# 1NC Evergreening V.

## 1

### CP

#### CP text: States should add more stringent requirements for filing patents for medicines.

Newsome 17, A [(JD candidate George Washington School of Law). (2017). Side effects of evergreening may include decreased competition & increased prices in the pharmaceutical industry. AIPLA Quarterly Journal, 45(4), 791-822] Justin

The current framework for evaluating a patent application, particularly the requirements of utility and nonobviousness, is insufficient for evaluating whether a secondary patent should be issued for a drug. Given that courts are tied to the low bar for utility and inconsistent with their application of nonobviousness,1 04 it is necessary to pass legislation creating a new utility requirement tailored to secondary pharmaceutical patents. This Note's Author proposes legislation language as follows: 35 U.S.C. § 106: Patentable Pharmaceutical Inventions

(a) Utility requirement for secondary patent: In the case of a pharmaceutical invention claiming an improvement on a patented invention, the applicant shall demonstrate through clear and convincing evidence in the written description that such invention has increased efficacy as compared to the original.

(b) Increased efficacy defined: As used in part (a), "increased efficacy" refers to a proven improvement in the mechanism of action, as disclosed in the patent claims. 0 5

(c) Mechanism of action defined: As used in part (b), "mechanism of action" refers to the process by which a drug functions to produce a therapeutic effect, as disclosed in the patent claims. 06

Under this legislation, the USPTO could grant a secondary patent only if the new formula's mechanism of action, or production of the intended pharmacological effect, in fact improves upon the patented drug's mechanism of action. For example, because VidaDrug is a chemotherapy drug, the new formula must include a change in the mechanism of action which causes an improvement in the efficacy of the drug's tumor-shrinking abilities to be eligible for a secondary patent. A formula tweak that reduces side effects is insufficient, because the underlying purpose of the drug - to treat cancer - remains unaffected.

#### Solves best.

Newsome 17, A [(JD candidate George Washington School of Law). (2017). Side effects of evergreening may include decreased competition & increased prices in the pharmaceutical industry. AIPLA Quarterly Journal, 45(4), 791-822] Justin

Pharmaceutical patents are inherently different from software or manufacturing patents. 144 Pharmaceutical companies create life-saving drugs that carry a very serious benefit for a vulnerable group of consumers - patients. Because of this, the pharmaceutical industry should be held to a higher standard if its companies seek to prohibit affordable generic drugs from coming to the marketplace.

1. An Efficacy-Focused Standard Will Motivate Pharmaceutical Companies to Channel Resources to Creating Real Innovation Pharmaceutical companies argue that patent-life-cycle-management strategies (their preferred name for those tactics described herein as evergreening) are essential to ensuring they recoup R&D costs. 145 However, creation of a standard such as the one proposed here would ensure that pharmaceutical companies are properly incentivized to channel R&D resources to creating measurable change in the drugs, rather than creating minor changes that prolong the time they can profit off of monopolies at the expense of patients. For those industries in which R&D is more productive, like the pharmaceutical industry, "patent procedures should be refined to tighten the relationship between patents and the underlying inventions."14 6
2. A Higher Standard for Secondary Pharmaceutical Patents Will Increase Competition & Lead to Lower Prices The patent system enables pharmaceutical companies to retain market exclusivity for their drugs, allowing them to set high prices without an eye toward competition.1 47 The companies cite the need to recoup R&D costs as the driving factor for their pricing decisions,148 but critics say their main motivation is making a profit.'49 While the pharmaceutical companies' argument may hold weight, high prices for drugs have a negative impact on those patients who need those drugs, but cannot afford them.150 Tightening patent laws to prevent pharmaceutical companies from retaining patent protection for minor changes in their patented drugs will allow other companies to enter the marketplace sooner and drive prices down through competition. 5

## 2

### K

#### Capitalism causes massive violence and inevitable extinction – the role of the ballot is to endorse the best organizational tactics.

Escalante 19 [Alyson Escalante, M.A., Department of Philosophy @ University of Oregon, “Truth and Practice: The Marxist Theory of Knowledge,” 09/08/19, tinyurl.com/8jksnexs] pat

The world we live in today is in a dire state. Climate destruction continues at a fast pace, and every with every passing day, capitalism proves itself to be incapable of addressing this. Capitalist production and its endless drive for resources to match artificial market demands has created a climate crisis that leaves us on the brink of potential extinction.

Governments around the world are turning to far right and fascist leaders to assuage their fears of an uncertain future, and the most marginalized and oppressed suffer because of it. Fascism is on the rise, and history tells us very clearly what that can result in without opposition.

The decaying US empire continues to lash out in violence across the globe in a desperate attempt to re-assert its power and hegemony. Whole countries are destroyed in its desperate bids for more fossil fuels. The world burns from America’s white phosphorus weaponry.

The need for a revolutionary movement capable of replacing capitalism with something better has never been so clear. The choice between socialism or barbarism has never been so stark. More and more people are starting to realize that reform cannot save us, that capitalism and imperialism themselves are the problem, and that we must unite and band together to fight for a better world.

The question then is: how will we know what strategies, what tactics, and what ideas to unite around? If the skeptics and postmodernists are correct that knowledge is always relative and localized, then we cannot built a global and universal strategy to unite around. If they are correct then we are doomed to small acts of localized or individual resistance in the face of apocalypse. To embrace such a vision of the world (with its accompanying epistemological skepticism) is to embrace defeat.

The masses do not want to embrace defeat, they want to know how to fight back. Marxism can provide the tools necessary to engage in that fight.

Marxism, with its self criticism and its insistence on incorporating the valuable ideas of its critics has created a means for unifying workers across the globe with anti-colonial and anti-imperialist struggles. The Marxist belief in the possibility of true ideas, tested and verified in practice, creates the possibility for unity on a global scale. The scientific status of Marxism means that as our climate changes, as our world looks more and more grim, Marxism will adapt through struggle and practice; it will provide us with the ideas and tools we need to fight and win.

There will be no victory for the workers of the world without the ability to wield a revolutionary science. What is at stake in questions of Marxist epistemology is the very possibility of creating a philosophical and scientific basis for revolution. We must defend this possibility. We must defend the scientific status of Marxism, and must insist on the possibility of victory.

#### The aff’s positioning of competition as intrinsic good 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 unsustainable and causes extinction -- multiple intertwined crises make collapse inevitable which means its try-or-die -- we got charts.

von Weizsäcker and Wijkman ‘17

Ernest Ulrich von Weizsäcker, Professor and Director of the United Nation Centre for Science and Technology for Development, Founder and President of the Wuppertal Institute, Member of the German Bundestag, chairing the Committees on Globalization and the Environment, Dean of the graduate School of Environmental Science and Management at the University of California, appointed Co-Chair of UNEP’s International Resource Panel, Anders Wijkman, chairman of the Swedish Association of Recycling Industries, member of the Board of the Swedish Development Authority (SIDA), appointed chair of the Swedish Cross-Party Committee on Environmental Objectives, member of the European Parliament, Assistant Secretary-General of the United Nations and Policy Director of UNDP, Secretary General of the Swedish Red Cross and Director General of the Swedish Agency for Research Cooperation with Developing Countries, Member of the Swedish Royal Academy of Sciences, the World Future Council and the International Resource Panel, 2017 (“Come On! Capitalism, Short-termism, Population and the Destruction of the Planet – A Report to the Club”, November 11th, Available Online via Subscription to Springer, Accessed 03-20-2018)

