## 1

#### Biotech industry strong now – new innovation and R&D coming

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

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

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

What about SPACs?

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

Fundamentals continue strong

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

In the present day, many biotechs, along with the wider pharmaceutical industry, are taking steps to address the COVID-19 pandemic. Together, biotechs and pharma companies have [more than 250 vaccine candidates in their pipelines](https://www.mckinsey.com/industries/pharmaceuticals-and-medical-products/our-insights/on-pins-and-needles-will-covid-19-vaccines-save-the-world), along with a similar number of therapeutics. What’s more, the crisis has shone a spotlight on pharma as the public seeks to understand the roadblocks involved in delivering a vaccine at speed and the measures needed to maintain safety and efficacy standards. To that extent, the world has been living through a time of mass education in science research and development.

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

Another factor acting in the sector’s favor is that larger pharmaceutical companies still rely on biotechs as a source of innovation. With the [top dozen pharma companies](https://www.mckinsey.com/business-functions/m-and-a/our-insights/a-new-prescription-for-m-and-a-in-pharma) having more than $170 billion in excess reserves that could be available for spending on M&A, the prospects for further financing and deal making look promising.

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

More innovation on the horizon

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

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

#### Secondary patents are necessary for innovation of otherwise mediocre drugs—core to cancer and HIV treatments

**Holman 2018** (Christopher, Professor of Law, University of Missouri-Kansas City School of Law. “Why Follow-On Pharmaceutical Innovations Should Be Eligible For Patent Protection” <https://www.ip-watch.org/2018/09/21/follow-pharmaceutical-innovations-eligible-patent-protection/> September 21, 2018)DR 21

The attack on secondary pharmaceutical patents is based in part on the flawed premise that follow-on innovation is of marginal value at best, and thus less deserving of protection than the primary inventive act of identifying and validating a new drug active ingredient. In fact, follow-on innovation can play a critical role in transforming an interesting drug candidate into a safe and effective treatment option for patients. A good example can be seen in the case of AZT (zidovudine), a drug ironically described in the Guidelines as the “first breakthrough in AIDS therapy.” AZT began its life as a failed attempt at a cancer drug, and it was **only years later that its potential application in the fight against AIDS was realized**. Follow-on research resulted in **a method-of-use patent** directed towards the use of AZT in the treatment of AIDS, and it was this patent that incentivized the investment necessary to bridge the gap between a promising drug candidate and a safe, effective, and FDA-approved pharmaceutical. Significantly, because of the long lag time between the first public disclosure of AZT and the discovery of its use in the treatment of AIDS, patent protection for the molecule per se was unavailable. In a world where follow-on innovation is unpatentable, there would have been no patent incentive to invest in the development of the drug, and without that incentive AZT might have languished on the shelf as simply one more failed drug candidate.

Other examples of important drugs that likely never would have been made available to patients without the availability of a “secondary” patent include Evista (raloxifene, **used in the treatment of** osteoporosis and to reduce the risk of invasive breast cancer), Zyprexa (olanzapine, used in the treatment of schizophrenia), and an orally-administrable formulation of the antibiotic cefuroxime.

Pharmaceutical development is prolonged and unpredictable, and frequently a safe and effective drug occurs only as a result of follow-on innovation occurring long after the initial synthesis and characterization of a pharmaceutically interesting chemical compound. The inventions protected by secondary patents can be just as critical to the development of drugs as a patent on **the active ingredient itself.**

#### One and done model kills innovation—chilling effect

**Magiera 2021** (Melissa S., J.D. Candidate, 2021, Indiana UniversityRobert H. McKinney School of Law; B.S. 2017, Indiana University Purdue University Indianapolis – Indianapolis, Indiana. Recipient of the Papke Prize for Best Note in Volume 54, endowed by and named in honor of David R. Papke, former R. Bruce Townsend Professor of Law and faculty advisor to the Indiana Law Review “Leaving the Evergreening Problem to the Patent Experts--The USPTO, the PTAB, and the Federal Circuit” Indiana Law Review, 54(1), 195-220.)DR 21

Additionally, the pharmaceutical industry spends millions of dollars in researching new uses or safer ways to administer known drugs.94 A new use or method of administering or making a known drug should be rewarded with a patent; if not, many pharmaceutical companies will treat the discovered drugs as “one-and-dones.” 95 Patents are meant to be issued for innovations, not for products.96 Just because a patent is granted on a medicine does not mean that the innovation relating to the drug ends; in fact, many pharmaceutical companies continue to research “new ways to make the medicine, new populations who can benefit from its use, better ways to get it to and into patients, and new versions that expand options for patents.” 97 The effect of this legislation, if enacted, likely would be to focus on lowering the price of medicine for patients at the cost of denying rightful patents to pharmaceutical companies that could have made new medical advances for the good of society. 98 Any pharmaceutical company would be scrutinized for any additional innovation of a drug and may be subject to penalties.99 Eventually, this means that the pharmaceutical companies could halt further research on any patented drug, even if there is a better, undiscovered use for that drug. 100 If enacted, the legislation could also “erode[] incentives and threaten[] innovation,” which is what the patent system was created to protect. 101

#### Big pharma relies on evergreening as a major source of profit—empirics prove.

Chandler 15

Dr. Kelley Chandler, J.D. (B.S., Villanova University, 2015; J.D., Cornell Law School, 2020; Executive Editor, Cornell Journal of Law and Public Policy, Vol. 29); “PATENTS AND THE PHARMACEUTICAL INDUSTRY: CURBING THE ABUSIVE PRACTICES EMPLOYED BY BLOCKBUSTER DRUG COMPANIES TO PROLONG MARKET EXCLUSIVITY”; CORNELL JOURNAL OF LAW AND PUBLIC POLICY [Vol. 29:467]; 2015; <https://ww3.lawschool.cornell.edu/research/JLPP/upload/Chandler-note-final.pdf>; EMJ

