted as a sacred unifying mission by a great global phalanx of left-green civic action organizations (Extinction Rebellion is prominent).

A Guardian article describes the right-wing “sceptical” tactic. “Vested interests have long realized [that people-at-large trust climate scientists on the subject of global warming] and have engaged in a campaign to misinform the public about the scientific consensus. For example, a memo from communications strategist Frank Luntz leaked in 2002 advised Republicans, ‘Should the public come to believe that the scientific issues are settled, their views about global warming will change accordingly. Therefore, you need to continue to make the lack of scientific certainty a primary issue in the debate’. This campaign has been successful… The media has assisted in this public misconception, with most climate stories ‘balanced’ with a ‘sceptic’ perspective. However, this results in making the 2-3% seem like 50%... As a result, people believe scientists are still split about what’s causing global warming, and therefore there is not nearly enough public support or motivation to solve the problem.”

Both sides accuse the other of abusing “the science”. Both sides generate expansive pressures to describe more and more trends, issue more and more prescriptions, without ambiguity and shading, and judge more and more of the other’s claims pre-emptively. Individual issues (eg extreme weather) are not discussed in terms of their own evidence but are packaged together in ideological visions, the better to establish clear moral battle lines, disagreement being moral heresy.

This is the playing out of a larger process of polarization common when scientific disagreements become public. As described by sociologist of science Robert K. Merton, each group then responds to stereotyped versions of the other. “They see in the other’s work primarily what the hostile stereotype has alerted them to see, and then promptly mistake the part for the whole. In this process, each group … becomes less and less motivated to study the work of the other, since there is manifestly little point in doing so. They scan the out-group’s writings just enough to find ammunition for new fusillades.” (9)

The result is a “syndrome of exaggeration”: each side exaggerates evidence in its favour and downplays evidence against, which justifies the other in exaggerating evidence in its favour and downplaying evidence against; and back again. It is a syndrome in that the behaviour of each side confirms the negative expectations of the other. They often go at each other ad hominem, like adolescent school boys, including people who regard themselves as serious scientists. In the digital era members of both sides are able to quickly find one another and the enemy. (10)

Yet to talk of “two sides” is misleading, because the side championing the CCC is by far the dominant. Recall the Financial Times journalist Pilita Clark: “The world has rarely seen any environmental idea take off like the push to cut greenhouse gas emissions to net zero.” For political leaders and increasingly business leaders, being seen to give high value to protecting the public against all the ills attributed to “climate change” – including by pledging big changes to be made long after they leave office -- is a way to show foresight, statesmanship, leading on the front foot. Many right-wing politicians and business leaders now wish to present themselves as fighters against climate change, even as they continue to support fossil-fuel industries.

5. Finance and business interests

There are now powerful industrial interest groups promoting climate alarmism for profit-seeking reasons, including those invested in the switch from fossil fuels to renewables and those invested in the switch from combustion to electrical engines. The CEO of the electric vehicle car company Lucid (a former Tesla engineer) said recently that the transition to an EV world will happen faster than anyone expects, driven by the environmental imperative. He said, “The environment is in crisis. The world needs millions of electric cars tomorrow”. He did not suggest where all the electricity will come from.

Many big players in finance see opportunities for speculative profits by playing up climate dangers. Goldman-Sachs in 2005 authored the firm’s environmental policy, which said “voluntary action alone cannot solve the climate change problem”, from a firm that has consistently opposed government regulation. It and other financial firms supported what Matt Taibbi called “a new commodities bubble disguised as an ‘environmental plan’” – a carbon credit market in the form of cap-and-trade. Coal plants, utilities, natural gas distributors and some other industries are assigned carbon emission limits. To exceed the limits they must buy credits from those who emit less than their limit. As of 2010, the volume of the market in the US was estimated as $1 trillion annually. Goldman and the others were making themselves central actors in the market. The best thing about it is that the emission limits keep being lowered, implying that the price is guaranteed to keep rising, to the benefit of the intermediaries.

On top of all this, the whole “sustainable investing” movement provides opportunities for big profits at the intersection of the already thick alphabet soup of sustainability disclosure regulations (TCFD, SASB, GRI, CDSB among others, in the case of the EU) and the lack of meaningful, reliable data. “At the moment, the risk is that it is ‘garbage in, garbage out’”, says the head of sustainable finance at S&P Global Ratings.

So the fact that the financial sector is “worried” about climate change could be taken to be part of the problem, underlining the need for public authorities to take charge and frame parameters within which private operations produce public benefits. (11)

Conclusion

I have argued that the “plausible” risks of climate change are commonly exaggerated within the climate community. Recall for example, Christiana Figueres, 2020, “The scary thing is that after 2030 it basically doesn’t really matter what humans do”; Kevin Drum, 2019, “[The Green New Deal] would only change the dates for planetary suicide by a decade or so”; Frank Fenner, 2010, “We’re going to become extinct. Whatever we do now is too late.” Many more in the same doomsday vein.

We have seen that the standard global warming models have a powerful built-in bias to exaggerate the rate of future temperature rise, as seen in (most of) them “hindcasting” temperature rises several times faster than actually observed. We have seen that forecasters commonly take “worst-case scenarios” as “likely scenarios in the absence of radical action” (eg reaching net zero carbon emissions by 2050), to the point where Nature recently published a paper sub-titled, “Stop using the worst-case scenario for climate warming as the most likely outcome”.

The dismaying thing is that scientists and advocates have been making catastrophising global warming forecasts of this kind for decades past, normally dated some 10 to 30 years into the future. The due date comes without catastrophe, but never a retrospective holding to account. Rather, on to the next catastrophising forecast another 10 to 30 years ahead. Scientists-writers-activists know the catastrophe forecasts get the attention, the clicks, the research funding. We saw the exaggeration mechanism spelled out by Richard Betts of the BBC, Holman Jenkins of the Wall St Journal, and climate scientist Judith Curry.

The built-in exaggeration of the costs of climate change blunts the parallel with nuclear power plants. We know with high certainty the costs of nuclear explosions. We know the costs of global temperature going above 1.5 C above “pre-industrial” much less certainly, and we can see the mechanisms by which the likely costs are being systematically exaggerated.

On the other hand, there is abundant evidence that even without the doomsday exaggerations the plausible risks of climate change could be very serious, in particular because of the inherent political economy difficulty of getting needed global or regional cooperation when political action is mostly at the level of sovereign nation states (see the G20).

Coal power generation is the single biggest source of GHG emissions, and emissions from coal consumption will probably not fall fast, whatever the promises. First, coal is cheap, accessible and generates reliable power for many developing countries; in Asia, coal alone generates 40 percent of energy consumption, much higher than the world average of 29 percent. (12) Second, developing countries, including China, assert a strong claim on carbon space to power their economic development. They see it partly as a matter of fundamental justice, since developed countries emitted most of the CO2 that is already in the atmosphere and seas as the necessary condition for them becoming developed. Developed countries promise finance and technical assistance on a massive scale to accelerate the energy transition in developing countries – and have a long track record of leaving promises as promises. (See the global distribution of Covid vaccines. See the results of vaunted “voting reform” in the World Bank, leaving the US with 17% and China with 6%.) What is more, the Japanese government plans up to 22 new coal power plants, as it closes nuclear plants in the wake of Fukushima.