1.1 Introduction: The World in Disarray We all know that the world is in crisis. Science tells us that almost half of the top soils on earth have been depleted in the last 150 years1 ; nearly 90% of fish stocks are either overfished or fully fished.2 Climate stability is in real danger (Sects. 1.5 and 3.7); and the earth is now in the sixth mass extinction period in history.3 Perhaps the most accurate account of the ecological situation is the 2012 ‘Imperative to act’,4 launched by all the 18 recipients (till 2012) of the Blue Planet Prize, including Gro Harlem Brundtland, James Hansen, Amory Lovins, James Lovelock and Susan Solomon. Its key message reads, ‘The human ability to do has vastly outstripped the ability to understand. As a result, civilization is faced with a perfect storm of problems, driven by overpopulation, overconsumption by the rich, the use of environmentally malign technologies and gross inequalities’. And further, ‘The rapidly deteriorating biophysical situation is barely recognized by a global society infected by the irrational belief that physical economies can grow forever’. 1.1.1 Different Types of Crisis and a Feeling of Helplessness The crisis is not cyclical but growing. And it is not limited to the nature around us. There are also a social crisis, a political and a cultural crisis, a moral crisis, as well as a crisis of democracy, of ideologies and of the capitalist system. The crisis also consists of deepened poverty in many countries and the loss of jobs for a considerable part of the population worldwide. Billions of people have reached a state of mind where they don’t trust their government anymore.5 Seen from a geographic point of view, symptoms of crisis are found nearly everywhere. The ‘Arab Spring’ was followed by a series of wars and civil wars, serious human rights violations and many millions of refugees. The internal situation is not better in Eritrea, South Sudan, Somalia, Yemen or Honduras. Venezuela and Argentina, once among the richer states of the world, face huge economic challenges, and neighbouring Brazil has gone through many years of recession and political turmoil. Russia and several East European countries are struggling with major economic and political problems in their post-communist phase. Japan finds it difficult to overcome decadelong stagnation, and to deal with the 2011 tsunami and ensuing nuclear disaster. And the temporary economic upswing several African countries have enjoyed lost its dynamism as soon as the prices of mineral resources collapsed, and partly due to very unusual droughts. Land grabbing is plaguing much of Africa, but also other parts of the world, leading to involuntary dislocations of millions of people and the related problems with refugees both within countries and abroad.6 The response of governments has been concentrated, at worst, on managing their own political image, and at best to treat the symptoms of the crisis, not the cause. The problem is that the political class in the whole world is strongly influenced by investors and by powerful private companies. This indicates that the current crisis is also a crisis of global capitalism. Since the 1980s, capitalism has moved from furthering the economic development of countries, regions and the world towards maximizing profits, and then to a large extent profits from speculation. In addition, the capitalism unleashed since 1980 in the Anglo-Saxon world, and since 1990 worldwide, is mainly financial. This trend was supported by excessive deregulation and liberalization of the economy (see Sect. 2.4). The term ‘shareholder value’ popped up in the business pages of the media worldwide, as if that was now the new epiphany and guardrail for all economic action. In reality, it served to narrow business down to short-term gains, often at the expense of social and ecological values. The myth of shareholder value has been effectively debunked in a recent book by Lynn Stout.7 A different, if related, feature of ‘disarray’ is the rise of aggressive, mostly rightwing movements against globalization in OECD countries, often referred to as populism. These have become overt through Brexit and the Trump victory in the United States. As Fareed Zakaria observes, ‘Trump is part of a broad populist