1. Evergreening The practice of evergreening is described as “obtaining multiple patents that cover different aspects of the same product,” which has the effect of extending the patent term of the drug in question.83 Evergreening may take the form of acquiring additional patents on the active ingredients, methods of manufacturing, formulations, or chemical intermediates of a drug, to name a few.84 When a company first files a patent application on the active ingredient, its patent will be set to expire 20 years from the filing date.85 However, if the company files an application for a secondary patent five years later based upon a secondary feature of the drug, such as an improved method of manufacturing, the approval of the secondary patent will prevent a generic company from using that method until the secondary patent expires.86 The practical effect of this strategy is that a generic company seeking to enter the market will not be able to use the method of manufacture until the end of the second patent term, five years after the original patent term has expired.87 Although a generic company is free to produce and sell the active ingredient once the patent on that ingredient expires, development of a generic drug is often difficult and costly without the ability to employ certain manufacturing methods.88 In this way, brand companies build a “patent portfolio” around single drugs as a creative way to avoid surrendering market exclusivity due to primary patent expiration.89 Studies show that evergreening has increased significantly since Hatch-Waxman passed.90 Features of a drug which are covered by a secondary patent are considered “peripheral”91 and include things such as tablet coating or products produced from drug ingestion, dosages, or delivery routes.92 For example, the patent application for the active ingredient of the drug Paxil, which is used to treat depression, was filed on December 17, 1974.93 Of the several peripheral patent applications that were filed, the most recent patent was filed in 1998.94 If a generic had not succeeded in Paragraph IV litigation in 2003, this would have given Paxil an additional sixteen years of patent term exclusivity beyond the initial 20 years.95 Even given the generic challenger’s success, Paxil’s developers still enjoyed years of exclusivity beyond the original patent term due to their peripheral patents.96 Similarly, peripheral patents on internal coatings for the heartburn drug, Prilosec, afforded the manufacturer extra market exclusivity.97 Through strategically staggering patent applications on active drug ingredients and incremental drug improvements, a brand company can very “effectively extend the aggregate period of patent protection that applies to that product”98 even where the patent is later invalidated.99 Another consequence of the Hatch-Waxman Act on evergreening practice was that brand companies were being granted multiple 30-month stays on generic approval by the FDA.100 Before the generic’s approval, brands could acquire secondary patents and list them in the Orange Book, triggering an obligation for the generic to certify a challenge to the new patent and notify the brand of their intent to continue to market.101 Because this notification provided the brand company with the right to initiate a lawsuit, companies could plan their patent applications strategically in order to be able to file multiple lawsuits so as to trigger a new 30-month stay months after the existing 30-month stay began to run, giving the brand extra exclusivity through precluding generic approval at the FDA.102 Congress addressed this issue in 2003 through an amendment to the Hatch-Waxman Act, known as the Medicare Modernization Act, which prohibits multiple 30-month stays.103 Despite this change, evergreening remains a significant issue in the pharmaceutical space because secondary patents “remain enforceable proprietary rights against generic firms”104 which “increase the infringement minefield that generics must navigate when bringing a product to market.”105 The costs to society are rising drug prices and reduced access to necessary treatments.106 2. Product Hopping A related strategy within the evergreening category is the practice of product hopping, which denotes the brand-company practice of making an incremental change to a blockbuster drug which will soon be facing patent expiry, “secur[ing] patents on that new formulation, and then discontinu[ing]” the first drug.107 This takes place before any generics are on the market, and is usually combined with an aggressive marketing scheme in order to promote the new drug to consumers and physicians.108 Once the new drug has permeated the market, people are less likely to switch again, even if a generic alternative becomes available.109 Further, as Arti Rai and Barak Richman noted in their May 2018 article, because the new drug is not “therapeutically equivalent” to the old formation, State-level drug substitution laws that allow pharmacists to substitute generic drugs prevent substitution of the generic version of Drug 1 for Drug 2 prescriptions. In short, patients . . . pay monopoly prices for a branded Drug 2 because there is no generic alternative, and the market for Drug 1 evaporates just as a generic becomes available.110 Prilosec is a potent example of product hopping because the manufacturer successfully introduced an ostensibly new and improved version of Prilosec, widely known as “Nexium,” and influenced the market to “hop” before the patent expired on Prilosec.111 Although Prilosec was not completely withdrawn from the market, the manufacturer switched it from the prescription market to the over-the-counter market, and pharmacists were not able to substitute generic Prilosec for prescription Nexium due to the fact that they were technically different.112 While it is true that patients sometimes have the option to purchase the cheaper drug or the over-the-counter version when it remains on the market, the fact that pharmaceuticals represent a “unique market with noticeable information asymmetry” makes this much less likely.113 Additionally, because doctors are not actually purchasing the drugs, cost considerations are often overlooked when they are writing prescriptions, and they may have other incentives that factor into their decisions.114 3. The New Business Model Given the stakes, it is no surprise that brand pharmaceutical companies are increasingly turning to evergreening strategies to gobble up more market exclusivity for their blockbuster drugs.115 In the year 2000 alone, Prilosec’s manufacturer, AstraZeneca, reported that the drug brought in $6.3 billion,116 which is a substantial percentage of their overall revenue of $15.8 billion during that year.117 Due to the sheer amount of revenue that brand-pharmaceutical companies stand to gain or lose, it is reasonable to conclude that there is a new business model that pervades the pharmaceutical market.118 This model consists largely of evergreening and product hopping practices “turning out scores of minor variations, some of which become market blockbusters”119 which then “generate steady profits throughout the ups and downs of blockbusters coming off patents.”120 Notwithstanding that one of the goals of Hatch-Waxman was to spur brand companies to truly innovate and pioneer NCEs, only a miniscule percentage of brand company expenditures go towards researching new molecules.121 However, it would seem that the Hatch-Waxman Act lead to a pharmaceutical market which now “depend[s] less on the breakthrough research that executives emphasize than on rational actors exploiting ever broader and longer patents and other government protections against normal free market competition.”122 Contrary to Congressional intent, evergreeing and product hopping issues have only been exacerbated in the post-Hatch-Waxman atmosphere.123 It seems more and more that “when patent law realities are combined with…rational business decisions, all considerations point towards a focus on incremental drugs.”124 Hence, the new business model.125

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

Marjanovic and Feijao 20 [(Sonja Marjanovic, Ph.D., Judge Business School, University of Cambridge. Carolina Feijao, Ph.D. in biochemistry, University of Cambridge; M.Sc. in quantitative biology, Imperial College London; B.Sc. in biology, University of Lisbon.) "How to Best Enable Pharma Innovation Beyond the COVID-19 Crisis," RAND Corporation, 05-2020, https://www.rand.org/pubs/perspectives/PEA407-1.html] TDI

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

#### COVID incentivizes engineered bioterror- extinction

Walsh, 20 -- Axios Future correspondent [Bryan Walsh, "The coronavirus pandemic reawakens bioweapon fears," Axios, 5-14-2020, https://www.axios.com/coronavirus-pandemic-pathogen-bioweapon-45417c86-52aa-41b1-8a99-44a6e597d3a8.html, accessed 9-7-2020]

The coronavirus pandemic reawakens bioweapon fears

The immense human and economic toll of the COVID-19 pandemic only underscores the threat posed by pathogens that could be deliberately engineered and released.

Why it matters: New technology like gene editing and DNA synthesis has made the creation of more virulent pathogens easier. Yet security and regulation efforts haven't kept pace with the science.

What's happening: Despite some claims by the White House, overwhelming scientific evidence indicates that the novel coronavirus was not accidentally released from a lab or deliberately engineered, but naturally spilled over from an animal source.

That doesn't mean the threat from bioweapons isn't dire. Along with AI, engineered pandemics are widely considered the biggest existential risk facing humanity.

That's in part because a pathogen could be engineered in a lab for maximum contagiousness and virulence, well beyond what would arise through natural selection.

Case in point: a 2018 pandemic simulation put on by the Johns Hopkins Center for Health Security featured a fictional engineered virus called Clade X that combined the contagiousness of the common cold with the virulence of the real-life Nipah virus, which has a mortality rate of 40-75%. The resulting simulated global outbreak killed 150 million people.

COVID-19 isn't anywhere near that fatal, but the pandemic has shown the vulnerability of the U.S. and the world to biological threats both natural and manmade.

"Potential adversaries are of course seeing the same things we’re seeing," says Richard Pilch of the Middlebury Institute of International Studies. "Anyone looking for a radical leveling approach — whether a state actor like North Korea or a motivated terrorist organization — may be influenced by COVID-19 to consider pursuing a biological weapons capability."

Background: Bioweapons were officially banned by the Biological Weapons Convention in 1975, though North Korea is suspected of maintaining an offensive bioweapons program.

A particular concern about biowarfare and bioterror, though, is that many of the tools and methods that could be used to create a weaponized virus are largely indistinguishable from those used in the course of legitimate scientific research. This makes biotechnology "dual-use" — and that much more difficult to safely regulate without cutting off research that could be vitally important.

While earlier bioweapons fears focused on the possibility that a state or terror group could try to weaponize a known dangerous agent like smallpox — which would require somehow obtaining restricted pathogens — new technology means that someone could obtain the genetic sequence of a germ online and synthesize it in the lab.

"If you've been trained in a relevant technical discipline, that means you can make almost any potentially harmful agent that you're aware of," says Kevin Esvelt, a biologist at the MIT Media Lab and a member of the CDC's Biological Agent Containment Working Group. That would include the novel coronavirus that causes COVID-19, which was recently synthesized from its genetic sequence in a study published in Nature.

How it works: Currently, synthetic DNA is ordered through commercial suppliers. But while most suppliers screen DNA orders for the sequences of dangerous pathogens, they're not required to — and not all do, which means safety efforts are "incomplete, inaccurate, and insecure," says Esvelt.

Screening efforts that look for the genetic sequences of known pathogens also wouldn't necessarily be able to detect when synthetic DNA was being used to make something entirely novel and dangerous.