Then comes a question: does drawing attention to the doomsday exaggerations of the CCC – “disaster”, “catastrophe”, “extinction”, “fiddling while the planet burns” - serve to reduce the political and public pressures for necessary ameliorative action, in a world where powerful fossil lobbies seek to block or delay such action for reasons independent of “evidence”? Should “Third Way” essays like this one not be published, because “give them (deniers, sceptics) an inch and they will take a mile”? To what extent must mass publics be “panicked” in order to induce enough collective political and business action – national, international – to substantially slow the growth of GHG emissions? If we can sustain emission- and temperature-curbing action only by holding up the certainty of disaster, catastrophe, extinction, then better to let the doomsday exaggerations continue as the necessary condition for that ameliorative action. What is the harm, when the alternative is ruin for humanity and the biosphere?

The danger is that the repeated wild exaggerations produce a public backlash, a discrediting, and a strengthening of the many “deniers” who see “leftists, governments, and the United Nations” as the source of malevolence in the world. A more accurate accounting of the evidence would (hopefully) produce a more calibrated and sustained public and business response.

What to do? (13)

The IPCC should allocate some 10% of its budget to a Red Team, dedicated to independent scrutiny of its evidence and conclusions (especially the Summary for Policymakers). (14) The IPCC should revise its mandate to require it explicitly to focus on interactions between natural forces and human actions, as it is now almost required not to, biassing its assessment of the state of scientific knowledge towards “man-made global warming” as an almost separate system.

Learned societies should more actively seek to understand and publicize the reasons for repeated large-scale discrepancies between “hindcasts” and “forecasts” on the one hand and actual observations on the other, discrepancies strongly biased towards “disaster”.

It is particularly important that the knee-jerk attribution of extreme weather events to global warming be challenged with reference to evidence. Judith Curry explained – quoted earlier -- why CCC advocates have a powerful incentive to attribute cases of extreme weather to global warming, tout court. She has recently written, “Apart from the reduced frequency of the coldest temperatures, the signal of global warming in the statistics of extreme weather events remains much smaller than that from natural climate variability, and is expected to remain so at least until the second half of the 21rst century.” She goes on to amplify a point made earlier about the limits of the climate models used for the IPCC assessment reports: they are driven mainly by predictions of future GHG emissions. They do not include predictions of natural climate variability arising from solar output, volcanic eruptions or evolution of large-scale multi-decadal ocean circulations. They do a particularly poor job of simulating regional and decadal-scale climate variability. (15)

Participants on both sides have to learn the art of respecting the principle of free speech while maintaining the standards of civil discourse.

While I have stressed the CCC’s support for urgent and radical changes to the way we live, work and govern, some CCC champions argue that the world economy could continue on a largely unchanged growth trajectory provided that we switch fast from fossil fuels to renewables. Indeed, this switch is beginning to happen fast, with coal and nuclear energy production unable to compete without subsidies in areas where natural gas, wind and solar resources are readily available.

But to say that life can continue as before provided we substitute renewables for fossil fuels obscures the huge difficulties for many developing countries of getting out of fossil fuels while growing fast enough to reduce the income gap with developed countries.

We must give high priority to investments in “clean coal” technologies, such as carbon capture, storage and use, to make the dirtier coal cleaner in existing and new coal-power plants; and link coal-power retirement to the coming on-stream of attractive alternatives. The multilateral development banks have recently or will soon announce bans on coal power. The G7 leaders meeting in mid 2021 promised to stop using government funds to finance new international coal power plants by the end of 2021. China’s Belt and Road Initiative should increase its pressure on host countries to cut back on dirty coal and boost clean coal and renewables.

A high and immediate priority is to build a robust financing and technical assistance mechanism for help from developed to developing countries. The Paris Agreement instituted a Mitigation pillar and an Adaptation pillar. Intense debate took place around the third, Loss and Damage, the name of a mechanism to compensate for the destruction that Mitigation and Adaptation cannot prevent. Developed countries by and large have sought to marginalize the Loss and Damage pillar, as they have long sought to marginalize Special and Differential Treatment for developing countries in trade and investment agreements. “Finance is something that really rich countries, particularly the US, have made sure that there is no progress and not even discussion on”, remarked Harjeet Singh, senior advisor at Climate Action Network International. (16)

My “forecast” is that in the next two to three decades to midcentury we will make rapid progress in scientific knowledge about weather and climate, helped by longer and more accurate satellite and ocean records and by a new generation of climate models that operate at one to ten kilometers scale (as distinct from the current models’ 50 kilometer scale). We will probably continue to make rapid progress in decoupling GHG from GDP growth, with a combination of state direction-setting and private innovation focused on transformations in energy, transport, buildings, industry and agriculture, using incentives like research and development subsidies and tax credits for technology investment, and penalties for carbon-intensive activities. (17) In transport, this entails coordination across urban planning decisions, public transport investment, future of remote working, infrastructures for electric charging and hydrogen loading. (18) Transformations in these systems are already underway, and the prospect of vast new green investments, supported and under-written by the state, will intensify them. These green investments will open productive investment opportunities previously limited by stagnant wages and rising debt, which have driven investment into increasingly speculative ventures. If by two or three decades ahead it looks as though the second half of this century could well experience globally extreme climate and ocean events, we will be much more knowledgeable about what to do than we are today. (19)

### DA Mergers

#### Existing patent protections solves – pay for delay is an unnecessary artificial extension of exclusivity

Kotlikoff 08 - Professor of Economics Boston University

Laurence J. Kotlikoff, “Stimulating Innovation in the Biologics Industry: A Balanced Approach to Marketing Exclusivity,” September 2008, http://people.bu.edu/kotlikof/New%20Kotlikoff%20Web%20Page/Kotlikoff\_Innovation\_in\_Biologics21.pdf

Limiting Monopoly Protection to Increase Economic Efficiency

If less monopoly protection can be more when it comes to stimulating invention, the same holds true when it comes to improving economic efficiency. In his fundamental paper on optimal patent life, William Nordhaus argues that “the optimal life for drastic process inventions seems to be very small, in the order of one-tenth of the actual life of patents. The reason for the very small (optimal) life seems to be that drastic inventions are very important inventions and thus have a great deal of potential deadweight loss if they have long life.”50 Drastic inventions refer here to inventions that lead to major reductions in the prices facing consumers once patent protection terminates. But the fact that the true economic cost for consumers of consuming a product is quite low means they should be consuming a lot of it. But with extended monopoly protection this doesn’t happen, or at least doesn’t happen for a very long time. The resulting consumer loss in welfare is called a deadweight loss. Glenn Loury reaches a similar conclusion to Nordhaus, but in a more realistic setting in which the overall economy’s conditions change when patent policy is modified. Loury states, “Social welfare can be maximized by appropriately limiting entry and firm investments with licensing fees and finite patent life.