Chart, line chart

Description automatically generated

upsurge running through the Western world. … In most (countries), populism remains an opposition movement, although one that is growing in strength; in others, such as Hungary, it is now the reigning ideology’.8 This phenomenon of right-wing populism can be explained to an extent by the ‘trunk valley of the elephant curve’ (Fig. 1.1) 9 showing the decline of developed world middle classes, during a 20-year period. While more than half of the world’s population was enjoying over 60% income rises, OECD’s middle classes suffered losses caused mainly by the deindustrialization and job losses in major parts of the United States, Britain and other countries. In the United States, the median income increased by a meagre 1.2% since 1979. The stunning income growth on the left-hand side of the curve, the ‘back of the elephant’, lifting some two billion people out of poverty, was caused mainly by China’s and some other countries’ economic success. What remains invisible on the picture is the far end of ‘the trunk of the elephant’: The richest 1% of the world and, more revolting, the richest eight persons of the world now own as much wealth as the poorest half of the world population combined, a figure publicized by Oxfam during the 2017 World Economic Forum.10 The ‘elephant curve’ gives an incomplete picture for a second reason. The Oxford Poverty and Human Development Initiative (OPHI) has proposed a Multidimensional Poverty Index (MPI) going beyond just income and including ten indicators around health, education and living standards. Using that MPI, OPHI counts 1.6 billion people living in ‘multidimensional poverty’ in 2016 – nearly twice as many as the number of people living in extreme poverty measured by income alone.11 Thirdly, the interpretation of the curve requires an analysis of the people in each percentile group. In fact, they tend to move. And the curve does not distinguish those in Russia and East European countries who lost much of their income after 1990 from those in Detroit or middle England who, for very different reasons, also were among the losers.12 Another fact cannot be seen in the picture: the massive shift of money and income from the manufacturing and trade sectors to the financial sector.13 Bruce Bartlett, a senior policy advisor to both the Reagan and Bush administrations, argues that this ‘financialization’ of the economy is the cause of income inequality, falling wages and the poor performance. David Stockman, Reagan’s director of the Office of Management and Budget, agrees, describing our current situation as ‘corrosive financialization that has turned the economy into a giant casino since the 1970s’.14 Populist politicians in the OECD countries see themselves as speaking for the forgotten ‘ordinary’ people and for genuine patriotism, but they tend to fight and antagonize the people representing democratic institutions – what an irony! For the European Union (EU), the strongest trigger for populism has been the millions of refugees who came or would like to come to Europe from the Near East, from Afghanistan and from Africa. Even the most generous European countries have reached their own assumed limits for receiving these masses of refugees. The EU institutions were too weak (not too powerful, as they are depicted by the new nationalists) to deal with the ‘refugee crisis’, resulting eventually in an identity crisis in the EU. Once a success story of an entity ensuring peace and economic development, the EU has lost some of its unifying narrative. The populist right-wing movements or parties see and criticize the EU as the culprit for all kinds of undesired events. The irony is that continuing the success story would require more, not less, powers for the Union. The Union should be entrusted with border protection, a well-funded common asylum and refugee policy to deal with the refugee crisis and maintain the advantages of the Schengen agreement. And for the re-stabilization of the Euro, the EU or at least the Euro zone needs a common fiscal policy, as the new French President Emmanuel Macron is proposing. But it is these very measures of which nationalist populists are most afraid. The EU in its present form is not without shortcomings. Free market principles have come to dominate EU policymaking, leading to a subordination of other policies, like environment. Notably the UK wanted that priority, as it preferred to see the EU chiefly as a union for mutual trade. And the austerity policies pursued have blocked many benign investments and led to unnecessary suffering among tens of millions of Europeans. Such shortcomings, however, should never be used to put in question the overall objectives of the EU – a union of peace, the rule of law, human rights, cultural understanding and sustainability. Addressing the global crisis of democracy, the German Bertelsmann Foundation has published a 3000-page empirical report on progress (or lack thereof) on democracy and a social market economy, as measured by the Bertelsmann Transformation Index (BTI).15 Over the last few years, the report sees a consistent decay of such parameters as civil rights, free and fair elections, freedom of opinion and of press, freedom of assembly and separation of powers. Within the same time frame, the number of countries in which authoritarian, mostly religious, dogmas influence political decision making rose from 22% to 33%. That report was published before the assaults on democracy and civil rights that occurred in summer 2016 in Turkey or the Philippines. Symptoms of tyranny are spreading, including in some of the countries with a solid tradition of freedom and democracy.16 Let us briefly turn to a different kind of crisis. Well, not exactly a crisis but an unpleasant feature in an otherwise fruitful communication tool, the ‘social media’. Aside from being practical and useful for everyday arrangements and exchange of news and reasonable opinions, social media also have become vehicles for enhancing conflicts and vilification of mostly innocent individuals, and for spreading ‘post truth’ nonsense. Much of the contents of social media political conversation is selfenhancing political rubbish, as those media serve as ‘echo chambers’ for networks of like-minded frustrated citizens.17 An empirical study from China found that anger and indignation are the emotions that are most likely to get viral in the social media, meaning they are multiplied faster and stronger than other emotions.18 The Internet and the social media are also vehicles for ‘bots’ (short for robots) that can disrupt or destroy messages, multiply nonsense and create all kinds of mischief. There are dozens of types of malicious bots (and botnets) to harvest email addresses, to grab content of websites and reuse it without permission, to spread viruses and worms, to buy up good seats for entertainment events, to increase views for YouTube videos or to increase traffic counts in order to extract money from advertisers. A more frightening cause of disarray relates to terrorism. In earlier times, humanity’s violent conflicts occurred mostly between different countries. In recent times, systemic and at least partly religious conflicts prevail, using terror attacks with the explicit intention of making people feel insecure. During much of the twentieth century, religions remained quiet, non-aggressive and geographically confined to rather stable territories. This no longer is true. Partly because of globalized populations moving or being forced to leave their home territories, some factions of Islam have expanded geographically and are claiming strong influence over national states, for example, attacking countries like France with its tradition of laicism that does not permit religion to dominate politics. What tends to be underrepresented in the media is the positive role of religions. In Christian-dominated Europe, liberal and tolerant religion became part of the European identity a century after the Enlightenment successfully discredited the earlier doctrinaire, authoritarian and colonialist-missionary manifestations of the faith. During the Cold War, Christian goals of social cohesion helped build the system of ‘Western values’, often described as the social welfare state, or the ‘social market economy’ (for its partial demise, see Sect. 2.4). With a view towards leading Islam into an equally benign and co-operative social role, some Islamic scholars, such as Syrian born Bassam Tibi, call on Muslims in Europe to integrate into democratic society.19 Tibi, however, is not popular among radical Muslims, to put it mildly. But to understand the radicalization of Islam, one must not underestimate the role played by the West, in particular the United States, in interfering with Near Eastern states. Some would say that the troublesome situations mentioned so far, the recurring topics of media headlines, are only the surface of our world’s ‘disarray’. Deeper and more systemic problems include the breath-taking speed of technological development that may very easily run out of control. One trend is digitization that potentially threatens millions of jobs (see Sect. 1.11.4). Another trend or development can be observed in the biological sciences and technologies. The enormous acceleration of genetic engineering through the CRISPR-Cas9 technology20 is causing fears of monster creation or the extinction of species or varieties not seen as valuable under human utilitarian criteria. Generally, a non-specific feeling is spreading that ‘progress’ has scary sides and that the genie may already have left the bottle (see Sect. 1.11.3). No doubt there is a need to analyse and understand the symptoms and roots of the variety of crises, political, economic, social, technological and environmental. It is also important to recognize the extent to which people perceive the various phenomena of disarray and feel disoriented, and to recognize that the reality and the feelings of disarray have a moral and even religious dimension. 1.1.2 Financialization: A Phenomenon of Disarray An important part of the disorientation relates to financial markets. Historians will look back at the last 30 years with concern, when looking at the explosion in bank balance sheets, backed up by declining levels of equity and massive borrowing. One of the results was a temporary private-sector-led boom. The other was a massive increase in the world’s financial sector (finance, insurance, real estate – FIRE), often called financialization, and subsequently the financial crisis of 2008–2009. Excessive risk-taking developed into a crisis that was close to bringing the whole financial system to a halt. When the bubble burst, many governments were forced to step in with broad support programmes. Governments caught by the new mind-set (see Sect. 2.4) were intimately involved in all of this. True, there are many examples of serious malpractices within the private financial sector. But had it not been for the systematic deregulation of the banks by governments, with the purpose of stimulating economic growth by issuing more debt, the situation would have been radically different. The causes behind the crisis were many and varied: – Excessive lending by the banking industry – Lack of action on the part of regulators and central banks to stop (i) excessive lending, (ii) the spread of exotic financial instruments (synthetic assets and bonds, collateralized mortgage obligations/CMOs, structured debt issues, etc.) and (iii) pure speculative transactions – Opaque tax havens, and the absence of a binding legal framework that is accepted and implemented by the international community, in general, and the major jurisdictions and financial centres – Securitization and distribution by investment banks and other financial actors of mortgage-related assets and investment vehicles transferring the credit risk from the original lender to the ultimate bondholders – Failure by some rating agencies and auditing firms to properly assess and report the inherent risks posed by many of the financial products A deeper analysis is presented by economists Anat Admati and Martin Hellwig21 about the main causes behind the financial crisis. Western banks borrowed far too much with far too little equity in their balance sheets to act as a buffer if things went wrong in their business – from trading in the multitrillion-dollar derivatives markets to often reckless lending on real estate. In the decades following the Second World War, banks operated with between 20% and 30% of their liabilities as equity. By 2008, that had shrunk to just 3%. Banks obviously believed that they had invented instruments that removed the risk, allowing them to run their banks with a tenth of the buffer they had before. It proved to be very unrealistic. But they counted with the state to underwrite their risks. Bankers have enriched themselves spectacularly in the process. They made themselves ‘too big to fail’ – and too big to jail. The 2008 financial crisis was mostly caused by that irresponsible greed.22 Yet, in 2009, not only did bankers avoid criminal prosecutions and receive hundreds of billions in government bailouts, but some still paid themselves record bonuses. At the same time, almost nine million households in the United States had to abandon their homes when the value of their houses plummeted and they could no longer service the adjustable-rate mortgages – the so-called foreclosure crisis.23 Financialization refers to the dominance of the financial sector in the global economy and the tendency for accumulated profits (and leverage) to flow into real estate and other speculative investment. Debt is an intrinsic element in this process. In the United States, for example, both household debt and private sector debt more than doubled relative to GDP between 1980 and 2007.24 The same is true for most OECD countries. At the same time, ‘the value of financial assets grew from four times GDP in 1980 to ten times GDP in 2007 and the finance sector’s share of corporate profits grew from about 10% in the early 1980s to almost 40% by 2006’.25 Adair Turner, chair of the UK’s Financial Services Authority in the years following the 2007–2008 crisis, regards unchecked private credit creation as the key system fault that led to that crisis with its devastating consequences.26 From this follows that the financial sector constitutes a significant and increasing risk factor in the economy. The degree of financialization varies from country to country but the increase in the power of finance is general. The current finance sector evolved in the context of the deregulation that gathered pace from the late 1970s and expanded dramatically after the 1999 removal of the separation between commercial and investment banking in the United States.27 This barrier had been put in place in 1933 by the Roosevelt administration in response to the Wall Street Crash of 1929, when a period of rampant credit creation and financial speculation collapsed. Similar speculation preceded the crisis of 2007–2008: The face value of financial products reached US$640 trillion in September 2008, 14 times the GDP of all the countries on earth.28 Lietaer et al.29 compare speculation with ordinary money transfers paying for goods and services: ‘In 2010, the volume of foreign exchange transactions reached $4 trillion per day’, which does not even include derivatives. In comparison, ‘one day’s exports or imports of all goods and services in the world amount to about 2% of those $4 trillion’. Transactions not paying for goods and services, almost by definition are speculative. Such financial products and transactions, the authors continue, lead regularly to monetary crashes, sovereign debt crises and systemic crashes with an average of more than ten countries in crisis every year. One of the consequences of this development is that a significant part of economic growth has been distributed to the wealthy, as mentioned with the new Oxfam figures in the previous subchapter. Practices within the financial sector demonstrate a disregard for the impact they have on both people and the planet. That includes a distinct short-termism, the ratio of banks’ reserves to their loans, the ratio of banks’ lending that support the real economy versus speculation in property and derivatives, unchecked credit creation – in fact money creation – and the failure to account for long-term climate and environmental risks. In the words of Otto Scharmer at MIT,30 ‘We have a system that accumulates oversupply of money in areas that produce high financial and low environmental and social returns, while at the same an undersupply of money in areas that serve important societal investment needs’. The failure to account for environmental risks means that the pressure on already scarce natural resources accelerates – trees are felled, waterways polluted, wetlands drained and the exploitation of oil, gas and coal accelerating, as long as there is demand. It also means that huge savings, among them pension funds, are locked into investments in fossil-based assets. Such assets are increasingly looked upon as high-risk assets (see Sect. 3.4).

#### Vote negative for proletarian internationalism -- only an organized global revolutionary struggle can overcome the destruction of capitalism.

Anastasi et al, 18 (editorial collective of Viewpoint Magazine, a militant research collective working to dialectically bring theory and practice into dialogue by studying cycles of struggle. Alphabetically, members of the editorial collective are as follows: Andrew Anastasi, graduate student in Sociology at CUNY; Cinzia Arruzza, Associate Professor of Philosophy at the New School for Social Research; Robert Cavooris, UC Santa Cruz graduate student and union representative, History of Consciousness Department; Maya Andrea Gonzalez, communist and revolutionary feminist in the Bay Area, graduate student in the Department of History of Consciousness at UC Santa Cruz; Asad Haider, Assistant Professor of Philosophy @ The New School, founding editor of Viewpoint Magazine, PhD in History of Consciousness Department @ UC Santa Cruz; Shuja Haider, widely-published writer and musician based in Brooklyn; Bue Rübner Hansen, writer and activist researcher in the Britain, Barcelona, and in migrant and refugee solidarity movements, PhD from Queen Mary University; Patrick King, graduate student at UC Santa Cruz; Rosa Lee, communist organizer and member of the Viewpoint editorial collective; Ben Mabie, managing editor at Viewpoint and editorial assistant at Verso Books, UCSC graduate; Sarah Mason, member of the Viewpoint editorial collective; Liz Mason-Deese, Assistant Professor, Department of Geography and Geoinformation Science, George Mason University; Dave Mesing, PhD student in Philosophy @ Villanova University; Magally Miranda-Alcazar, Eugene Cota-Robles Fellow and a Ford Foundation Predoctoral Fellow, PhD student in Chicana/o Studies @ UCLA; B.A. from the University of California, Santa Cruz (magna cum laude) with a double major in Community Studies and Feminist Studies, and has been published in The Nation, Verso and the New Left Review; Salar Mohandesi, Assistant Professor of History @ Bowdoin; Gavin Mueller, Lecturer in Media Studies at the University of Amsterdam, former contributing editor @ Jacobin; Evan Calder Williams, writer, translater, and artist, teaches theory at the Center for Curatorial Studies at Bard College and film production at Cooper Union, PhD in Literature from the University of California Santa Cruz and was a Fulbright Fellow in Italy for his research on cinema, industry, and revolt. “Internationalism against Imperialism,” *Viewpoint Magazine*, Issue 6, February 1, 2018, <https://www.viewpointmag.com/2018/02/01/internationalism-against-imperialism/>)