In the near future, desktop DNA synthesizers may be able to generate synthetic DNA in the lab, cutting out the need for commercial suppliers — and potential security screenings.

The democratization of biotechnology could unleash a wave of creativity and innovation, just as the democratization of personal computing did. But it also increases the number of people who could potentially make a dangerous engineered virus, whether deliberately or by accident.

## 2

#### Counterplan text: The member nations of the World Trade Organization ought to require stricter patentability standards for follow on patents by the drug’s originator.

#### Solves evergreening, but also leaves room for genuine innovation.

Christie et. al 21, A.F., Dent, C.H.R.I.S. and Studdert, D.M., 2021. Evidence of 'Evergreening' in secondary patenting of blockbuster drugs. *Melbourne University Law Review*, *44*(2), pp.537-564. //sid

It is reassuring that **the majority of follow-on innovation** associated with blockbuster drugs **is undertaken by entities other than the drug’s originator, and occurs both before and after expiry of the patent** over the drug’s API and the expiry of associated secondary patents held by the originator of the API. Th**is shows that patents** — both primary and secondary — **which are owned by the originators of blockbuster drugs do not give them a monopoly over further innovation in relation to the drug**. Thus, it appears that **policymakers do not need to be concerned that drug originators’ secondary patents stifle welfare-enhancing innovation by others**. The fact that **most of the follow-on innovation by others occurs after the granting of regulatory approval to market** the drug provides policymakers with a potentially valuable lever**.** It seems likely that any regulatory reforms which expedite the granting of drug approval will also expedite the commencement — and thus potentially increase the amount — of follow-on innovation that is undertaken by third parties. **Since such follow-on innovation is generally regarded as socially desirable, policymakers should seek to identify mechanisms that speed up the assessment of drug approval without compromising the effectiveness of that assessment**. Although the majority of blockbuster drug follow-on innovation is undertaken by third parties, a substantial amount (27%) is undertaken by the originator of the drug — resulting in an average of 13 secondary patents per drug. These secondary patents have greater private value than those held by others, and their typology is consistent with the theorised evergreening behaviour of drug originators. Considered together with our earlier study’s findings, these findings provide support for the view that secondary patenting by drug originators can have adverse welfare effects through extending the originator’s marketplace exclusivity over the drug. Policymakers must be alert to this possibility, and need to consider how to reduce its likelihood. We consider that those responsible for implementing, reviewing, validating and correcting patent examination practices — patent offices and, ultimately, courts — should ensure that the patentability requirements, especially those of inventive step (non-obviousness) and industrial application (utility), are applied rigorously to the types of follow-on innovation with the greatest potential to have an evergreening effect — namely, delivery mechanisms for, and formulations of, APIs.

## 3

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

Over the last decade or so, a powerful set of critiques has emerged to contest the dominant account just sketched out as well as the contemporary state of IP law.12 These arguments have come from many directions, some even arising from scholars who previously were champions of the dominant account.13 The most prominent and potent line of theoretical critique in the legal literature has come in the guise of arguments for free culture and the “information commons” and has been most influentially articulated by Lawrence Lessig and Yochai Benkler.14 Both have stressed the problems with expansive exclusive rights regimes in information and have also sketched a set of actually existing alternatives to market-based exclusionary forms of information and cultural production.

Lessig has written a series of influential books that have made him a “rock star of the information age,”15 particularly for young Internet and free-culture activists. He has argued powerfully, for example, that existing copyright law is in deep conflict with the radical new possibilities for creativity in the digital age. As he points out, when a mother posting a video of her toddler dancing to a Prince song on YouTube is threatened with a $150,000 fine for copyright infringement, something has gone seriously awry.16 Lessig also contends that copyright law today is too long, too expansive, and instantiates a “permission culture” that is antithetical to free expression in the age of the remix.17 As he puts it, “the Internet has unleashed an extraordinary possibility for many to participate in the process of building and cultivating a culture that reaches far beyond local boundaries,” creating the possibility of markets that “include a much wider and more diverse range of creators,” if not stifled by incumbents who use IP law to “protect themselves against this competition.”18

Benkler’s work has also been extraordinarily formative in the field, particularly for his insights into the multiplicity of modes of information production. As he has stressed, the conventional justification for IP does not account for the many successful and longstanding modes of market nonexclusionary information production.19 For example, attorneys write articles to attract clients, software developers sell services customizing free and opensource software for individual clients, and bands give music away for free to increase revenues from touring or merchandise.20 More pathbreaking still is Benkler’s account of the importance of “commons-based peer production,” a form of socially motivated and cooperative production exemplified by the volunteer network that maintains Wikipedia or the groups of coders who create open-source software products such as the Linux operating system.21 In the digital networked age, as Benkler describes, the tools of information production are very broadly distributed, “creating new opportunities for how we make and exchange information, knowledge, and culture.”22 These changes have increased the relative role in our information economy of nonproprietary production and facilitate “new forms of production [that] are based neither in the state nor in the market.”23 Because commons-based peer production is not hierarchically organized and is motivated by social dynamics and concerns, it also offers new possibilities for human development, human freedom, a more critical approach to culture, and more democratic forms of political participation.24

This line of critique has been profoundly generative and has helped launch an important new conceptualization of the commons as a paradigm. That paradigm, as a recent book puts it, “helps us ‘get outside’ of the dominant discourse of the market economy and helps us represent different, more wholesome ways of being.”25 Proponents of the commons concept draw upon contemporary articulations of successful commons-based resource management by Elinor Ostrom and her followers.26 They do mobilize retellings of the political and economic history of the commons in land in Europe before enclosure,27 and recent evidence from psychology and behavioral economics that suggests that humans have deep tendencies toward cooperation and reciprocation.28 They argue that A key revelation of the commons way of thinking is that we humans are not in fact isolated, atomistic individuals. We are not amoebas with no human agency except hedonistic “utility preferences” expressed in the marketplace. No: We are commoners—creative, distinctive individuals inscribed within larger wholes. We may have unattractive human traits fueled by individual fears and ego, but we are also creatures entirely capable of self-organization and cooperation; with a concern for fairness and social justice; and willing to make sacrifices for the larger good and future generations.29

This stands, of course, as a powerful rebuke to the neoliberal imaginary, which “constructs and interpellates individuals as . . . rational, calculating creatures whose moral autonomy is measured by their capacity for ‘self-care’— the ability to provide for their own needs and service their own ambitions.”30

III

Given this radical—and, in my view, critically important—attempt to rethink the subject at the core of neoliberal accounts, it is all the more striking that proponents of the commons often appear to adopt a neoliberal image of the state. For example, the introduction to a recently edited volume that gathers writings on the commons from seventy-three authors in thirty countries (entitled, tellingly, The Wealth of the Commons: A World Beyond Market and State) has this to say:

The presumption that the state can and will intervene to represent the interests of citizens is no longer credible. Unable to govern for the long term, captured by commercial interests and hobbled by stodgy bureaucratic structures in an age of nimble electronic networks, the state is arguably incapable of meeting the needs of citizens as a whole.31

The commons, they suggest, is a concept that seeks not only to liberate us from predatory and dysfunctional markets, but also from predatory and dysfunctional states. Something immediately seems incongruous here. If people are inherently cooperative reciprocators, why are states irredeemably corrupt? After all, as Harold Demsetz famously wrote in his 1967 attack on Arrow’s optimism about state production of information, “[g]overnment is a group of people.”32

Lessig, one of the progenitors of the language of the commons in the informational domain, often leads with a similar view of the state:

[I]f the twentieth century taught us one lesson, it is the dominance of private over state ordering. Markets work better than Tammany Hall in deciding who should get what, when. Or as Nobel Prize-winning economist Ronald Coase put it, whatever problems there are with the market, the problems with government are more profound.33

Lessig reveals his own sense of the power of this conception of the state when he seeks to tar IP law with the same brush; we should rebel against current IP law, he suggests, because we should “limit the government’s role in choosing the future of creativity.”34

Benkler is more measured but admits as well to viewing the state as “a relatively suspect actor.”35 We should worry, he suggests, that direct governmental intervention “leads to centralization in the hands of government agencies and powerful political lobbies,”36 a view that echoes the neoliberal account described above.