Conclusion

Biologic medications hold enormous promise for improving Americans’ health and well-being. Fulfilling that promise requires making sure that all Americans are able to access these medications at affordable prices within a reasonable period of time from their discovery. It also requires ensuring that tomorrow’s biological breakthroughs are able to build on today’s. Legislation now pending in Congress offers hope to millions of Americans that more affordable versions of biologic medications will soon become available through a competitive marketplace. But exclusivity provisions in three of the four main biogenerics bills significantly undermine the legislation’s objectives. These provisions constitute uncontestable grants of monopoly rights by government fiat — something that runs far afield of traditional U.S. patent policy. The provisions would substantially extend the duration of monopoly protection of brand biologic medicines and, thereby, materially delay the arrival of low-cost generic alternatives. These conveyances of exclusive marketing rights not only exclude competing biologic companies from entering the market with low-cost alternatives for extended periods of time. They also exclude other innovators from building, in a timely manner, on the stock of prior knowledge, much of which was accumulated at public expense. These bills also fail to anticipate and prevent evergreening under which brand companies can obtain repeated periods of exclusivity and monopolize biologic medicines essentially indefinitely. New medications that alleviate or cure terrible disease are such remarkable gifts to humankind that we must continue to appropriately reward true innovation in this field. But the new drugs of today are not those of tomorrow. And today’s inventors are generally not tomorrow’s. The reason is clear. Today’s inventors have strong incentives to protect their discoveries, not make new ones whose arrival on the market would undermine their existing profits and market share. And, as numerous papers in the economics literature on invention and monopoly protection point out, over-extending monopoly protection can easily boomerang. It may do little or nothing to incentivize new discovery and simply delay when the next discovery comes on board. In this case, providing greater incentive to innovate leads to less, not more, innovation over time. Without question, the American biologics drug industry is a golden goose, which is advancing the healthcare of our citizens. The presumption of many is that feeding this goose more and more will lead it to produce an ever-greater number of eggs at a faster pace. But doing so is very dangerous. After all, why should the goose produce as much when it has less incentive, and why should anyone look for a better goose if the current one cannot be displaced? Fortunately, we don’t need to guess how much to feed the biologics goose. Its chemical cousin — the pharmaceutical goose — is, from all appearances, essentially identical in its diet and response to incentives. What works for the pharmaceutical goose will surely work for the biologics one. And what works for the pharmaceutical goose in promoting and protecting innovation is the Hatch-Waxman legislation — a bill whose exclusivity provisions are sufficiently balanced as to not over-extend the duration of monopoly protection. Close to a quarter of a century’s experience speaks clearly. HatchWaxman provides its goose with a balanced diet — one that provides brand companies with appropriate incentives to develop and market their products, one that permits competitors to lower pharmaceutical prices to the public in a timely manner, and one that keeps new pharmaceutical discoveries coming at a rapid pace.

#### Perception – the plan is an expected continuation of the *Actavis* precedent

Carrier 18 – Michael A. Carrier is a Distinguished Professor at Rutgers Law and a leading authority in antitrust and intellectual property law with expertise in the pharmaceutical, high-technology, and music industries. Carl J. Minniti III, Rutgers Law School, J.D. 2017.

January 12, 2018, “BIOLOGICS: THE NEW ANTITRUST FRONTIER,” https://www.illinoislawreview.org/wp-content/uploads/2018/01/Carrier.pdf

In determining the appropriate antitrust analysis of settlements, an initial question centers on the application of FTC v. Actavis. We believe that, in a broad holding of general applicability, Actavis confirmed antitrust law’s vital role in evaluating the legality of settlements involving payment and delayed entry. The Court relied on **an array of previous cases to confirm that its precedents “make clear** that patent-related settlements can sometimes violate the antitrust laws.”

To be sure, the Court was not offering an antitrust assessment of biologic settlements. Nor could it have given that no court—even now, several years later—has considered settlements under the BPCIA. But we believe the **setting** of **complex pharmaceutical regulation under the BPCIA easily offers sufficient similarities to the Hatch-Waxman Act** to allow application of Actavis’s broad principles. In addition, payment to avoid the risk of biosimilar competition presents the same concerns highlighted in Actavis.

The linchpin in the antitrust analysis of settlements is whether a generic is excluded from the market based on a patent or payment. Exclusion based on a patent generally does not present antitrust concern because it is commonly understood that patent-term split agreements, by which brands and generics divide the remaining patent term by selecting a time for generic entry, do not violate the antitrust laws. The reason is that the parties’ compromise on the entry date reflects the odds of success in patent litigation. The greater the likelihood the patent is valid and infringed, the later in the period generic entry would be expected. The lower the likelihood, the earlier entry would be expected. A brand, however, is likely to gain additional exclusivity not explained by a patent by supplementing the parties’ entry-date agreement with a payment to the generic.

The same distinction between patent and payment should apply in the setting of biologics. The biologic manufacturer is entitled to rely on its patent to exclude a generic. But **it should not be able to pay a biosimilar to gain additional delay.** In determining whether there is payment, the court should consider, as one of us has explained before, whether the biologic manufacturer conveys “a type of consideration not available as a direct consequence of winning the lawsuit.” If the biosimilar manufacturer is able to obtain such consideration, “its exclusion from the market cannot be traced to the strength of the [biologic] patent.” In such a case, “the [biologic maker] is providing compensation beyond what even a valid and infringed patent would justify.”224 And, presenting antitrust concern, the biosimilar delays entering the market because of this payment.

One example of a form of payment that could arise in this setting involves a biosimilar’s access to a biologic’s distribution or reimbursement networks. In contrast to distribution through wholesalers and specialty distributors (each of which obtains a portion of revenues, reducing a biosimilar’s profitability), biologics could offer access to a “manufacturer direct” channel which, in selling directly to purchasers (e.g., specialty pharmacies and large hospitals), removes the “middleman.” Setting up an efficient supply chain is difficult and expensive, and not all biologics will be able to implement such a scheme. As a result, if a biologic has already set up direct distribution, one form of payment to a biosimilar could be access to, and integration into, the valuable network, which it would not be able to obtain through patent litigation.

Another type of payment could involve Group Purchasing Organizations (“GPOs”) or Pharmacy Benefit Managers (“PBMs”). GPOs are collections of providers that pool resources to maximize economies of scale in drug purchasing and sometimes function as distributors, gaining control over products offered to downstream purchasers.228 PBMs also manage prescription drug pro

[FOOTNOTES BEGIN]

221. HERBERT HOVENKAMP, MARK D. JANIS, MARK A. LEMLEY, CHRISTOPHER R. LESLIE, & MICHAEL A. CARRIER, IP AND ANTITRUST: AN ANALYSIS OF ANTITRUST PRINCIPLES APPLIED TO INTELLECTUAL PROPERTY LAW § 16.01[f] (3d ed. 2016). 222. Carrier, Payment After Actavis, supra note 219, at 9. 223. Id. 224. Id. 225. Id. 226. NIAZI, supra note 21, at 354–56; see also Jack McCain, Connecting Patients with Specialty Products, BIOTECHNOLOGY HEALTHCARE, Summer 2012, at 8, https://www.ncbi.nlm.nih.gov/pmc/articles/ PMC3411231/. 227. NIAZI, supra note 21, at 354–56. 228. Id. at 352, 353.