The challenge of reactivating an effective proletarian internationalism is made even more urgent by the aggressive rise of right-wing nationalisms, which have taken a range of organizational and ideological guises. The clarified ideological form of this rightward shift is an emboldened “possessive nationalism” in the North, which revolves around restrictive immigration and trade policies, as responses to the perceived erosion of territorial logics of sovereignty, and the hybridization of the ethno-national community.10 Any prolonged combat against these nativist impulses – especially as they seep into social-democratic or left-liberal parties in Europe and the United States – will need to reinforce the link between migration and imperialism, the former in many ways constituting the reflux of the latter. Here we might center the rich legacy and actuality of migrant struggles for communist politics, and how questions of mobility, control, and dispossession are now at the core of imperialist dynamics. The political and social, informal and formal spaces of migration remain an open field for investigation. As Etienne Balibar noted over 40 years ago, “the concrete knowledge of the causes and effects of immigration is a two-way guiding thread towards an understanding of imperialism,” a methodological linkage which “renders internationalism, more than ever, the very condition of struggles for workers’ liberation.”11 This raises the practical necessity of reconsidering the tactical repertoire and strategic horizons of anti-imperialism. The nearly two-decades-long “War on Terror” – a euphemism for a war on human welfare in the Middle East and a war against Muslims at home – has proven to be a difficult nub for anti-war and anti-militarist activism in “the belly of the beast,” particularly as U.S. violence, amidst ever-shallower domestic hegemony, takes forms other than that of U.S. boots on the ground. The fading – or destruction – of the anti-war movement after 2005, following massive demonstrations against the invasion of Iraq which featured considerable grassroots mobilization, is a critical episode to reflect upon. The ubiquity of manned and unmanned aerial bombardment, the diffuse and often cloaked nature of counterinsurgency operations, the multiplication of U.S. proxies, and dense financial ties have rendered the military conflicts of U.S. empire, perhaps the most visible manifestation of imperialism, an asymmetrical yet constant presence. Any sustained fight against it must be coordinated around several fronts. Recent experiences of mass protest show that a powerful anti-war movement, if it is to reappear, would do so in an altered shape and in close relation to other insurgent forces in society, an extension of their discursive and strategic reach. The high level of organized resistance to militarized border security and repressive immigration policies, the environmentalist/anti-extractivist campaigns around Standing Rock and elsewhere, and the nascent coalitions and activist milieus that have been fortified through the International Women’s Strike initiatives (resonant with calls from Latin America for a new feminist international) indicate a real potential to build a “popular anti-imperialism” from grounded social struggles, connecting the sites of contestation across neo-colonial and imperial frontiers. One can see how this changes the aims and targets of alter-globalization movements, exemplified in the militancy of summit-hopping demos that directly confront leading economic and financial bodies, or in the parallel institution-building and transnational networking of civil society organizations involved in the World Social Forums.12 A more adequate approach to questions of coordination and solidarity across borders would have to probe how political organization is tied to material practices of translation, and recognize that even localized concerns often involve the commonalities and divisions of the global labor force.13 The mutations of class struggle, where the wage-earning proletariat has given way to more diverse social alliances and associations of what Göran Therborn calls the “plebeian strata” or “popular classes,” has provided glimpses of what anti-imperialist mobilization could look like: new strategies of threading upsurges of disruption, combination, and antagonism as they extend over an unstable terrain.14 Today, it is necessary to re-situate the concept and question of imperialism. We agree with Lenin when we recognize that no revolution, even a national one, is possible without grasping the effects of imperialism on any local articulation of the working class. And we further agree that, of course, no national revolution would be sufficient for the goal of communism. In short, we see imperialism as both an obstacle to and enemy of internationalism and we in turn view internationalism as a position to be composed in working class struggle itself. Thus, at the risk of simplifying our approach, we propose that to examine imperialism today is to bring it into the realm of class composition. This can involve no disavowal of the complicated history of Marxism and popular struggle with regard to imperialism, nor a simple repetition of any one of its moments. In our sixth issue of Viewpoint, we instead seek out the possibility of an encounter, bringing together historical accounts, artefacts of struggle, and theoretical interventions past and present. Thus we neither “endorse” all of the positions represented here nor reject those that might be absent from this issue, which is a situated engagement with the problem of opposing imperialism from within American empire; we are proud to offer these contributions as material for the long-term work of thinking and struggling against imperialism in the 21st century.

## 3

### DA

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

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

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

#### The affs wholesale attack on secondary patents ruins innovation---prefer contingencies that solve evergreening.

Holman 18 [Christopher; 9/21/18; Professor at the University of Missouri-Kansas City School of Law, where his primary research focus lies at the intersection of intellectual property and biotechnology; “*Why Follow-On Pharmaceutical Innovations Should Be Eligible For Patent Protection*,” Intellectual property watch, <https://www.ip-watch.org/2018/09/21/follow-pharmaceutical-innovations-eligible-patent-protection/>] Justin

Why Protect Follow-On Innovation? The attack on secondary pharmaceutical patents is based in part on the flawed premise that follow-on innovation is of marginal value at best, and thus less deserving of protection than the primary inventive act of identifying and validating a new drug active ingredient. In fact, follow-on innovation can play a critical role in transforming an interesting drug candidate into a safe and effective treatment option for patients. A good example can be seen in the case of AZT (zidovudine), a drug ironically described in the Guidelines as the “first breakthrough in AIDS therapy.” AZT began its life as a failed attempt at a cancer drug, and it was only years later that its potential application in the fight against AIDS was realized. Follow-on research resulted in a method-of-use patent directed towards the use of AZT in the treatment of AIDS, and it was this patent that incentivized the investment necessary to bridge the gap between a promising drug candidate and a safe, effective, and FDA-approved pharmaceutical. Significantly, because of the long lag time between the first public disclosure of AZT and the discovery of its use in the treatment of AIDS, patent protection for the molecule per se was unavailable. In a world where follow-on innovation is unpatentable, there long after the initial synthesis and characterization of a pharmaceutically interesting chemical compound. The inventions protected by secondary patents can be just as critical to the development of drugs as a patent on the active ingredient itself. The Benefits of Follow-On Innovation The criticism of patents on follow-on pharmaceutical innovation rests on an assumption that follow-on innovation provides little if any benefit to patients, and merely serves as a pretense for extending patent protection on an existing drug. In fact, there are many examples of follow-on products that represent significant improvements in the safety-efficacy profile. For example, the original formulation of Lumigan (used to treat glaucoma) had an unfortunate tendency to cause severe hyperemia (i.e., redeye), and this adverse event often lead patients to stop using the drug, at times resulting in blindness. Subsequent 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 research led to a new formulation which largely alleviated the problem of hyperemia, an example of the type of follow-on innovation that significantly benefits patients but that which would be discouraged by a patent regime that does not reward follow-on innovation. Follow-on pharmaceutical innovation can come in the form of an extended-release formulation that permits the drug to be administered at less frequent intervals than the original formulation. Critics of secondary patents downplay the significance of extended-release formulations, claiming that they represent nothing more than a ploy to extend patent protection without providing any real benefit to patients. In fact, the availability of a drug that can be taken once a day has been shown to improve patient compliance, a significant issue with many drugs, particularly in the case of drugs taken by patients with dementia or other cognitive impairments. Extended-release formulations can also provide a more consistent dosing throughout the day, avoiding the peaks and valleys in blood levels experienced by patients forced to take an immediate-release drug multiple times a day. Other examples of improved formulations that provide real benefits to patients are orally administrable formulations of drugs that could previously only be administered by more invasive intravenous or intramuscular injection, combination products that combine two or more active pharmaceutical agents in a single formulation (resulting in improved patient compliance), and a heat-stable formulation of a lifesaving drug used to treat HIV infection and AIDS (an important characteristic for use in developing countries with a hot climate). “Evergreening” – an Incoherent Concept Drug innovators are often accused of using secondary patents to “evergreen” the patent protection of existing drugs, based on an assumption that a secondary patent somehow extends the patent protection of a drug after the primary patent on the active ingredient is expired. As a general matter, this is a false assumption — a patent on an improved formulation, for example, is limited to that improvement and does not extend patent protection for the original formulation. Once the patents covering the original formulation have expired, generic companies are free to market a generic version of the original product, and patients willing to forgo the benefits of the improved formulation can choose to purchase the generic product, free of any constraints imposed by the patent on the improvement. Of course, drug innovators hope that doctors and their patients will see the benefits of the improved formulation and be willing to pay a premium for it, but it is important to bear in mind that ultimately it is patients, doctors, and third-party payers who determine whether the value of the improvement justifies the costs. Of course, this assumes a reasonably well-functioning pharmaceutical market. If that market breaks down in a manner that forces patients to pay higher prices for a patented new version of a drug that provides little real improvement over the original formulation, then it is the deficiency in the market which should be addressed, rather than the patent system itself. For example, if a drug company is found to have engaged in some anticompetitive activity to block generic competition in the market for the original product once it has gone off patent, then antitrust and competition laws should be invoked to address that problem. If doctors are prescribing an expensive new formulation of a drug that provides little benefit compared to a cheaper, unpatented original product, then that is a deficiency in the market that should be addressed directly, rather than through a broadside attack on follow-on innovation. In short, if is found that secondary patents are being used in a manner that creates an unwarranted extension of patent protection, it is that misuse of the patent system which should be addressed directly, rather than through what amounts to an attack on the patent system itself.