It should perhaps not surprise us that leading critics of neoliberal information policy embrace a neoliberal conception of the state. After all, neoliberalism is not merely an ideology, but also a set of policy prescriptions that may have helped to call forth the state that it has described. As David Harvey puts it, “[t]he neoliberal fear that special-interest groups would pervert and subvert the state is nowhere better realized than in Washington, where armies of corporate lobbyists . . . effectively dictate legislation to match their special interests.”37

There are, it must be said, few areas of law that better exemplify this problem than IP law. For example, Jessica Litman has documented the astonishing process through which the 1976 Copyright Act was drafted, in which Congress delegated most of the drafting to interest groups that were forced to negotiate with one another.38 Other scholars have offered similarly startling accounts of the genesis of the most important IP treaty today, the TradeRelated Aspects of Intellectual Property Rights (TRIPS) Agreement. TRIPS came into force in 1996, revolutionizing international IP law by both imposing new standards and by rendering them enforceable through the WTO’s disputeresolution system, which authorizes trade retaliation to enforce its judgments. Most countries in the world are members of TRIPS, and the Agreement introduced, for developing countries in particular, substantial new obligations, such as the obligation to grant patents on medicines and food-related inventions. Several excellent histories of the treaty have been written, documenting its beginnings as a brash idea proposed by “twelve chief executive officers (representing pharmaceutical, entertainment, and software industries).”39 As Susan Sell has described, the TRIPS Agreement was a triumph of industry organizing. Through TRIPS, Industry revealed its power to identify and define a trade problem, devise a solution, and reduce it to a concrete proposal that could be sold to governments.

#### Their positioning of capitalist competition as intrinsic good driven by IP reform acts to maintain the stability of capital accumulation.

* AT: Capitalism is when monopoly

Christophers 16 [Brett Christophers, Professor in the Department of Social and Economic Geography at Uppsala University, “The Great Leveler: Capitalism and Competition in the Court of Law,” 2016, Harvard University Press, pp. 8-15, EA]

The aforementioned argument that capitalism has historically migrated from a state of competitiveness to a state of monopoly or oligopoly is deficient in four primary respects, both empirical and conceptual in nature.

First, there is something deeply misleading about the either/or nature of this historical narrative. One of the most important—although rarely acknowledged—of Marx’s insights was that capitalism always, everywhere, requires both. It needs competition, assuredly, not least to drive technological innovation and the reinvestment of profits, and thus growth. But it also needs monopoly—not merely to enhance visibility within and control over otherwise potentially chaotic business environments, but also to underwrite capitalist, market-based trade per se. Not for nothing does David Harvey argue, after Marx, that the “monopoly power of private property” is “both the beginning point and the end point of all capitalist activity.”20 For the legal institution of private property does confer monopoly: the exclusive power to dispose of said property as the owner alone sees fit.

Capital’s seemingly paradoxical need for both competition and monopoly is explored in Chapter 1, which extracts from Marx a conceptualization of capitalism that critically informs the remainder of the book: that of capitalism always, necessarily, teetering on a knife edge, balanced precariously between the contradictory forces of competition and monopoly, and perennially in danger of lapsing too far to one side or the other. “The problem,” Harvey shrewdly observes, “is to keep economic relations competitive enough while sustaining the individual and class monopoly privileges of private property that are the foundation of capitalism as a political-economic system.”21

And it is here that our economic laws crucially enter the picture. In metaphorical terms, the law acts as a powerful leveler: a pincer of sorts on the critical, combustible nexus of monopoly and competition, applicable from one side of the knife edge, the other, or both. Antitrust (competition) law, meaningfully enforced, serves to constrain monopoly power where it coheres too readily, thus boosting competition; IP law acts from the other side, allowing a degree of monopoly power where none “naturally” coheres, and limiting competition in the process. This conceptualization of economic law is sketched out in Chapter 3. Together, such laws help to ensure that over the long term, market-based capitalism is not too competitive (driving down prices and profits) but, in Harvey’s terms, remains competitive enough (avoiding stagnation and rent-seeking). In the process, the laws in question historically have contributed substantially to keeping capitalist accumulation regimes broadly in balance.

At the pivot of this overall mechanism sits the phenomenon of profit. Following the lead of scholars such as Robert Brenner, this book places front and center the relationship between profitability and the interrelated dynamics of competition and monopoly.22 As, indeed, did the classicals: Profit rates were, as Chapter 1 will show, fundamental to their theorization of competition. But it is vital to recognize, as writers such as Keith Cowling have done, that this relationship does not assume a simplistic less-competition-means-more-profit form, isolated as it were from other contributory factors.23 Indeed, the book shows that excesses neither of competitive intensity nor of monopoly power support long-term stability of profit-making and accumulation.

Instead, it leans more toward the type of argument proffered by Gérard Duménil and Dominique Lévy, which is that the dynamics of profitability strongly influence the state’s attempts to regularize regimes of accumulation, and that stabilizing capitalism is thus in no small part a question, ultimately, of stabilizing profitability.24 Or, as David Gordon and coauthors have written, the reproduction of capitalism is “fundamentally conditioned by the level and stability of capitalist profitability. As profits go, in short, so goes the economy.”25 The book’s particular slant on such conceptions is to consider corporate profits more in relative than absolute terms—and relative to, especially, labor and wages. While a comparable focus has recently been adopted by Thomas Piketty in his much discussed Capital in the Twenty-First Century, the inspiration underlying the approach taken here lies much further back in time, in the work in particular of Michal Kalecki.26 For as Kalecki showed both historically and conceptually, the relation of capital with labor, and profit with wages, is centrally implicated in the monopoly-competition relation and the balance that capitalism requires of it. Kalecki, it is fair to say, would have had some very interesting things to say about the Apple wage-suppression antitrust lawsuit.

A second and related problem with the linear historical narrative of from-competition-to-monopoly is its positing of monopoly and competition not only as mutually exclusive alternatives, but as separable ones. Once more, we can turn to Marx for an effective disabusal of this figuring. Monopoly and competition, he argued, are much more closely related, and much more closely connected, than is typically recognized. “Monopoly produces competition, competition produces monopoly,” he maintained, somewhat aphoristically, in a letter he wrote to Pavel Annenkov in 1846.27 Capital not only requires both but is in fact the expression, inter alia, of their synthesis—a synthesis that Marx, in trademark dialectical fashion, described not as a “formula” but as a “movement,” specifically “the movement whereby a true balance is maintained between competition and monopoly.”28 Such movement comprises opposing but connected economic dynamics of centralization and decentralization. When one or the other dynamic becomes disproportionately powerful, Marx argues, the “counteracting tendency” kicks in to return capital to a balanced configuration of monopoly and competition.

This balanced organization of productive forces—always inherently unstable and always prone to knife-edge slippages—is very close to what Edward Chamberlin would later call “monopolistic competition.”29 Such monopolistic competition internalizes monopoly and competition in dialectical relation with one another and is the capitalist norm—and always has been. “The notion of a bygone ‘competitive’ stage of capitalism where firms were price-takers is,” as Duménil and Lévy insist, “a fiction derived from the neoclassical analytical apparatus.”30 Equally fictional, albeit a fiction usually emanating from a very different analytical source, is the notion of a contemporary “monopoly” stage of capitalism absent meaningful competition.31

The historical, U.S.- and U.K.-based narrative related in this book therefore turns on precisely this dialectical, restless synthesis of monopoly and competition, and its ever-evolving, historically and geographically specific forms. In recent years, it is Harvey who has provided the most provocative reading of this dialectic and of its centrality to capitalism. It is, Harvey argues, one of numerous “moving” contradictions that plague the capital form, and with which capital constantly wrestles as it enters into and out of crisis.32 Harvey repeats Marx’s observation that capital requires a balance of competitive and monopolistic forces. He then derives from this postulate the propositions that crisis occurs when such forces become imbalanced—although this is not the only cause of crisis—and that such crisis can only be “fixed” once balance is restored. The result is that capital historically “oscillates” between relative excesses of monopoly and competition, always finding balance hard to achieve, let alone sustain.33 Understanding capital and its historical development in this particular regard, Harvey insists, requires us to recognize “how successful capital has generally been in managing the contradictions between monopoly and competition” and that “it uses crises to do so.”34

Such success, and the role played by crises or by threats thereof, are two of this book’s central, recurring themes. However, Harvey’s framing raises two vital questions that he fails, in his admittedly brief account of monopoly and competition, to answer.