[FOOTNOTES END]

grams for downstream buyers and, in some cases, after negotiating rebates with manufacturers, limit the drugs sold under their plans. This latter role ensures that they “are very important” to a biosimilar manufacturer in controlling access to a biosimilar product.

We envision a scenario by which a settlement could include payment in the form of a biologic bringing a biosimilar under its umbrella, granting access to certain GPO and PBM agreements to which it would otherwise not have access.

Where there is payment, the court should consider its size. The Actavis Court compared the payment’s size to litigation costs. It stated that payments that “amount to no more than a rough approximation of the litigation expenses saved through the settlement” could be justified. Litigation costs in the biologics setting will generally be higher than in the small-molecule setting. In contrast to litigation in the Hatch-Waxman setting, with a generic in the initial stage only needing to review the Orange Book, law firms must conduct substantial pre-application investigations to identify patents that could be raised in the patent dance.

Finally, where there is at-risk entry, a settlement could include a “payment” from the biologic to the biosimilar, but that payment could constitute a legitimate forgiveness of damages. This presents **a nuanced case** that could be explained by the results of patent litigation. In other words, if the biologic wins, it is entitled to recover damages from the biosimilar. But if the biosimilar wins, it will not be required to pay anything. As a result, a biologic firm’s partial waiver of damages that the biosimilar could have owed falls within the range of what the latter could have obtained through successful litigation. In short, just like it has done in the Hatch-Waxman setting, the distinction between patent and payment can provide an appropriate framework for the antitrust analysis of settlements between biologics and biosimilars.

#### NUQ and turn – A] P4D shields weak patents from scrutiny – undermines transformative innovation

Frank & Kerber 15 – School of Business and Economics, Philipps-University Marburg; Professor of Economics, School of Business and Economics, Philipps-University Marburg

Severin Frank and Wolfgang Kerber, “Patent Settlements in the Pharmaceutical Industry: What Can We Learn From Economic Analysis?” MAGKS Joint Discussion Paper Series in Economics, November 2015, <https://www.econstor.eu/bitstream/10419/129293/1/845189549.pdf>

The problem of patent settlements in the pharmaceutical industry stems from the fact that a large number of granted patents are found invalid in patent litigation, which gives patent holders large incentives to defend their weak patents through settlements with reverse payments to challenging generic firms. An important reason is that patent offices do not invest enough time and resources in patent examination (esp. in regard to "prior art") and therefore tend to grant too many patents which often would not survive a challenge in patent litigation ("weak patents"). Empirical studies show that litigated patents are found invalid in 50% (or more) of all cases (Lemley/Shapiro 2005, p. 76). This result could be interpreted as a defect of the patent system. However, Lemley (2001) argued from an economic perspective, that such a result might also be efficient, because it might not be worthwhile to make deep and costly examinations of all patent applications, because many of the granted patents turn out as not valuable (rationally ignorant patent offices). But both interpretations lead to the conclusion that it is necessary that the patent system has effective legal instruments for challenging and weeding out invalid patents. It is an open question in the patent literature, whether and to what extent the institutional design of the entire patent system (with all its rules about granting, opposing, and challenging patents in courts) leads to an efficient patent system or - as in the meantime most legal and economic scholars claim - that the existing patent systems are deeply flawed and suffer from serious problems (Shapiro 2004, pp. 1018, Hall/Harhoff 2004, pp.4). An economic perspective on this problem of weak patents has led to the development of the concept of "probabilistic" patents or “partial property rights” which has played a major role in the patent settlement discussion.13 The basic idea is simple: Whereas from a legal perspective a patent right is either valid or not, the economic value of a granted patent right before litigation depends also crucially on the expected probability of defending it in patent litigation. If this probability is, e.g., θ = 0.25, then the expected value of the patent for the patent owner is much lower than the value of a fully defendable (iron-clad) patent right. This probability θ is used for defining the strength of a patent. This "probabilistic" character of a patent has been used in the patent settlement discussion in two different ways: Since the patent strength θ reflects the winning probabilities of the settling parties in patent litigation, it influences the ranges of the settlements (in regard to agreed entry dates and/or the size of reverse payments). In the economic models but also in argumentations of legal scholars, this has led to conclusions that a 25% chance of defending a patent against a challenging generic firm would lead to a settlement on an agreed entry date without reverse payment of 25% of the remaining patent duration (e.g. Elhauge/Krüger 2012, pp. 295). However, it can also be used for the analysis of the innovation incentives that such a probabilistic patent offers (e.g. how large are the incentives for an innovation that allows for a patent with a patent strength of 25%). In their seminal paper "How Strong are Weak Patents?" Farrell/Shapiro (2008, p. 1348) assume that innovation incentives for probabilistic patents are optimal, if the proportionality principle is fulfilled, i.e. that incentives for an innovation from a probabilistic patent are proportional to its patent strength, i.e. that the rents from a patent with θ = 0.5 should be half of the rents of an iron-clad patent (θ = 1) and twice the rents for a patent with θ = 0.25. Farrell/Shapiro (2008) have suggested that profits from weak patents might be relatively too large in comparison to stronger patents, leading to a distortion of innovation incentives in favour of "innovations" that only with a small probability are true innovations that should be rewarded by patent protection (see below section 5). It is well known that the challenging of potentially invalid patents can suffer from serious incentive problems. Since all patent systems rely on private litigation for challenging patents, the private incentives for challenging patents suffer from a public good problem, because the costs and risks of patent litigation is borne by the challenging firm, whereas the benefits of having eliminated an invalid patent right accrues to everybody. This externality of challenging patents cannot only lead to too small incentives for challenging firms, but also implies that patent settlements between originator and generic firms can have negative (external) effects on third parties, because the settlement helps to maintain an unjustified exclusive right. Due to these third-party effects, the usual normative notion that private parties should be free how to settle their conflicts in private litigation is problematic in the case of patent litigation. Therefore rules for critically scrutinizing and limiting the scope of patent settlements are justified also from an economic perspective. However, this is not only a problem of patent settlements. Shapiro (2003) showed that patent owners can achieve the same result of defending their weak patents also through licensing agreements (with too low license fees), mergers, and patent pools leading him to the conclusion that all of these transactions should be put under antitrust scrutiny.

**Omicron thumps the M&A market**

**Burnett 21** – Legal Analyst for Bloomberg Law

Grace Maral Burnett, "ANALYSIS: Could Omicron Bring More M&A Deal Terminations?," Bloomberg Law, 11-29-2021, https://news.bloomberglaw.com/health-law-and-business/analysis-could-omicron-bring-more-m-a-deal-terminations

This year we have seen terminations in a total of 252 mergers and acquisitions deals. This year-to-date termination count falls well below 2020’s total of 321 for the same category of transactions. Could the omicron variant of the Covid-19 virus, which the World Health Organization just designated as a variant of concern on Nov. 26, potentially shift the trend toward more deal terminations?

Post-Designation Spike?