### 1NC – AT: Underview

#### Reject 1AR theory- A] 7-6 time skew means it’s endlessly aff biased B] I don’t have a 3nr which allows for endless extrapolation C] 1AR theory is skewed to the aff because they have a 2ar judge psychology warrant.

#### Reasonability on 1AR shells –it checks 2AR sandbagging by preventing really abusive 1NCs while still giving the 2N a chance.

#### DTA on 1AR shells - They can blow up a blippy 20 second shell to 3 min of the 2AR while I have to split my time and can’t preempt 2AR spin which necessitates judge intervention

# Case

## 1NC – Solvency

### 1NC – AT: WTO Jurisdiction

#### The WTO can’t enforce the aff- causes circumvention.

Lamp 19 [Nicholas; Assistant Professor of Law at Queen’s University; “What Just Happened at the WTO? Everything You Need to Know, Brink News,” 12/16/19; <https://www.brinknews.com/what-just-happened-at-the-wto-everything-you-need-to-know/>] Justin

Nicolas Lamp: For the first time since the establishment of the WTO in 1995, the Appellate Body cannot accept any new appeals, and that has knock-on effects on the whole global trade dispute settlement system. When a member appeals a WTO panel report, it goes to the Appellate Body, but if there is no Appellate Body, it means that that panel report will not become binding and will not attain legal force.

The absence of the Appellate Body means that members can now effectively block the dispute settlement proceedings by what has been called appealing panel reports “into the void.”

The WTO panels will continue to function as normal. When a panel issues a report, it will normally be automatically adopted — unless it is appealed. And so, even though the panel is working, the respondent in a dispute now has the option of blocking the adoption of the panel’s report. It can, thereby, shield itself from the legal consequences of a report that finds that the member has acted inconsistently with its WTO obligations.

### 1NC – Diff Sectors

#### Companies will just obtain a patent in a different sector.

Thomas 15 [John R; Visiting Scholar, CRS; “Tailoring the Patent System for Specific Industries, Congressional Research Service,” CRS; 2015; <https://crsreports.congress.gov/product/pdf/R/R43264/7>] Justin

In view of the concerns noted above, commentators have gone so far to say that “it has become increasingly difficult to believe that a one-size-fits-all approach to patent law can survive.”75 To the extent the current patent system creates a blanket set of rules that apply comparably to distinct industries, it likely over-encourages innovation in some contexts and under-incentivizes it in others.76 Further, some observers have asserted that the need of firms to identify and access the patented inventions of others may differ among industries.77 As a result, the case can be made that distinct industrial, technological, and market characteristics that exist across the breadth of the U.S. economy compel industry-specific patent statutes. However, others have questioned the wisdom and practicality of such line-drawing.78 The following concerns, among others, have been identified:

• Over its long history, the U.S. patent system has flexibly adapted to new technologies such as biotechnology and computer software. Legislative adoption of technology-specific categories may leave unanticipated, cutting-edge technologies outside the patent system.79

• Defining a specific industry or category of technologies may prove to be a contested proposition.

80 • Over time, new industries may emerge and old industries may consolidate. The dynamic nature of the U.S. economy suggests greater need for legislative oversight within a differentiated patent regime.

81 • Even if an industry or technology remains relatively stable, the innovation environment within it might change. For example, technological or scientific advances might open new possibilities for research and development within hidebound industries—but also increase expense and risk for those firms.

82 • Distinct patent rights among industries or technologies may lead to strategic behavior on behalf of patent applicants. For example, a computer program that controls a fuel injector within an automobile could possibly be identified as either an automobile-related or a computer-related invention.

83 •The legislative effort to enact sector-specific patent laws may provide an opportunity for politically savvy firms to exert more lobbying and political power, at the possible expense of less sophisticated firms.

### 1NC – AT: Feldman

#### 1] Indict their Feldman evidence – the underlying research ignores key factors

Risch 17

[Michael; “Data for the Evergreening Debate,” Written Description; 11/21/17; <https://writtendescription.blogspot.com/2017/11/data-for-evergreening-debate.html>] Justin -recut CAT

The Orange Book is a list of drugs and pharmaceuticals that the U.S. Food and Drug Administration ([FDA](https://www.investopedia.com/terms/f/fda.asp)) has approved as both safe and effective. Although it is commonly called the Orange Book, its formal name is Approved Drug Products with Therapeutic Equivalence Evaluations.

**Feldman and Wang** argue that the Orange Book has been used by companies to "evergreen" their drugs - that is, to extend exclusivity beyond patent expiration. The paper is on SSRN and the abstract is here:

Why do drug prices remain so high? Even in sub-optimally competitive markets such as health care, one might expect to see some measure of competition, at least in certain circumstances. Although anecdotal evidence has identified instances of evergreening, which can be defined as artificially extending the protection cliff, just how pervasive is such behavior? Is it simply a matter of certain bad actors, to whom everyone points repeatedly, or is the problem endemic to the industry?

This study examines all drugs on the market between 2005 and 2015, identifying and analyzing every instance in which the company added new patents or exclusivities. The results show a startling departure from the classic conceptualization of intellectual property protection for pharmaceuticals. Key results include: 1) Rather than creating new medicines, pharmaceutical companies are recycling and repurposing old ones. Every year, at least 74% of the drugs associated with new patents in the FDA’s records were not new drugs coming on the market, but existing drugs; 2) Adding new patents and exclusivities to extend the protection cliff is particularly pronounced among blockbuster drugs. Of the roughly 100 best-selling drugs, almost 80% extended their protection at least once, with almost 50% extending the protection cliff more than once; 3) Once a company starts down this road, there is a tendency to keep returning to the well. Looking at the full group, 80% of those who added protections added more than one, with some becoming serial offenders; 4) The problem is growing across time.