First, how has this success been achieved? “Capital,” Harvey writes, “has organically arrived at a way to balance and rebalance the tendencies towards a monopolistic centralisation and decentralised competition through the crises that arise out of its imbalances.”35 Again, there is no objection here, except to press: “organically,” how? This book fashions an answer. This answer rests on the role of the law. When capital has become sufficiently overcentralized and monopolistic to threaten its own successful, profitable reproduction, antitrust law has been called upon to help restore the necessary degree of balance. This balance will never be perfect and at rest; in a dialectical relation, such as that between monopoly and competition, it never can be. When the dangerous excess has been of competition, by contrast, IP law has come to the rescue. Such laws, needless to say, have not effected this work of rebalancing by themselves, and this book documents their interaction with other pertinent dynamics; but their role has been paramount.

The other problematic question raised by Harvey’s framing brings us directly to our third point of divergence with the Baran and Sweezy or Foster and McChesney reading of capitalist development. Consider here the agency behind the successful, crisis-based management and rebalancing of monopolistic and competitive forces envisioned by Harvey: “capital has been successful . . .”; “capital has arrived at . . .” But what, or who, is this capital, and has its form remained constant? For Harvey, clearly, capital is the capitalist class: those that own the means of production. Yet this singularization of responsibility for regulating and reregulating the core dynamics of the capitalist economy raises all manner of questions that Harvey fails to address. Is this capitalist class homogeneous? Does it share consistent objectives in terms of economic development and management? And even if it does (and of course, it does not), what is its relation with the state and with the different tools of economic regulation, the law among them, that the state uses to govern and shape economic conduct?

If Harvey’s stimulating propositions call for circumspection on account of their simplifying structural abstractions, the connection to the “monopoly capital” thesis is that it too tends to rely upon just such totalizing, even reified, concepts. “Monopoly capital” is itself one such. One of the consistent themes of the tradition renewed by The Endless Crisis—one extending back through Baran and Sweezy’s Monopoly Capital to Rudolf Hilferding’s Finance Capital (1910) and even Lenin’s Imperialism (1917)—is its tendency not only to associate potent monopoly powers with a new stage or phase of capitalism but to depict the latter in terms of a consciously regulated and (centrally) planned system in which market-based competition largely disappears from view.36 For Lenin, this system fused the interests of capital and state (state monopoly capitalism); for Hilferding the fusion was tripartite, with finance capital also integral. But Marx, for all the stereotypes to the contrary, never saw capitalism as such. It was a totality, to be sure, but one that needs to be continually reproduced and reconstituted. This process occurs in and through the disparate actions of government, workers, consumers, businesses, and so on; when such reconstitution occurs in ways that imperil accumulation, crisis looms.

The point of saying all this is not simply to oppugn a totalizing view of “monopoly capital,” but to contrast with it the approach taken in this book, particularly to the law and its mobilization. There is not, and has not been, a single hand on the tiller, for all the obvious importance of the state as the law’s formal originator; there is no single, homogeneous entity pulling the levers, so to speak, of political-economic regulation— no consistent regime of conscious, systematic control. As with other modalities of economic regulation or governance, the law, in practice, does not “work” like that.

For one thing, there is an important difference between the written law and its interpretation. Two courts can interpret and apply the same law or laws in markedly different ways and with very different consequences. Perhaps the clearest example of this, at least in this book (Chapter 6), concerns U.S. antitrust law in the second half of the twentieth century: The nature and degree of enforcement of this law underwent a dramatic transformation in the late 1970s and early 1980s, but the law itself did not materially change. Intellectual training, social and political context, even judicial personality: These variables, and more, all matter to the law’s practical materialization. As such, we must remain constantly alive to the simple fact that, as Peter Carstensen has put it, “court doctrine is not the whole of the law in practice.”37 Relatedly, much of the enforcement of IP rights occurs at a significant remove from courts—specifically in, as argued by William T. Gallagher, the everyday practices of IP owners and their lawyers, whose “negotiations” with alleged infringers take place largely in the “shadow” of IP law.38

For another thing, just as the state never enacts new economic laws in total isolation from the influence and interests of capital, so both capital(s) and state—and indeed other economic agents—use the law to their own ends, and these ends are far from necessarily commensurate. Think, once again, about our two Apple cases. Who, in each case, instigated the legal action? Who put the law to work in their own interests? In the IP case it was Apple itself. In the class-action suit it was labor. But the latter suit was in fact itself based upon a prior government investigation launched by the Department of Justice’s Antitrust Division in 2010.39 Three legal cases, then, all driven by different actors with different motivations, but all revolving around the same political-economic locus: the knotty complex of profit generation and accumulation constituted by Apple Inc. And if the law, together with its agents, is so palpably nonsingular at the scale of the political economy of just one company, on what reasonable grounds could we ever envision it thus—as a vehicle of conscious, unified control—in relation to the political economy of capitalism more widely? The “great leveler” indicated in the book’s title, in short, is not some omnipotent regulator in charge of the law; it is the law per se.

How, then, might we more accurately characterize the human and institutional agency analyzed in the following pages in relation to the law, its mobilization, and its political-economic effects? At a general level, the conclusion reached by Paul David in his examination of the history of IP law fits particularly well: “The complex body of law, judicial interpretation, and administrative practice that one has to grapple with in this field was not created by some rational, consistent, social welfare-maximizing public agency. What one is faced with, instead, is a mixture of the intended and unintended consequences of an undirected historical process on which the varied interests of many parties, acting at different points (some widely separated in time and space), have left an enduring mark.”40 More specifically, however, we will see that although IP and competition laws have indeed performed their work under the influence of varied individuals and groups, the vast majority of the latter are ultimately committed to, and institutionally invested in, the reproduction, in as smooth a fashion as possible, of capitalism in more or less its existing form. And even more specifically, the “smoothness” here alluded to means the reproduction of capitalism especially without the kinds of problems—identified in Chapter 3—that tend to emerge when the necessary balance between monopoly and competition is substantially disrupted.

On all the above grounds, therefore, this book’s argument diverges from that which we find in the all-too-common narrative of competitive capitalism historically segueing into monopoly capitalism. Of course, none of this is to suggest that nothing has changed historically in the capitalist constellation of monopoly-competition structures and dynamics. Far from it. But the book’s fourth and final quarrel with the conventional narrative is that what has substantively, perhaps irrevocably, changed is not the relative levels of competitive intensity and monopoly power—as in, that era had more competition, this one has more monopoly—so much as the source of monopoly powers and the degree of defensibility thereof.

Capitalism, this argument runs, is always characterized by competitive undercurrents; were it not, it would not be capitalism. Meanwhile, and arising partly out of these competitive dynamics (the Marxian argument), there is an endemic drive to fashion monopoly powers. Yet the means of assembly of such powers do not remain constant, and neither does the ability of monopolistic capitalists to defend the powers thus amassed. Capitalists—and indeed the states committed to stabilizing capitalism, with the law one obvious apparatus at their disposal—must constantly find new ways of putting monopoly in place and keeping it there. “As monopoly privileges from one source diminish,” Harvey observes, “so we witness a variety of attempts to preserve and assemble them by other means.”41 Mindful, thus, of Marx’s dictum that the monopoly-versus-competition dualism is a red herring that confuses a dialectical relation for an oppositional one, this book focuses instead on the ways in which the unstable balance between the two forces is maintained—and it posits the law as the primary, necessarily mutable, instrument of such maintenance.