Given what we’ve seen in response to the declaration of the pandemic in March 2020 and the WHO’s designation of the delta variant as a variant of concern (VOC) in May 2021, it seems conceivable that in the next few months we could see somewhat elevated termination counts. The highest monthly total of terminations since the beginning of last year occurred in May 2020, the second month following the declaration of the pandemic. (Our dataset includes deals valued at $1 million or greater for the control of the company, or for assets to be acquired, that were terminated after the parties entered into a definitive agreement.) And this year, June and July totals went up following the lowest number of terminations seen since the beginning of 2020 in May, the same month the delta variant was designated as a VOC.

[[Figure Omitted]]

It makes sense that we would see a one- or two-month lag in terminations after a major Covid-19 event: first the markets react, travel is restricted (again), business and valuation impacts ripple, then it takes some time for negotiations to fail. All this being said, as we have previously remarked, the M&A market has been resilient and has not at any point seen sky-high termination levels in response to this pandemic. In fact, as we’ve noted before, annual totals for 2020 and 2021 thus far are on par with—or lower than—the 2019 total.

Larger Deals at Risk

Although the overall termination count this year is lower than 2020’s, the dollar totals tell a different story. Nearly double the dollar volume has been associated with terminations this year, meaning, of course, that it’s the larger deals that have been terminated in 2021. The aggregate value of this year’s terminations is $321 billion, resulting in an average deal size of $1.3 billion. In 2020, $174.2 billion in deals were terminated, with an average deal size of $543 million.

Of the 252 deals terminated thus far in 2021, 122 were also announced in 2021, 102 were announced in 2020, and the remainder were announced in prior years. The average deal size for the terminated deals that were both announced and terminated in 2021 was $1.8 billion, whereas the deals announced last year but terminated this year have had an average deal size of $759 million.

### DA FTC

#### Fiat solves – new authority comes with new funding authorization

Bannan is policy counsel at New America’s Open Technology Institute, focusing on platform accountability and privacy, and Gambhir, New America's Open Technology Institute, ‘21

(Christine and Raj, “Does Data Privacy Need its Own Agency?” <https://d1y8sb8igg2f8e.cloudfront.net/documents/Does_Data_Privacy_Need_its_Own_Agency.pdf>)

Proposals delegating privacy law enforcement to the FTC generally bolster an existing bureau or establish a new bureau within the agency. Senator Wyden’s Mind Your Own Business Act of 2019 would create a new 50-person Bureau of Technology within the FTC and add 125 employees to the Bureau of Consumer Protection—100 of whom would do privacy enforcement work.102 This would bring the total number of FTC employees doing privacy enforcement work up to about 190. While the Wyden bill does not provide figures for how much adding 175 new employees would cost, former FTC Chairman Joseph Simons estimated that a $50 million budget increase from Congress would enable the FTC to hire 160 new staff.103 Under this proposal, the number of employees working on privacy would more than triple. However, it would still only be about one-tenth the size of the Eshoo-Lofgren DPA proposal.

#### Non-unique and turn – A] FTC is already taking an aggressive approach in HC

Cornell 9/16 – Head of the U.S. antitrust practice at global antitrust powerhouse Clifford Chance LLP

Tim Cornell, 20 years of antitrust experience, has advocated on behalf of dozens of clients before the US Federal Trade Commission, the US Department of Justice, and the federal courts, with Robert Houck, Peter Mucchetti, and Brian Yin, Antitrust Litigation 2021, Last Updated September 16, 2021, <https://practiceguides.chambers.com/practice-guides/antitrust-litigation-2021/usa/trends-and-developments>

After an eventful year of antitrust litigation related to healthcare in 2020, all indications are that 2021 will be just as action-packed.

In October 2020, subscriber plaintiffs and defendants in the Blue Cross Blue Shield (BCBS) multi-district litigation (MDL) in Alabama reached a preliminary agreement on a USD 2.67 billion settlement fund, along with sweeping reforms aimed at restoring competition in the healthcare insurance industry. The litigation is an amalgamation of claims going back to 2012 accusing dozens of local insurers (so-called "Blues") of using restrictive practices to suppress competition.

Then in January 2021, President Trump signed the Competitive Health Insurance Reform Act, eliminating certain antitrust exemptions health insurers had previously enjoyed under the McCarran Ferguson Act. While these exemptions were limited, commentators have suggested that the availability of the defense may have had a chilling effect on antitrust litigation in healthcare. The plaintiffs' success in the BCBS cases and the elimination of these antitrust protections for health insurers may result in more antitrust cases against health insurers in the next few years.

Meanwhile, the multitude of suits in the long-running generic drug price fixing matters has continued to progress. In July 2020, the federal judge overseeing the multidistrict litigation initially selected the complaint filed by a coalition of 44 state attorneys general against Teva to act as a "bellwether" case (a procedure whereby a representative action among many lawsuits proceeds first to trial to help shape subsequent litigation). But in August 2020, a grand jury indicted Teva on criminal price-fixing charges, as part of the DOJ's ongoing antitrust investigation of the generic drug industry. Concerned for the complications the civil and criminal matters could pose to one another, the court vacated its bellwether selection. In May 2021, the judge instead chose the states' complaint asserting a price fixing conspiracy affecting various dermatology treatments and other drugs. Meanwhile, the DOJ has continued to pursue its own generic drugs investigations, having criminally charged at least seven companies and a number of executives, while indicating that more indictments are expected.

The FTC also has continued to make healthcare a priority for antitrust enforcement. In the Spring of 2020, the FTC announced that it would increase resources it put towards the review of previously consummated healthcare deals, sending requests for information to a number of health insurers that had recently merged. Around the same time, the FTC initiated a challenge of Jefferson Health's proposed acquisition of Albert Einstein Healthcare Network in Philadelphia. In a rare defeat for the agency, a federal court rejected the challenge in December 2020. Seemingly undeterred, however, the FTC has continued to challenge hospital mergers, including in Memphis [In re: Methodist Le Bonheur Healthcare and Tenet Healthcare Corporation, FTC No. 9396] and New Jersey [In re: Hackensack Meridian Health, Inc. and Englewood Healthcare Foundation, FTC No. 9399].

In his 9 July 2021 Executive Order, President Biden continued his administration's focus on antitrust and healthcare issues. The order directs federal agencies to seek solutions to address anticompetitive conditions affecting the US economy, including the high cost of prescription medication and healthcare services, increasing hospital consolidation, and other areas related to healthcare.

#### B] Plan reverses current tradeoffs

Feldman 8/27 – Distinguished Professor of Law Chair & Director of the Center for Innovation, UC Hastings Law

Robin Feldman, Arthur J. Goldberg Distinguished Professor of Law, Albert Abramson ’54 Distinguished Professor of Law Chair, and Director of the Center for Innovation, The Price Tag of 'Pay-for-Delay', UC Hastings Research Paper Forthcoming, 27 Aug 2021, <https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3846484>

Given that agreements between competitors are disfavored, the test for agreements between brands and generics in the context of Hatch-Waxman litigation should begin with a presumption that the agreement is anticompetitive. This approach respects the essential design of the Hatch-Waxman system to ensure rapid entry of generic drugs, in part, by providing an incentive for generic drug companies to challenge patents that are invalid or invalidly applied.182 Only when the public interest is clearly served should the presumption fall.