I think the data the authors have gathered is extremely important, and I think that their study sheds important light on what happens in the pharmaceutical industry. That said, as I explain below, my takeaways from this paper are much different from theirs. My concerns are fourfold. First, even assuming that every one of the efforts listed by the the study were an attempt to evergreen, I have no sense for whether evergreening actually happened. This study doesn't provide any data about generic entry or pricing. For example, the study describes 13 listings for OxyContin, but I'd bet dollars to donuts that there was plenty of generic oxycodone available. Similarly, many of the new listings are changes from Drug 1.0 to "new and improved!" Drug 2.0. This, of course, has been criticized as anti-competitive (since generics rely on auto-substitution laws), but the study presents no data about whether insurers refuse to pay for Drug 2.0 and instead require the generic, nor does it explain why generics can't do their own advertisements to get doctors to prescribe Drug 1.0. Second, many of these listings and the new patents that go with them are for advances, like extended release and dissolvables. These can be critically important advances, and they are preferred by consumers. Thus, one person's "evergreening" is another person's innovation. I take extended release drugs (and expensive generic) to avoid side effects and I gave my son dissolvable Prevacid when he wouldn't stop crying with GERD (and was glad for it). Without consumer data or patent data, it is impossible to tell just how much evergreening is going on (or how harmful it is). Now, if these patents are obvious because making them dissolvable or extended is easy, I'm all for stripping protection - but that's a different issue. Third, the article speaks of orphan drug approvals as if they are a bad thing. This made me bristle, quite frankly. My mother has an extremely rare autoimmune disease that is very painful. I often wondered, isn't there some incentive to develop drugs to treat it? Turns out there is, and though she got no relief, apparently a bunch of other rare diseases did, and that's the whole point behind orphan drug exclusivity. Concern about this exclusivity seems misguided anyway. If it turns out that drug companies are gaming it and nobody actually needs the drug, then the the loss is not too large, because it's a small population and nobody needs the generic anyway. And if it turns out that they do need it, the Orange Book only limits labeling, and doctors are free to prescribe a generic for off-label use. Without evidence that doctors refuse to do so, there's no real evidence that Orphan exclusivity does much harm. In another personal story, my wife was prescribed a generic drug in a different formulation than the patented tablet for off-label use. Fourth, and most generally, the article speaks of new patents as if there is no innovation. New use discoveries are important. Many of our most important drugs are not for their original uses. As far as I know, generics are not barred from finding new uses and patenting them, either, though admittedly their hands are tied for patient use. So, where the authors see evergreening, I see innovation. Maybe. Maybe it's obvious. But we can't tell that from this high level, and I'm not ready to write it all off as evergreening. It is telling that I was able to provide four personal stories about how supposed evergreening efforts benefited, would have benefited, or did not increase costs for my family or me (and thankfully none of them involved oxycodone).

## 1NC – Advantage

### 1NC – Evergreening

#### Prefer legal studies.

Parker and Mooney 7 [Scott and Kevin; “Is ‘evergreening’ a cause for concern? A legal perspective,” Journal of Commercial Biotechnology; 2007; <https://link.springer.com/article/10.1057/palgrave.jcb.3050066>] Justin

THE LEGAL BACKGROUND The patent system provides an incentive for companies to incur the cost and risk of research by providing the time-limited exclusive right to commercialise a patented product. At the heart of the patent system in the UK (and all other fully TRIPs compliant countries) is the requirement that to qualify for the monopoly right that the patent confers (20 years from the date of filing the patent application) the invention covered by the patent must be novel, non-obvious (ie it involves an inventive step) and capable of industrial application (‘utility’ or ‘usefulness’ in the US). The novelty and inventiveness of the patent is evaluated against the ‘state of the art’, which consists in general of every item of information which has ever been made available to the public by any kind of publication, or by use, anywhere in the world, at any point in time before the first filing date of the patent. It is a basic principle of patent law that once details of a product have entered the public domain (by being published anywhere without patent protection, or when any patents for the product or proposal expire or lapse), then everyone has freedom to use that information and any obvious developments of it. So before assuming that any new development relating to a known compound can be patented, we have to ask: 1 Is this new? Any previous publication or use, no matter how obscure, of the same invention destroys novelty and prevents a patent being issued or, if issued in ignorance of such a publication, this will subsequently cause the patent to be declared invalid if sought to be enforced. 2 Is there an inventive step? A patent cannot be granted for anything which is simply an obvious development or variant on any individual piece of information which is part of the state of the art. It is no answer that the piece of information in question may never have come to the attention of the fictitious ‘person skilled in the art’ who is central to any determination of ‘obviousness’. 3 Is there a proposed industrial application for the invention (in the broad sense of having some useful purpose)? The invention does not have to demonstrate an improvement on what is already known, but it cannot be speculative. It must have a use. For example, a DNA sequence for a recombinant gene fragment with a well-defined function is a patentable invention whereas a DNA sequence alone without any indication of function or of its useful attributes is not. 4 Does the patent describe how to put the invention into effect? The patent must be ‘enabling’; it must add to public knowledge, and contribute in its own right to the state of the art. In this way each new patent moves the frontier of the state of the art forward and makes it more difficult to find improvements which are neither old nor obvious. This disclosure enables third parties to implement the invention once the patent has expired and, is the consideration (in the legal sense) for the monopoly right granted by a patent. HOW THE PATENT SYSTEM DEALS WITH ‘EVERGREENING’ The criteria of patentability set out above apply equally to all inventions from the most basic mechanical patent to the most complex microelectronic or biotechnological invention. Similarly patent law does not distinguish between the invention of a wholly new product and inventions relating to improvements upon an existing product. The same criteria for patentability apply. ‘Double patenting’ is prohibited. That is to say the same invention cannot be covered by more than one patent. Thus for an improvement upon an existing pharmaceutical product to be patentable in its own right it will need to satisfy the criteria of novelty and non-obviousness taking into account the earlier product and all that is known about it in the public domain at the time that the second patent is applied for. If a patent is granted in respect of this improvement it will only cover the improvement to which it relates and will not extend to the originator product. That is to say a patent for a new product in a class will always be broader than any subsequent patent covering an improvement, modification or derivative of that product and so the exclusivity granted is in broad terms commensurate with the scope of the scientific advance that it reflects. An important corollary to the prohibition on ‘double patenting’ is that a patent covering an improved version of a pharmaceutical (or any other) product does not preclude a generic company from copying all forms of the originator product once the patents protecting these forms have expired. For example, if a company selling a patented pharmaceutical reformulates that product as a syrup for paediatric administration and then patents the new formulation, generic competition to the original adult formulation will be possible once the patents covering it expire or are invalidated. The existence of the patent on the paediatric formulation will not delay or prevent generic competition on the original formulation. The innovator company will, however, continue to have the exclusive right to sell the paediatric formulation for the remainder of the life of the patent covering this specific improvement. If in the above example the improvement made is not a paediatric formulation but a slow release formulation that allows once daily dosing and so improves patient compliance as a result of increased convenience, doctors and patients will have a choice between generic versions of the original formulation or the new once-daily product once any patent on the original formulation expires. The patents on the slow release formulation will not delay or prevent marketing of the original formulation. The market will then decide whether the benefits offered by the improved formulation make it worth paying for in the face of cheaper versions of the original product. The answer to this question will inevitably vary from market to market and between different patient populations. Either way the patient would appear to benefit from the increased choice available. A simple and further example of this is ibuprofen. The supermarket shelf carries premium-priced ibuprofen formulations which typically are quicker acting or easier to take than the traditional tablet. These formulations may be patent protected. Customers can, however, decide for themselves whether the added benefit is worth the extra cost. The patents do not prevent anybody from buying the ordinary, cheapest kind of tablet. Reference to patents covering the colour and scoring of tablets has been made in several articles criticising the pharmaceutical industry (without the specific patents that are complained of being identified).4 It is informative to consider how the patent system would apply to such ‘developments’. To the best of the authors’ knowledge no patents have ever been granted for the colour of pharmaceutical products. In fact, since UK patent law (and most others) expressly excludes the patenting of ‘aesthetic creations’ the colour of a pharmaceutical product could only ever be patentable if either: (a) it could be established that the colour itself produces a technical effect, such as a therapeutic benefit caused by increased compliance, that is novel and not obvious; or (b) that the means of obtaining that colour, the manufacturing process of colouring the tablet, is itself novel and not obvious. It goes without saying that for a ‘pink pill’ patent application the technical effect, novelty and inventiveness would be scrutinised carefully. Nevertheless, the application would be looked at on its own facts and applying the patentability criteria described above. Similarly, as regards the scoring of tablets, the same standard of patentability and scrutiny must be satisfied. It would need to be established that tablets had never been scored in this way before and that to do so was not an obvious departure from what has gone before. Without further investigation it should not be assumed that such an invention would be of no value to patients (eg it could be that compliance among children would be improved if the tablet is more cleanly cut as a result of the means of scoring employed). There are plenty of examples of developments (reformulations, new salts, combinations and the like) that have real therapeutic benefit but which at first blush may seem trivial. Again, the more minor that a variation is (eg a pink tablet or means of scoring the tablet) the more narrow the relevant patent protection will be and the easier it should be for a competitor to design around the patent without needing to seek to invalidate it. For example, if a patent is (or has been) granted that covers a particular colour of tablet or a particular means of scoring such tablet then such a patent would not stop a competitor from marketing (respectively) a different colour tablet or a tablet that is not scored or that is scored in a different way. In summary, therefore, the patent system is inherently adapted to reflect how much innovation in fact takes place (by way of improvements to existing technology) and to prevent ‘evergreening’. It allows the use of ‘old’ technology while protecting (and thus providing incentives for) improvements to that technology. Another factor to be taken into account in any debate on the patenting of ‘minor variations’ is that it is not only the company that owns the patents covering the originator product that can patent improvements thereto. Other companies (including generics) can (and do) do this, with the consequence that there may be a number of companies having similar products (some of which may for a variety of reasons be better suited to particular patients) and healthy competition in the marketplace. ‘STRATEGIC PATENTING’ A related charge that is sometimes made against innovator companies is that they file numerous patents on multiple attributes of a single product so as to create a ‘patent thicket’ that so complicates third-party research that it strangles innovation, or that they are guilty of what is sometimes referred to as ‘strategic patenting’.5 Implicit in these charges is that the only reason for filing these patents is maintenance of market share for as long as possible after the expiry of the patents covering the originator product itself. This is a serious charge that deserves to be looked at in more detail. Of course, pharmaceutical and biotechnology companies (like companies in all other R&D-based industries) have patenting strategies. In no other industry is there any suggestion that companies should restrict themselves to patenting inventions that meet some higher standard over and above the basic criteria for patentability or that companies should not seek protection for certain types of technological advance or that exceeding a certain number of patents in a technical area is per se reprehensible. When one considers that intellectual property rights are the life-blood that propels pharmaceutical advances in the private sector (and to an increasing extent in the public sector as well) and takes into account the sums that are typically spent on a new product during the 10–15-year-period from discovery through pre-clinical and clinical trials to regulatory approval and market launch, any company that did not do all that it could to protect its inventions would be acting negligently towards its shareholders. On the subject of patenting strategies in the pharmaceutical industry the UK Patents Court judge Mr Justice Jacob (now Lord Justice Jacob) said in the case of Synthon v SmithKline Beecham ‘I ask myself whether SB have done anything blameworthy…and I cannot see that they have. On the contrary, so far as I can see, they have employed competent and careful patent agents to obtain for them the best patent position which they think they can get. It may be good, it may be bad, but they are doing their job and I see no criticism whatever in the conduct of SB’.6 If one accepts that the nature of pharmaceutical and biotechnological innovation (as with other R&D based industries) is most often incremental and cumulative then it follows that the patent system should reflect this reality. This is indeed the case. As we have seen above, the patent system does not distinguish between ‘breakthroughs’ and ‘incremental improvements’ in terms of the patentability requirements that apply. At the same time a greater reward (a broader patent) is granted in respect of the ground breaking research than for inventions directed at solving further technical hurdles and optimisation of the initial invention. In the experience of the authors most of the patents that have been challenged by generic companies wishing to enter the market were applied for during the development of the originator product rather than once it has been established as a commercial success. This reflects the organic process of drug discovery and development and the time lag between drug discovery development, clinical testing and regulatory approval (ie that inventions are made in overcoming the various technical challenges faced during drug development). Nevertheless, some innovations are made at a later stage. For example, it may be that it is only after the product has been prescribed to a population of patients post-launch that it will become evident that further improvements need to be made to improve efficacy, deal with a compliance (or other) problem or expand the target patient population or disease indications. Such improvements may stem from greater experience of the product, problems unexpectedly encountered in particular patient populations or other advances made in the field. Given that the purpose of the patent system is to encourage innovation and (in the pharmaceutical sector) to lead to better medicines, it would be strange indeed if this incentive was removed or diminished once the first product of a particular type has been launched.