#### Capitalism is an a priori impact under any framework -- it’s the greatest existential threat and the biggest affront to human rights and causes value to life deprivation.

Ahmed 20 (Nafeez Ahmed -- Visiting Research Fellow at the Global Sustainability Institute at Anglia Ruskin University's Faculty of Science & Technology + M.A. in contemporary war & peace studies + DPhil (April 2009) in international relations from the School of Global Studies @ Sussex University, “Capitalism is Destroying ‘Safe Operating Space’ for Humanity, Warn Scientists”, https://www.resilience.org/stories/2020-06-24/capitalism-is-destroying-safe-operating-space-for-humanity-warn-scientists/, 24 June 2020, EmmieeM)

The COVID19 pandemic has exposed a strange anomaly in the global economy. If it doesn’t keep growing endlessly, it just breaks. Grow, or die.

But there’s a deeper problem. New scientific research confirms that capitalism’s structural obsession with endless growth is destroying the very conditions for human survival on planet Earth.

A landmark study in the journal Nature Communications, “Scientists’ warning on affluence” — by scientists in Australia, Switzerland and the UK — concludes that the most fundamental driver of environmental destruction is the overconsumption of the super-rich.

This factor lies over and above other factors like fossil fuel consumption, industrial agriculture and deforestation: because it is overconsumption by the super-rich which is the chief driver of these other factors breaching key planetary boundaries.

The paper notes that the richest 10 percent of people are responsible for up to 43 percent of destructive global environmental impacts.

In contrast, the poorest 10 percent in the world are responsible just around 5 percent of these environmental impacts:

The new paper is authored by Thomas Wiedmann of UNSW Sydney’s School of Civil and Environmental Engineering, Manfred Lenzen of the University of Sydney’s School of Physics, Lorenz T. Keysser of ETH Zürich’s Department of Environmental Systems Science, and Julia K. Steinberger of Leeds University’s School of Earth and Environment.

It confirms that global structural inequalities in the distribution of wealth are intimately related to an escalating environmental crisis threatening the very existence of human societies.

Synthesising knowledge from across the scientific community, the paper identifies capitalism as the main cause behind “alarming trends of environmental degradation” which now pose “existential threats to natural systems, economies and societies.” The paper concludes:

“It is clear that prevailing capitalist, growth-driven economic systems have not only increased affluence since World War II, but have led to enormous increases in inequality, financial instability, resource consumption and environmental pressures on vital earth support systems.”

Capitalism and the pandemic

Thanks to the way capitalism works, the paper shows, the super-rich are incentivised to keep getting richer — at the expense of the health of our societies and the planet overall.

The research provides an important scientific context for how we can understand many earlier scientific studies revealing that industrial expansion has hugely increased the risks of new disease outbreaks.

Just last April, a paper in Landscape Ecology found that deforestation driven by increased demand for consumption of agricultural commodities or beef have increased the probability of ‘zoonotic’ diseases (exotic diseases circulating amongst animals) jumping to humans. This is because industrial expansion, driven by capitalist pressures, has intensified the encroachment of human activities on wildlife and natural ecosystems.

Two years ago, another study in Frontiers of Microbiology concluded presciently that accelerating deforestation due to “demographic growth” and the associated expansion of “farming, logging, and hunting”, is dangerously transforming rural environments. More bat species carrying exotic viruses have ended up next to human dwellings, the study said. This is increasing “the risk of transmission of viruses through direct contact, domestic animal infection, or contamination by urine or faeces.”

It is difficult to avoid the conclusion that the COVID19 pandemic thus emerged directly from these rapidly growing impacts of human activities. As the new paper in Nature Communications confirms, these impacts have accelerated in the context of the fundamental operations of industrial capitalism.

Eroding the ‘safe operating space’

The result is that capitalism is causing human societies to increasingly breach key planetary boundaries, such as land-use change, biosphere integrity and climate change.

Remaining within these boundaries is essential to maintain what scientists describe as a “safe operating space” for human civilization. If those key ecosystems are disrupted, that “safe operating space” will begin to erode. The global impacts of the COVID19 pandemic are yet another clear indication that this process of erosion has already begun.

“The evidence is clear,” write Weidmann and his co-authors.

“Long-term and concurrent human and planetary wellbeing will not be achieved in the Anthropocene if affluent overconsumption continues, spurred by economic systems that exploit nature and humans. We find that, to a large extent, the affluent lifestyles of the world’s rich determine and drive global environmental and social impact. Moreover, international trade mechanisms allow the rich world to displace its impact to the global poor.”

The new scientific research thus confirms that the normal functioning of capitalism is eroding the ‘safe space’ by which human civilisation is able to survive.

The structures

The paper also sets out how this is happening in some detail. The super-rich basically end up driving this destructive system forward in three key ways.

Firstly, they are directly responsible for “biophysical resource use… through high consumption.”

Secondly, they are “members of powerful factions of the capitalist class.”

Thirdly, due to that positioning, they end up “driving consumption norms across the population.”

But perhaps the most important insight of the paper is not that this is purely because the super-rich are especially evil or terrible compared to the rest of the population — but because of the systemic pressures produced by capitalist structures.

The authors point out that: “Growth imperatives are active at multiple levels, making the pursuit of economic growth (net investment, i.e. investment above depreciation) a necessity for different actors and leading to social and economic instability in the absence of it.”

At the core of capitalism, the paper observes, is a fundamental social relationship defining the way working people are systemically marginalised from access to the productive resources of the earth, along with the mechanisms used to extract these resources and produce goods and services.

This means that to survive economically in this system, certain behavioural patterns become not just normalised, but seemingly entirely rational — at least from a limited perspective that ignores wider societal and environmental consequences. In the words of the authors:

“In capitalism, workers are separated from the means of production, implying that they must compete in labour markets to sell their labour power to capitalists in order to earn a living.”

Meanwhile, firms which own and control these means of production “need to compete in the market, leading to a necessity to reinvest profits into more efficient production processes to minimise costs (e.g. through replacing human labour power with machines and positive returns to scale), innovation of new products and/or advertising to convince consumers to buy more.”

If a firm fails to remain competitive through such behaviours, “it either goes bankrupt or is taken over by a more successful business. Under normal economic conditions, this capitalist competition is expected to lead to aggregate growth dynamics.”

The irony is that, as the paper also shows, the “affluence” accumulated by the super-rich isn’t correlated with happiness or well-being.

Restructure

The “hegemonic” dominance of global capitalism, then, is the principal obstacle to the systemic transformation needed to reduce overconsumption. So it’s not enough to simply try to “green” current consumption through technologies like renewable energy — we need to actually reduce our environmental impacts by changing our behaviours with a focus on cutting back our use of planetary resources:

“Not only can a sufficient decoupling of environmental and detrimental social impacts from economic growth not be achieved by technological innovation alone, but also the profit-driven mechanism of prevailing economic systems prevents the necessary reduction of impacts and resource utilisation per se.”

The good news is that it doesn’t have to be this way.

The paper reviews a range of “bottom-up studies” showing that dramatic reductions in our material footprint are perfectly possible while still maintaining good material living standards.

In India, Brazil and South Africa, “decent living standards” can be supported “with around 90 percent less per-capita energy use than currently consumed in affluent countries.” Similar possible reductions are feasible for modern industrial economies such as Australia and the US.

By becoming aware of how the wider economic system incentivises behaviour that is destructive of human societies and planetary ecosystems critical for human survival, both ordinary workers and more wealthy sectors — including the super-rich — can work toward rewriting the global economic operating system.

This can be done by restructuring ownership in firms, equalising relations with workers, and intentionally reorganising the way decisions are made about investment priorities.

The paper points out that citizens and communities have a crucial role to play in getting organised, upgrading efforts for public education about these key issues, and experimenting with new ways to work together in bringing about “social tipping points” — points at which social action can catalyse mass change.