A presumption offers a variety of advantages to the judiciary and regulatory systems. It would ease the burdens on regulators such as the FTC, which tend to lack the resources needed to scrutinize and, if necessary, litigate each of the dozens of brand-generic settlements that occur annually. 183 [FN 183] 183 See Feldman & Misra, Fatal Attraction, supra note 8, at 260–261 (noting that, although all brand-generic agreements under the Hatch-Waxman Act must be filed with the FTC, the agency’s delays in publishing pay-for-delay reports, and the reports’ relative lack of specificity, suggests limited resources to address the problem of pay-for-delay). [End FN] In addition, by shifting the burden to the companies themselves, a presumption avoids rewarding those who concoct increasingly elaborate schemes. The company would have to establish how a complex and convoluted scheme works and why it is procompetitive.

#### Enforcement of <<their thing>> fails – new rulemaking agenda overstretches the agency

Wilson, FTC Commissioner, ‘12/10/21

(Christine S., Dissenting Statement of Commissioner Christine S. Wilson

Annual Regulatory Plan and Semi-Annual Regulatory Agenda, <https://www.ftc.gov/system/files/documents/public_statements/1598839/annual_regulatory_plan_and_semi-annual_regulatory_agenda_wilson_final.pdf>)

The context in which the Commission announces this ambitious and resource-intensive rulemaking agenda gives independent cause for concern. The “surge in merger filings” has been a central focus of Chair Khan since her arrival at the agency.2 To address the uptick in merger filings, staff from many non-merger divisions throughout the agency have been commandeered to review pre-merger notification materials.3 These filings are subject to statutory timeframes, but the FTC has struggled to meet its timing obligations.4 Consequently, the FTC’s Bureau of Competition is now sending warning letters to merging parties whose statutory timeframes have expired, warning that the agency’s investigations continue and threatening that if they proceed to consummate their transactions, they do so at their own peril.5 It is puzzling that we would unleash an avalanche of rulemakings while also confronting a tsunami of merger filings.

Merger wave or no merger wave, my Democrat colleagues have long aspired to a more expansive rulemaking agenda for the agency.6 This year, they began taking steps to implement that goal. Acting Chairwoman Slaughter created a new rulemaking group within the FTC’s Office of General Counsel to “help build [the] Commission’s rulemaking capacity and agenda for unfair or deceptive practices and unfair methods of competition.”7 She also launched a review of the Commission’s Rules of Practice to “streamline” rulemaking procedures under Section 18 of the FTC Act.8 Chair Khan then ushered those changes across the finish line.9 While the Annual Regulatory Plan and Semi-Regulatory Agenda characterize those changes to our Rules of Practice as “eliminating extra bureaucratic steps and unnecessary formalities,” in reality those changes fast-track regulation at the expense of public input, objectivity, and a full evidentiary record.10 The Statement of the Commission issued in conjunction with those rule changes confirmed a desire for an ambitious rulemaking agenda,11 which predictably is reflected in this plan.

The regulatory plan identifies many rulemakings that will be launched in the coming months, including a trade regulation rule on commercial surveillance “to curb lax security practices, limit privacy abuses, and ensure that algorithmic decision making does not result in unlawful discrimination.”12 This rule may implicate competition as well as consumer protection issues, as the Statement of Regulatory Priorities notes that “surveillance-based business models” impact not just consumers but competition.13

And taking a big step into uncharted waters, the plan states that “the Commission will also explore whether rules defining certain ‘unfair methods of competition’ prohibited by Section 5 of the FTC Act would promote competition and provide greater clarity to the market.”14 In deference to President Biden’s recent Executive Order,15 the Commission may consider competition rulemakings relating to “non-compete clauses, surveillance, the right to repair, payfor-delay pharmaceutical agreements, unfair competition in online marketplaces, occupational licensing, real-estate listing and brokerage, and industry-specific practices that substantially inhibit competition.”16 As if this list is insufficiently lengthy, the plan observes that “[t]he Commission will explore the benefits and costs of these and other competition rulemaking ideas.”17 In the absence of further detail, the reader is left to daydream about the additional rulemaking adventures that await.

## 1AR

### Prices

#### Non-unique – Court extended antitrust scrutiny to small molecule drugs already

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Morgan, February 2021, “Molecule Size Doesn’t Matter: The Case for Harmonizing Antitrust Treatment of Pay-for-Delay Agreements,” Columbia Journal of Law and Social Problems, http://blogs2.law.columbia.edu/jlsp/wp-content/uploads/sites/8/2021/02/Volume-54-Marmaro.pdf

More specifically, this Note will discuss reverse payments, also known as “pay-for-delay” agreements, that occur when a branded drug manufacturer pays a rival drug company to delay its launch of a drug that will compete with the brand.8

These reverse payment agreements are executed in the context of settling patent infringement litigation in which the patent-holding brand company pays its rivals to agree not to compete for a period of time when the rival otherwise likely would have entered the market.9

“Payment” takes a variety of forms but is typically a share of the extra monopoly profits that the brand expects to secure from the delayed competition — an amount that may exceed the rival’s expected profits from competing on the market.11 These “pay-for-delay” agreements are known as “reverse payments” because of the inverted direction of compensation where a plaintiff, the brand-name patent holder who commenced the infringement suit, pays an amount to the defendant, the rival accused of allegedly infringing the brand’s patents, to settle the suit it commenced.12

It was not until 2013 that the U.S. Supreme Court addressed the legality and antitrust consequences of these agreements in FTC v. Actavis.

The Court held that these pay-for-delay agreements could have anticompetitive effects and were not shielded by patent law from antitrust scrutiny or justified by public policy favoring settlements.14 Furthermore, **it held the judicial standard of review for reverse payment agreements under federal antitrust law was the rule of reason**.15

It rejected the Federal Trade Commission’s (FTC) argument that these settlements should be presumptively illegal or per se illegal because the Court could not conclude that these agreements would almost always be anticompetitive, noting that some might be justified for procompetitive reasons.16

Since Actavis, the FTC has found the number of patent settlement agreements that on their face show pay-for-delay is decreasing, i.e., explicit cash settlement payments, but that the number of settlements with restrictions on generic entry that include other alleged forms of compensation have more than doubled from 2015 to 2016.17

#### Prices are too high to attribute to R&D needs

Lexchin 20 – MSc, MD

Joel Lexchin, Md1,2, 1-17-2020, "Affordable Biologics for All," JAMA Network, Original Investigation Out-of-Pocket Spending for Rheumatoid Arthritis Biologics in Medicare Part D Alexandra Erath, BA; Stacie B. Dusetzina, PhD, https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2764808

Although biologics only account for 2% of all prescriptions written in the US, they are responsible for $120 billion or 37% of net drug spending and, since 2014, for 93% of the overall growth in total spending.3 None of the usual explanations for the price of biologics stand up to scrutiny. Research and development costs for biologics are higher than those for small molecule drugs ($391 million vs $309 million) but not enough to account for their prices. Furthermore, there is no difference in the median premarket development time between biologics and small molecule drugs that would justify the 12 years of data exclusivity that the former group received in 2010. Interviews with 4 leaders in biologics development revealed that, contrary to frequent claims, development costs were not the reason for the prices of the multiple sclerosis drugs. Instead, initial price decisions were based on the price of existing competitors and revenue maximization and corporate growth were the reasons for price escalations.4

Use of biosimilars, which have a similar role for biologics as generics do for small molecule drugs, could be associated with lower spending, but by the end of 2019, only 11 of the 26 biosimilars that were approved by the US Food and Drug Administration were actually marketed, and even when biosimilars are available, market penetration is often very poor. This situation is in contrast to the one in Europe, where by May 2018, 39 biosimilars had been launched; in some countries, biosimilars have completely captured a particular market.