#### Evergreening is good---your authors misunderstand it.

Banana 19 [BananaIP; “DEMYSTIFYING THE EVERGREEN MYTH,” Executive Office of the President of the United States; 7/19/19—originally appeared 5/19/14; [https://www.bananaip.com/ip-news-center/chapter-iii-demystifying-evergreen-myth-comprehending-apprehension-apprehending-comprehension/]](https://www.bananaip.com/ip-news-center/chapter-iii-demystifying-evergreen-myth-comprehending-apprehension-apprehending-comprehension/%5d) Justin

Evergreening is like any other business strategy that market players would adopt to seek a competitive edge in the market. It doesn’t stop anyone from making the product claimed in the expired patent, but only makes sure that they can differentiate themselves from the other generic products through incremental inventions. More often than not, the R&D efforts and investments that go into the making of these incremental inventions can be very high and their results invaluable for treatment.

One of the rationales of the patent system is to incentivize innovation which is believed to lead to the progress in technology. A patent application is published 18 months after it is filed so as to ensure that the knowledge in the patent is made public for aspiring inventors to design around and build on it. Anyone, including the owner of an existing patent and their competitors, is free to invest in research in this direction as early as 18 months from the filing of such a patent. If a competitor files for an incremental patent, it is branded as innovation, but when a patent holder files for an incremental patent, it is looked upon as innovation leading to life cycle management or Evergreening.

In most parts of the world, life cycle management is considered as positive development. However, to the frustration of many pharmaceutical companies, symbolically represented by Bayer, life cycle management is quite a tricky business in India, thanks to the infamous Section 3(d) of the Indian Patent Act, often alluded to as the anti-evergreening law, which bears the burden of keeping a check on incremental pharmaceutical inventions that add no therapeutic value. Section 3(d) states that “the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance, or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus, unless such known process results in a new product or employs at least one new reactant” is not patentable.

### 1NC – AT: Radhakrishnan

#### Their Radhakrishnan ev is circular. The only evidence of a “Big pharma” conspiracy is that Pharma files a lot of secondary patents, which entirely begs the question of whether those patents are bad. And it doesn’t make any of the sweeping epistemological indicts implied by the tagline. The CP better solves because we have an independent judicial check that the patent really is non-obvious.

### 1NC – AT: Bio Weapons

#### No impact to bioweapon---multiple barriers.

Mueller 10—Chair of National Security Studies at the Mershon Center for International Security Studies and a Professor of Political Science at Ohio State University [John, *Atomic Obsession – Nuclear Alarmism from Hiroshima to Al-Qaeda*, Oxford University Press, Emory Libraries]

Properly developed and deployed, biological weapons could potentially, if thus far only in theory, kill hundreds of thousands, perhaps even millions, of people. The discussion remains theoretical because biological weapons have scarcely ever been used. For the most destructive results, they need to be dispersed in very low-altitude aerosol clouds. Since aerosols do not appreciably settle, pathogens like anthrax (which is not easy to spread or catch and is not contagious) would probably have to be sprayed near nose level. Moreover, 90 percent of the microorganisms are likely to die during the process of aerosolization, while their effectiveness could be reduced still further by sunlight, smog, humidity, and temperature changes. Explosive methods of dispersion may destroy the organisms, and, except for anthrax spores, long-term storage of lethal organisms in bombs or warheads is difficult: even if refrigerated, most of the organisms have a limited lifetime. Such weapons can take days or weeks to have full effect, during which time they can be countered with medical and civil defense measures. In the summary judgment of two careful analysts, delivering microbes and toxins over a wide area in the form most suitable for inflicting mass casualties-as an aerosol that could be inhaled-requires a delivery system of enormous sophistication, and even then effective dispersal could easily be disrupted by unfavorable environmental and meteorological conditions.

### 1NC – AMR

#### AMR won’t risk extinction---squo solves, but the impact’s inevitable

Biba 17 – New York City–based freelance science journalist [Erin, 6/8/2017, “How we can stop antibiotic resistance”, BBC, <http://www.bbc.com/future/story/20170607-how-we-can-stop-antibiotic-resistance>] AMarb