While a sense of doom and apathy about the prospects for such change is understandable, mounting evidence based on systems science suggests that global capitalism as we know it is in a state of protracted crisis and collapse that began some decades ago. This research strongly supports the view that as industrial civilization reaches the last stages of its systemic life-cycle, there is unprecedented and increasing opportunity for small-scale actions and efforts to have large system-wide impacts.

The new paper shows that the need for joined-up action is paramount: structural racism, environmental crisis, global inequalities are not really separate crises — but different facets of human civilization’s broken relationship with nature.

Yet, of course, the biggest takeaway is that those who bear most responsibility for environmental destruction — those who hold the most wealth in our societies — urgently need to wake up to how their narrow models of life are, quite literally, destroying the foundations for human survival over the coming decades.

#### The alternative is a global socialist movement that ends globalization

Galant 19 [(Michael, a coordinator of the Wire Pillar of the Progressive International, former economics and trade fellow at Young Professionals in Foreign Policy, MPP from Harvard University’s Kennedy School and BA in political economy from Brown University) “The Battle of Seattle: 20 years later, it's time for a revival” Open Democracy, 11/30/2019. <https://www.opendemocracy.net/en/oureconomy/battle-seattle-20-years-later-its-time-revival/>] BC

20 years ago today, the streets of Seattle became front lines in the global class war.

Over the course of five days, some 40,000 individuals, representing unions, environmental groups, and Leftist organizations from around the world came together in an attempt to disrupt the Ministerial Conference of the World Trade Organization (WTO).

Using direct action tactics, activists physically delayed access to the meeting and led marches, rallies, and teach-ins that drew massive crowds. Protesters of all stripes were attacked by a violent police force – attracting international media coverage. The demonstrations outside became a wedge that would help drive the negotiations inside to collapse. The Battle of Seattle was won.

But the war continued. Seattle was about more than any single organization. The WTO was a symbol of the larger project of neoliberal globalization that was, in 1999, well on its way to reshaping the world in the interest of capital. The Battle of Seattle would become an equally potent symbol of resistance. The WTO protests marked the moment that the Alter-Globalization Movement (AGM), also known as the Global Justice, or disparagingly, the Anti-Globalization Movement, was launched into the public consciousness.

Much has changed in the two decades since. The AGM won many meaningful victories and experienced many more profound losses. Eventually, the movement faded. Today’s global economy resembles the neoliberal nightmare the Seattle protesters were fighting against more than the world they were fighting for. But recent years have revealed cracks in the surface. With an opportunity to finish what was started, it’s time to revive the spirit of Seattle.

Globalization and its dissent

Neoliberal globalization is a political project intended to raise the power of capital to the international level – to cement its supremacy as an immutable universal law beyond the reach of political communities. “Free trade” agreements and WTO rules establish the primacy of profit over democracy, labor, environmental, and consumer protections. World Bank and IMF loan conditions impose austerity, privatization, and deregulation on nations of the Global South. An international system of tax havens allows corporations and wealthy individuals to hoard their plundered resources. Global supply chain fragmentation shields multinationals from accountability for their abuses. Investment treaties unleash finance and corporations to cross borders in search of opportunities for exploitation, setting off a regulatory race to the bottom. If there was doubt before that capitalism must be confronted at the global level to be defeated, the power grab that is neoliberal globalization puts those doubts to rest. Capital is global. Labor must be too.

Yet there are forces preventing such global solidarity. Beginning during the Cold War, the majority of Northern labor accepted a compromise: support a foreign policy that enacts the interests of capital, and benefit from a share of the spoils in the form of minor concessions, a tempered welfare state, and cheap consumer goods. This tacit agreement survived largely intact into the neoliberal era – dividing the interests of a global working class and quelling demands for systemic global change.

The Alter-Globalization Movement rejected the compromise. While activists in the Global South had long resisted destructive free trade agreements and World Bank austerity, occasionally with solidarity from the North, the extremity of turn-of-the-century neoliberalism led to the explosion of a movement that refused to accept the mere crumbs of neocolonial extraction, and sought instead to build an alternative global economy for the many, both North and South.

This was a movement that brought together American anarchists with Korean peasants; libertarian socialist indigenous groups in Mexico with US anti-sweatshop activists; the International Confederation of Free Trade Unions with the Industrial Workers of the World; the Brazilian Movement for Landless Workers with Greenpeace; Filipino anti-capitalist scholars with French farmer activists best known for physically dismantling a McDonald’s. Their demands were many and varied – from land redistribution to the abolition of the World Bank, from a renegotiated NAFTA to the protection of indigenous knowledge of seeds from privatization – but all shared a vision of a global solidarity that would overcome the forces of neoliberal globalization.

Organizing under such a big tent, the AGM is better understood as a dispersed, informal network – a “movement of movements” – than a unified political structure. This fluid network manifested in many forms. The flagship World Social Forum regularly convened activists in an alternative to the annual World Economic Forum. Transnational advocacy networks campaigned on issues such as Global South debt relief. Northern activists used their positions of relative privilege to support local campaigns in the South, fighting water privatization in Bolivia and indigenous displacement from hydroelectric dams in India. And, as in Seattle, meetings of international organizations became rallying points for major global demonstrations.

With these organizing methods, the movement achieved substantial victories. The Jubilee 2000 campaign led to significant debt relief for Southern nations. Potentially disastrous trade agreements from the FTAA to TPP have been, at least temporarily, defeated. International Financial Institutions like the IMF and World Bank – while still agents of global capital – have vastly improved their lending practices since the 90’s. But its greatest successes were intangible: the AGM undermined the hegemonic ambitions embodied in Thatcher’s “There Is No Alternative”, slowed neoliberal globalization’s seemingly inexorable onslaught, and kept alive the flame of resistance during an otherwise nadir of Leftist politics.

The AGM should not, however, be romanticized. Emerging in a moment when the failures of 20th century socialist politics weighed heavily on the Left’s imagination, the AGM turned too far in the opposing direction. Big-tentism led to a dilution of demands and paved the way for the NGO-ization of the World Social Fora. A preference for all things decentralized made grabbing headlines easy, but building lasting political structures difficult. Resistance was often treated as an intrinsically valuable ends, rather than a means to taking power. And criticisms of “neoliberalism” typically fell short of identifying the true enemy – capitalism – or advancing a coherent alternative – socialism.

Ultimately, the neoliberal plan for the global economy succeeded more than not. While resistance to neoliberal globalization would rage on in the South, Northern solidarity faded. The September 11th attacks were the beginning of the end. Energy shifted to the anti-war movement, the state expanded its repression of Leftist organizing, and increased pressures toward “patriotism” led some to reconsider the old foreign policy compromise. By the mid-2000’s, little was left of what the AGM once was.

A call for revival

It’s time to rekindle the flame.

The global economy is still structured in the interest of capital. But the neoliberal consensus has begun to waver under the weight of its own contradictions.

The Right has a response to the crisis. Reactionary nationalists like Trump and Johnson seize upon existing systems of oppression to scapegoat the symptoms of a failed economic model. The problem is not that the global working class has lost out to a global capital class. The problem is that “we” – White, Christian, cishet, native-born Americans – have lost out to “them” – People of Color, immigrants, entire foreign countries, feminists, LGBTQ+ folks, and all those who threaten our supremacy in their struggles for liberation.

The Left must offer an alternative vision. The dramatic growth of socialist organizing and rise in popularity of social democratic politicians should offer great hope. But as the AGM understood, social democracy for the North is not enough. Our socialism must not mean merely a greater share of neocolonial extraction for Northern workers. Our socialism must rightly identify the global nature of our challenge, and unite across borders to confront a globalized capital.

That means internationalizing labor organizing to confront multinational corporations. Changing the rules of trade and investment. Ending tax havens. Building alternatives to the existing intellectual property regime. Holding corporations accountable for abuses in their supply chains. Supporting the struggles of peasants, indigenous peoples, and all global subaltern groups. Democratizing global governance. Opening borders to those displaced by the ravages of global capitalism. Advancing alternative models of development. Transforming, if not abolishing and replacing, the Bretton Woods Institutions. And confronting the all-important threat of climate collapse with, to begin with, a global Green New Deal. These are not minor addendums to a socialist platform. Class war is global. Internationalist demands are fundamental.