One reason why biosimilars have not been successful in the US even after they have been marketed has been the message from drug companies, medical societies, and patient groups—with the latter 2 often having connections to companies—that it is potentially dangerous to switch patients from a reference biologic to a biosimilar. This message continues to have resonance despite a systematic review5 concluding that that this type of switching is not associated with increased risk of immunogenicity-related safety concerns or with diminished efficacy. A second reason for the low uptake may be the increasing trend for companies marketing reference biologics to employ nurse educators or ambassadors to assist patients in using complicated medications and helping them to resolve drug-related problems and with insurance paperwork. If physicians were to switch their patients to a biosimilar, that assistance would not be available.

Calls for lower prices for biologics (and other drugs) are typically met with the concern that innovation will suffer. However, only a small minority of new biologics represent significant therapeutic advances over existing products.6 Moreover, for over a decade, drug companies listed on the S&P 500 Index collectively have spent more of their revenue on dividends and share buybacks than they have on research and development.7 In 2015, of the top 100 pharmaceutical companies by sales, 64 spent twice as much on marketing and sales than on research and development, 58 spent 3 times as much, 43 spent 5 times as much, and 27 spent 10 times as much.

### K Neolib

#### U.S. is dematerializing resource usage – market forces incentivize a switch away from resource-intensive practices

-air pollution

-GHGs

-ag

-nitrogen, potassium, phosphorus

-wood

-metal

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Andrew McAfee, “Why Degrowth Is the Worst Idea on the Planet,” *Wired*, 6 October 2020, https://www.wired.com/story/opinion-why-degrowth-is-the-worst-idea-on-the-planet/.

Easing Pollution, Not Exporting It

In some important areas, however, a very different pattern emerged after 1970: Growth continued, but environmental harm decreased. This decoupling occurred first with pollution, and first in the rich world. In the US, for example, aggregate levels of six common air pollutants have declined by 77 percent, even as gross domestic product increased by 285 percent and population by 60 percent. In the UK, annual tonnage of particulate emissions dropped by more than 75 percent between 1970 and 2016, and of the main polluting chemicals by about 85 percent. Similar gains are common across the highest-income countries.

How were these reductions achieved? The two possibilities are cleanup and offshoring. Either rich countries figured out how to reduce their “air pollution per dollar” so much that overall pollution went down even as their economies grew, or they sent so much of their dirty production overseas that the air at home got cleaner. The first of these paths reduces the total burden of human-caused pollution; the second just rearranges it.

The evidence is overwhelming that rich countries cleaned up their air pollution much more than they outsourced it. For one, a great deal of air pollution comes from highway vehicles and power plants, and rich countries haven’t outsourced driving and generating electricity to low-income ones. In fact, high-income countries haven't even offshored most of their industry. The US and UK both manufacture more than they did 50 years ago (at least until the Covid-19 pandemic sharply reduced output), and Germany has been a net exporter since 2000 while continuing to drive down air pollution. The rest of the world has been exporting its manufacturing pollution to Germany (to use degrowthers’ phrasing), yet Germans are breathing cleaner air than they were 20 years ago.

Rich countries have reduced their air pollution not by embracing degrowth or offshoring, but instead by enacting and enforcing smart regulation. As economists Joseph Shapiro and Reed Walker concluded in a 2018 study about the US, “changes in environmental regulation, rather than changes in productivity and trade, account for most of the emissions reductions.” Research about the cleanup of US waters also concludes that well-designed and enforced regulations have successfully reduced pollution.

It is true that the US and other rich countries now import lots of products from China and other nations with higher pollution levels. But if there were no international trade at all, and rich countries had to rely exclusively on their domestic industries to make everything they consume, they’d still have much cleaner air and water than they did 50 years ago. As a 2004 Advances in Economic Analysis and Policy study summarized: “We find no evidence that domestic production of pollution-intensive goods in the US is being replaced by imports from overseas.”

The rich world’s success at decoupling growth from pollution is an inconvenient fact for degrowthers. Even more inconvenient is China's recent success at doing the same. China’s export-led, manufacturing-heavy economy has been growing at meteoric rates, but between 2013 and 2017 air pollution in densely populated areas declined by more than 30 percent. Here again the government mandated and monitored pollution declines and so decoupled growth from an important category of environmental harm.

Prosperity Bends the Curve

China's progress with air pollution is heartening, but it's not surprising to most economists. It's a clear example of the environmental Kuznets curve (EKC) in action. Named for the economist Simon Kuznets, EKC posits a relationship between a country's affluence and the condition of its environment. As GDP per capita rises from an initial low level, so too does environmental damage; but as affluence continues to increase, the harms level off and then start to decline. The EKC is clearly visible in the pollution histories of today's rich countries, and it's now taking shape in China and elsewhere.

Also consider air pollution death rates around the world. As the invaluable website Our World in Data puts it, “Rates have typically fallen across high-income countries: almost everywhere in Europe, but also in Canada, the United States, Australia, New Zealand, Japan, Israel and South Korea and other countries. But rates have also fallen across upper-middle income countries too, including China and Brazil. In low and lower-middle income countries, rates have increased over this period.”

The EKC is a direct refutation of a core idea of degrowth: that environmental harms must always rise as populations and economies do. It's not surprising that today's degrowth advocates rarely discuss the large reductions in air and water pollution that have accompanied higher prosperity in so many places around the world. Instead, degrowthers now focus heavily on one kind of pollution: greenhouse gas emissions.

The claims made are familiar ones: that any apparent reductions in greenhouse gas emissions in rich countries are due to offshoring rather than actual decarbonization. Thanks to the Global Carbon Project, we can see if this is the case. GCP has calculated “consumption-based emissions” for many countries going back to 1990, taking into account imports and exports, yielding the greenhouse gas emissions embodied in all the goods and services consumed in each country each year.

For several of the world's richest countries, including Germany, Italy, France, the UK, and the US, graphs of consumption-based carbon emissions follow the familiar EKC. The US, for example, has 22reduced its total (not per capita) consumption-based CO2 emissions by more than 13 percent since 2007.

These reductions are not mainly due to enhanced regulation. Instead, they've come about because of a combination of tech progress and market forces. Solar and wind power have become much cheaper in recent years and have displaced coal for electricity generation. Natural gas, which when burned emits fewer greenhouse gases per unit of energy than does coal (even after taking methane leakage into account), has also become much cheaper and more abundant in the US as a result of the fracking revolution.