First, the entire world needs to get on board. Two years ago this essentially happened when member states of the WHO agreed to accept a Global Action Plan – by then, antibiotic resistance was a problem that had already been on the radar for many decades. The plan lays out extensive solutions and best practices that all countries can take to reduce resistance. “That’s historic,” says Sprenger. Before then, he says, the only people actively discussing how to reduce resistance were people within medical circles, for the most part. "95% of the worldwide population is now living in a country where they have developed a national action plan. All these countries have increased activities in education, training, and prevention control.” In the last couple of decades we’ve seen decreases in prescription to children in the US – Dr Katherine Fleming-Dutra Then, last year, the UN addressed the issue before the General Assembly – only the fourth time in history that a health issue was discussed there. And just this May the G20 leaders signed a declaration on global health that included tackling antibiotic resistance. So it’s definitely a grand challenge that world leaders are taking seriously. Much of the WHO action plan focuses on hospital stewardship and supervision. The CDC is currently working closely with American hospitals to provide guidelines and education for the safe and reasonable prescription of antibiotics. “We have made some progress,” says Dr Katherine Fleming-Dutra, an epidemiologist at the CDC. “In the last couple of decades we’ve seen decreases in prescription to children in the US. We have seen less progress in adults. The rate in adults has been relatively stable.” Once hospitals and physicians get on board with reducing prescriptions the next step is to change regulations around agriculture. Ten years ago the European Union banned antibiotics as growth promoters. And just this January, the US Food and Drug Administration removed growth from the indicated use of antibiotics on drug labelling. According to Dr William Flynn, deputy director for science policy at FDA’s Center for Veterinary Medicine, “There was a real recognition that this was something [farmers] needed to take seriously and respond to. We’re encouraged by the fact that they were engaging and working with us to find ways to make it work.” But other countries need to follow suit – as evidenced by the recent revelations about antibiotic resistance coming out of China. One of the most important steps in tackling resistance is tracking it. The CDC have set up a system called the National Antimicrobial Monitoring System (NARMS). “Surveillance for antibiotic resistant bacteria is a big part of our mission,” says Dr Jean Patel, deputy director of the office of Antimicrobial Resistance at the CDC. “We do this to measure the burden of infection and also characterise the types of resistance we see. This helps us strategise how best to prevent resistance.” We can only really slow the development of resistance. We’re not going to stop it completely. Even appropriate use of antibiotics does contribute to resistance – Amanda Jezek, Vice President for Public Policy and Government Relations, Infectious Diseases Society of America The CDC funds state health departments around the US (and coordinates with laboratories worldwide) to maintain a network of antibiotic resistant bacteria data and samples. Says Patel: “We can use this to give us national estimates of infection rates to see how bacteria are changing, test new drugs against bacteria, and we also have used the bacteria we collect through this to help with vaccine development.” Though, it should be noted, the continued success of the programme could be in jeopardy as US President Donald Trump’s proposed budget suggests cutting funds to the CDC by 17% (or $1.2 billion). But there are also some non-traditional methods being attempted. Emory University in Atlanta, Georgia, has established a unique Antibiotic Resistance Center. One of its main goals is to build diagnostic tests using mutated bacteria collected by the national surveillance system and physicians in their own clinic that can spot resistant bacteria. “The goal is to have scientists, clinicians, and epidemiologists all working together to address this issue. That’s something that hasn’t traditionally happened. There has been division between what the scientists and clinicians are doing,” says the centre’s director David Weiss. “I’m not a doctor. I need to know from the clinicians a lot of what they’re seeing on the front lines to help guide our research to be as relevant as possible.” A comprehensive, collaborative approach could work: last year, the National Health Service of England announced that in 2015, antibiotic prescribing reduced by 5.3% compared to 2014. Public Health England says that more responsible prescribing is key: it says that it advised the NHS in 2015 on the development of better practices that aim to slash prescriptions by 10% from 2013 to 2014 levels. Lastly, there need to be incentives that encourage the development of new antibiotics. The US National Institute of Health and the Biomedical Advanced Research and Development Authority have set up a biopharmaceutical accelerator called CARB-X. The fund is allotting $48 million to support antibiotic drug discovery projects. “They work with companies in the very early discovery stages to give them funding and technical support to get to the point that they have a product they can do clinical trials with,” says IDSA’s Jezek. Along those same lines, the IDSA is also currently working to develop legislation that would provide funding for clinical trials so that companies can avoid those hefty costs and stand a chance of making a profit from new antibiotics. With all of these programmes working together, and similar efforts taking place around the world, there is a lot of hope that humanity will manage to get a handle on the problem. Still, “we can only really slow the development of resistance. We’re not going to stop it completely,” says Jezek. “Even appropriate use of antibiotics does contribute to resistance.” And that means the challenge will always be immense. As long as there are humans and those humans carry and transmit disease – which they will – the entire world will have to continue fighting for resistance.

**1NC – Health Diplomacy**

#### They can’t resolve neglected areas just by having more innovation – nothing abt the aff changes the distribution globally.

#### Capitalism ensures science diplomacy will be exploited by wealthy nations to

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#### The aff is co-opted by an agenda of “health diplomacy” that only further expands capitalist imperialism

Andrea Patanè 21. Marxist, Published: 15 May 2021. “COVID-19 pandemic: patents and profits” <https://www.marxist.com/covid-19-pandemic-patents-and-profits.htm> brett

Far from an act of ‘international solidarity', this latest move from the US government is a calculated political risk, and will be implemented in the interests of US imperialism. A section of the more serious wing of the bourgeoisie understands that a proper economic recovery can happen only if the pandemic is suppressed worldwide. As we have explained elsewhere, wealthy countries risk losing billions of dollars if the pandemic is brought under control only within their own borders, because new variants (like those in India and Brazil) can always mutate elsewhere and reinfect their populations, causing further economic disruption. Therefore, even on a capitalist basis, it is expedient in the long-term for the rich countries to facilitate a global vaccination campaign. Even Pope Francis anointed the demand from his seat in Rome! Biden’s announcement is also an act of vaccine diplomacy. America’s main rivals, China and Russia, have been shoring up their spheres of influence by distributing their Sinopharm and Sputnik V vaccines to poor countries left out by the vaccine nationalism of the US and Europe. Chinese and Russian vaccines have been exported into countries traditionally under western spheres of influence, including Brazil and Hungary. Pushing to waive IP protections on COVID-19 vaccines is therefore partly an effort to push back against the encroachment of rival imperialist powers, which have so far outcompeted Washington in the global vaccination drive. Biden’s announcement is also an attempt to restore the standing and authority of US imperialism on the world stage, which has been bruised by the ‘America First’ vaccine nationalist policy started by Donald Trump, and continued by Biden. According to the FT, Katherine Tai (top US trade envoy) and Jake Sullivan (national security adviser) made the case to Biden that pushing for the waiver “was a low-risk way to secure a diplomatic victory”, after coming under fire for not “respond[ing] quickly enough to the unfolding COVID-19 crisis in India”. Here you have it, straight from the horse’s mouth. Under capitalism, vaccines – rather than providing a way out of the pandemic – are tools for ‘low-risk diplomatic victories’. As if this was some sort of football match between world leaders! In short, Biden is stepping in to prioritise the interests of US imperialism as a whole over the immediate interests of the Big Pharma capitalists. But we should say clearly: this cynical attempt to claim the moral high ground came only after the US used its massive economic clout to secure enough vaccines to inoculate its own population several times over. And in fact, the wartime Defense Production Act is still in effect, which forces US manufacturers to fulfil domestic demands for medical equipment before exports are permitted. This de facto export ban has created bottlenecks in the supply chain that have already undermined the WHO-led COVAX programme to vaccinate poor countries. Rest assured, Biden’s policy remains ‘America First’, just by somewhat more calculated means than his predecessor.

#### Science diplomacy is more likely to increase conflict – innovation rate & political interests

Dickson 09 [David Dickson David Dickson has been the Chief Executive Officer and President of McDermott International, Inc. since December 16, 2013. Mr. Dickson served as the Chief Operating Officer and Executive Vice from October 31, 2013, to December 16, 2013. He served as the Chief Executive Officer and President of Global Industries Ltd.] The limits of science diplomacy, 4-6-2009, SciDev.Net, accessed 8-26-2021 https://www.scidev.net/global/editorials/the-limits-of-science-diplomacy///ramamurty

But whether scientific cooperation can become a precursor for political collaboration is less evident. For example, despite hopes that the Middle East synchrotron would help bring peace to the region, several countries have been reluctant to support it until the Palestine problem is resolved. Indeed, one speaker at the London meeting (organised by the UK's Royal Society and the American Association for the Advancement of Science) even suggested that the changes scientific innovations bring inevitably lead to turbulence and upheaval. In such a context, viewing science as a driver for peace may be wishful thinking. Conflicting ethos Perhaps the most contentious area discussed at the meeting was how science diplomacy can frame developed countries' efforts to help build scientific capacity in the developing world. There is little to quarrel with in collaborative efforts that are put forward with a genuine desire for partnership. Indeed, partnership — whether between individuals, institutions or countries — is the new buzzword in the "science for development" community. But true partnership requires transparent relations between partners who are prepared to meet as equals. And that goes against diplomats' implicit role: to promote and defend their own countries' interests. John Beddington, the British government's chief scientific adviser, may have been a bit harsh when he told the meeting that a diplomat is someone who is "sent abroad to lie for his country". But he touched a raw nerve. Worlds apart yet co-dependent The truth is that science and politics make an uneasy alliance. Both need the other. Politicians need science to achieve their goals, whether social, economic or — unfortunately — military; scientists need political support to fund their research. But they also occupy different universes. Politics is, at root, about exercising power by one means or another. Science is — or should be — about pursuing robust knowledge that can be put to useful purposes. A strategy for promoting science diplomacy that respects these differences deserves support. Particularly so if it focuses on ways to leverage political and financial backing for science's more humanitarian goals, such as tackling climate change or reducing world poverty. But a commitment to science diplomacy that ignores the differences — acting for example as if science can substitute politics (or perhaps more worryingly, vice versa), is dangerous.