Organizations that remain from the AGM, international labor, and newcomers like Justice Is Global, the Fight Inequality Alliance, and Bernie Sanders and Yanis Varoufakis’s Progressive International, are already struggling for this vision. But its fruition depends on the backing of a far broader movement.

Like the AGM, we must take a global frame of analysis, and see neoliberal globalization as a concerted effort to undermine our power. Unlike the AGM, we must understand that neoliberalism is merely one manifestation of a greater enemy.

Like the AGM, we must build diverse, anti-racist, anti-sexist, anti-xenophobic movements that transcend borders. Unlike the AGM, we must not allow fears of centralization to undermine a coherent platform.

Like the AGM, we must reject a class compromise that sacrifices the possibility of a better world for the crumbs of colonialism. Unlike the AGM, we must build lasting political structures that back our rejection with political power.

20 years ago, the streets of Seattle echoed with a chant that would become the defining motto of the movement: “another world is possible!” It still is – if we’re willing to fight for it.

## Case

TL:

#### They don't solve their aff -- all they do is ensure companies only get one protection per invention -- either orphan drug rights, a patent, or data exclusivity -- but theres no brightline for whats a new or old invention, so they cant stop evergreening. Companies will just slightly modify their invention and get a separate new patent and the aff has no litmus test for when an invention is significantlly new/different enough from past inventions.

#### Minor tweaks of drugs are key to ensure adequate treatment- otherwise patients skip doses or medicines fail in hot climates – forces people to go underground to get effective new drugs which decks aff solvency

**Holman 2018** (Christopher, Professor of Law, University of Missouri-Kansas City School of Law. “Why Follow-On Pharmaceutical Innovations Should Be Eligible For Patent Protection” <https://www.ip-watch.org/2018/09/21/follow-pharmaceutical-innovations-eligible-patent-protection/> September 21, 2018)DR 21

Follow-on pharmaceutical innovation can come in the form of an extended-release formulation that permits the drug to be administered at less frequent intervals than the original formulation. Critics of secondary patents downplay the significance of extended-release formulations, claiming that they represent nothing more than a ploy to extend patent protection without providing any real benefit to patients. In fact, the availability of a drug that can be taken once a day has been shown to improve patient compliance, a significant issue with many drugs, particularly in the case of drugs taken by patients with dementia or other cognitive impairments. Extended-release formulations can also provide a more consistent dosing throughout the day, avoiding the peaks and valleys in blood levels experienced by patients forced to take an immediate-release drug multiple times a day.

Other examples of improved formulations that provide real benefits to patients are **oral**ly administrable formulations of drugs that could previously only be administered by more invasive intravenous or intramuscular **injection**, combination products that combine two or more active pharmaceutical agents in a single formulation (resulting in improved patient compliance), and a heat-stable formulation of a lifesaving drug used to treat HIV infection and AIDS (an important characteristic for use in developing countries with a hot climate).

#### There’s a reason the aff’s authors are blogs not lawyers – Evergreen doesn’t prolong patents -- secondary patents *only* cover the improvement, but the original patent dies regardless.

**Holman 2018** (Christopher, Professor of Law, University of Missouri-Kansas City School of Law. “Why Follow-On Pharmaceutical Innovations Should Be Eligible For Patent Protection” <https://www.ip-watch.org/2018/09/21/follow-pharmaceutical-innovations-eligible-patent-protection/> September 21, 2018)DR 21

“Evergreening” – an Incoherent Concept

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

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

#### That solves pricing and monopoly- the improvement might be patented but generics of the original compound become incredibly cheap.

**Holman 2016** (Christopher, Professor of Law, University of Missouri-Kansas City School of Law; J.D., University of California, Berkeley; Ph.D., University of California, Davis. “IN DEFENSE OF SECONDARY PHARMACEUTICAL PATENTS: A RESPONSE TO THE UN’S GUIDELINES FOR PHARMACEUTICAL PATENT EXAMINATION” *Indiana Law Review* 50, 2016)DR 21

Rather than the blanket presumption against patents on new formulations endorsed by the Guidelines, which would tend to deny patent protection for both minor improvements and highly significant improvements, the needs of patients would be better served if the market and the judgment of patients and healthcare providers were allowed to determine the value of a new formulation on an existing drug. If the improvement is of such significance that it justifies a substantial cost premium, then society has benefited from the development of this improved mode of drug delivery, and payment of the premium is justified, in the same way that it is by development of a therapeutically useful new active ingredient. If the improvement is nominal, then payers should refuse to pay the premium, which they can do by simply purchasing the original formulation from generic companies at a discounted price. If there are market inefficiencies that somehow induce payers to pay the premium even though the improvement is minimal, then those market inefficiencies should be addressed, rather than attempting to address it by changing the standard for patentability in a discriminatory manner that targets specific categories of inventions.

#### Vague standards for new patents are unenforceable and explode costs – the link alone turns case because the plan is unenforceable

Madigan & O'Connor 19 [Kevin Madigan joined CPIP in January of 2016. As Deputy Director, Kevin works closely with CPIP scholars in their research and promotion of comprehensive intellectual property law and policy. Before joining CPIP, Kevin worked as an intellectual property Research Associate at Finnegan Henderson Farabow Garrett & Dunner and also interned at the Recording Industry Association of America. Sean O’Connor, noted innovation law scholar, is a Professor of Law and Faculty Director of the Center for Intellectual Property x Innovation Policy (C-IP2) at George Mason University, Antonin Scalia Law School. "“No Combination Drug Patents Act” Stalls, but Threats to Innovation Remain." https://cip2.gmu.edu/2019/06/27/no-combination-drug-patents-act-stalls-but-threats-to-innovation-remain/]

While the amendment provided for a rebuttal to the presumption of obviousness, the language was ambiguous and likely to render the patent system even more unreliable than it already is. The proposed statute said that an applicant may rebut the presumption of obviousness if the covered claimed invention “results in a statistically significant increase in the efficacy of the drug or biological product that the covered claimed invention contains or uses.” It is unclear what would qualify as “statistically significant,” and proving this vague standard would be nearly impossible.

In order to show a “statistically significant increase in efficacy,” long and costly head-to-head clinical trials would be necessary. To be clear, this is not a standard required by the FDA for new drug approval, let alone patentability.

#### Eliminating evergreening ends the pharmaceutical industry – incremental developments are key to global breakthroughs on emerging pathogens

Madigan & O'Connor 19 [Kevin Madigan joined CPIP in January of 2016. As Deputy Director, Kevin works closely with CPIP scholars in their research and promotion of comprehensive intellectual property law and policy. Before joining CPIP, Kevin worked as an intellectual property Research Associate at Finnegan Henderson Farabow Garrett & Dunner and also interned at the Recording Industry Association of America. Sean O’Connor, noted innovation law scholar, is a Professor of Law and Faculty Director of the Center for Intellectual Property x Innovation Policy (C-IP2) at George Mason University, Antonin Scalia Law School. "“No Combination Drug Patents Act” Stalls, but Threats to Innovation Remain." https://cip2.gmu.edu/2019/06/27/no-combination-drug-patents-act-stalls-but-threats-to-innovation-remain/]

Like most forms of innovation, the development of medicines and therapeutics is a process by which one builds and improves upon previous discoveries and breakthroughs. Sometimes those improvements are major advancements, but often they are incremental steps forward. In the pharmaceutical field, incremental or follow-on innovation frequently results in new therapeutic uses for existing drugs, which address serious challenges related to adverse effects, delivery systems, and dosing schedules. While they might not sound like medical breakthroughs on par with the discovery of penicillin, these advancements in the administration and use of pharmaceuticals improve public health and save lives.

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

Thomas 09

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

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