To ensure that these greenhouse gas declines continue to spread and accelerate, we should apply the lessons we've learned from previous pollution reduction success. In particular, we should make it expensive to emit carbon, then watch the emitters work hard to reduce this expense. The best way to do this is with a carbon dividend, which is a tax on carbon emissions where the revenues are not kept by the government but instead are rebated to people as a dividend. William Nordhaus won the 2018 Nobel Prize in economics in part for his work on the carbon dividend, and an open letter advocating its implementation in the US has been signed by more than 3,500 economists. It's an idea whose time has come.

How We Learned to Lighten Up

Tech progress and price pressure aren't just leading to the demise of coal. They're also causing us to exploit the planet less in many other important ways, even as growth continues. In other words, EKCs are not just about pollution any more.

A good place to start examining this broad phenomenon of getting more from less is US agriculture, where we have decades of data on both outputs—crop tonnage—and the key inputs of cropland, water, and fertilizer. Domestic crop tonnage has risen steadily over the years and in 2015 was more than 55 percent higher than in 1980. Over that same period, though, total water used for irrigation declined by 18 percent, total cropland by more than 7 percent.

That is, over that 35-year period, US crop agriculture increased its output by more than half while giving an area of land larger than Indiana back to nature and eventually using a Lake Champlain less water each year. This was not accomplished by increasing fertilizer use; total US fertilizer consumption in 2014 (the most recent year for which data are available) was within 2 percent of its 1980 level.

The three main fertilizers of nitrogen, potassium, and phosphorus (NKP) are an interesting case study. Their total US consumption (once other uses in addition to agriculture are taken into account) has declined by 23 percent since 1980, according to the United States Geological Survey. Yet some within the degrowth movement find ways to argue that these declines are also an illusion. These materials thus serve to clearly illustrate the differences in methodology, evidence, and worldview between ecomodernists like myself and degrowthers.

The USGS tracks annual domestic production, imports, and exports of NKP and uses these figures to calculate “apparent consumption” each year. Consumption of each of the three resources has declined by 16 percent or more from their peaks, which occurred no later than 1998. This seems like a clear and convincing example of dematerialization—getting more output from fewer material inputs.

As I argue in my book More From Less, dematerialization doesn’t happen for any complicated or idiosyncratic reason. It happens because resources cost money that companies would rather not spend, and tech progress keeps opening up new ways to produce more output (like crops) while spending less on material inputs (like fertilizers). Modern digital technologies are so good at helping producers get more from less that they're now allowing the US and other technologically sophisticated countries to use less in total of important materials like NKP.

Forest products provide another clear example of dematerialization in the US. Total annual domestic consumption of paper and paperboard peaked in 1999, and of timber in 2002. Both totals have since declined by more than 20 percent. Could these be mirages caused by offshoring that’s not properly captured? That’s highly unlikely, as the country is now onshoring more than it’s offshoring. The US has been a net exporter of forest products since 2009 and is now the world’s largest exporter of these materials.

Is the US economy also dematerializing its use of metals? Probably, but it’s hard to say for sure. The USGS tallies do show dematerialization in steel, aluminum, copper, and other important metals. But these figures don’t include the metals contained in imports of finished goods like cars and computers. America is a net importer of manufactured goods, so it could be that we’re using more metal year after year, but that much of this consumption is “hidden” from official statistics because of imports of heavy, complex products. However, my estimates indicate that this is extremely unlikely and that the country is in fact now reducing its overall consumption of metals.

### DA Mergers

#### It’s not a big deal

Feldman 8/27 – Distinguished Professor of Law Chair & Director of the Center for Innovation, UC Hastings Law

Robin Feldman, Arthur J. Goldberg Distinguished Professor of Law, Albert Abramson ’54 Distinguished Professor of Law Chair, and Director of the Center for Innovation, The Price Tag of 'Pay-for-Delay', UC Hastings Research Paper Forthcoming, 27 Aug 2021, <https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3846484>

One could argue that presuming anticompetitiveness in the event of a settlement between brand and generic companies would disincentivize the ability of parties to enter into good faith settlements to avoid the costs of litigation.187 Litigating parties are generally encouraged to settle their differences, sparing the legal system the time and expense of a trial. A presumption, however, can be rebutted by appropriate evidence within the purview of the companies. It is far less drastic a test than certain other types of agreements between competitors, which are illegal per se under antitrust law, such as horizontal price-fixing, bid-rigging, and market-allocation schemes.188

#### Most of them are bad, but we don’t touch the good ones

Feldman 8/27 – Distinguished Professor of Law Chair & Director of the Center for Innovation, UC Hastings Law

Robin Feldman, Arthur J. Goldberg Distinguished Professor of Law, Albert Abramson ’54 Distinguished Professor of Law Chair, and Director of the Center for Innovation, The Price Tag of 'Pay-for-Delay', UC Hastings Research Paper Forthcoming, 27 Aug 2021, <https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3846484>

Pinning pay-for-delay reform squarely on an outright ban may not prove tenable, and other commentators have proposed intriguing alternatives. By one policy, for instance, if companies are unable to prove that their patent infringement settlement value was less than the cost of litigation and other services, then all that the generic company can receive is what it would be entitled to by a court ruling that a brand patent is invalid or not infringed.179

In other words, all the brand company can promise is what the court would give the generic company if the parties proceeded with the patent infringement litigation, and the generic won. No-authorized-generic clauses, among other creative anticompetitive ploys, would be presumed illegal by this framework. At the same time, it would permit patent settlements to remain where they are potentially procompetitive, eliminating unnecessary litigation between drug companies. Other prospective solutions seek to improve upon the fines used currently to disincentivize pay-for-delay conduct. As our analysis demonstrates, even companies fined by the FTC for pay-for-delay may profit handsomely from the practice.180 Considering the failure of fines to sufficiently discourage pay-for-delay, some scholars have advanced alternative punishments for cited drug companies. For instance, a first-filing generic company that agreed to postpone production in exchange for a no-authorized-generic clause could be stripped of its 180-day exclusivity period.181 Additional legislation might stipulate that brand companies forfeit the chance to earn additional non-patent regulatory exclusivities for a drug whose monopoly period they paid off competitors to extend. This way, instead of simply reducing the profits of offending drug-makers, the repercussions of pay-for-delay redound as social benefit.

Despite potential remedy-related reforms, however, the most important change needed pertains to evaluating the anticompetitive nature of the agreement itself. The landmark decision in Actavis expressed optimism that courts would be able to manage the analysis in a more structured manner. That reality has not materialized. To resolve the problem, one should return to the basic notion that agreements between competitors are strongly disfavored under antitrust law.

Given that agreements between competitors are disfavored, the test for agreements between brands and generics in the context of Hatch-Waxman litigation should begin with a presumption that the agreement is anticompetitive. This approach respects the essential design of the Hatch-Waxman system to ensure rapid entry of generic drugs, in part, by providing an incentive for generic drug companies to challenge patents that are invalid or invalidly applied.182 Only when the public interest is clearly served should the presumption fall.