# 1NC R4

## 1

### 1NC – K

#### All capitalism is racial capitalism – racial capitalism uses the bodies of post-colonial subjects to prop up a new corporate empire of extraction. The flow of capital and information through Western notions of IP rights enables accumulation by dispossession from the Global South. The aff’s modification of the IP system merely enables disciplinary control by sanitizing the West’s imperial control over the knowledge economy. Racial and colonial logics undergird the IP system – piecemeal reforms like the aff only serve to erase Western culpability in stealing Indigenous knowledge and unethical clinical trials.

Chaurey ‘19 [Keeyaa Chaurey; Master’s Degree from The London School of Economics and Political Science (in Human Rights, Healthcare and Capitalism); January 2019; “Pirates and Property: The Moralities of Branded and Generic Medicines”; http://eprints.lse.ac.uk/102949/1/Keeyaa\_pirates\_and\_property\_submitted.pdf; Accessed 08-28-2021] AK

Behaviours of Accumulation and Extraction

Primitive accumulation’s seizing of land for property has become more abstract during accumulation as dispossession. Here, the accumulation of intellectual property is simply one aspect of a larger project of neoliberalisation. In this section I will outline the behaviours of accumulation and expansion that are evident in the globalisation of the intellectual property regime. I have already argued that these behaviours are self-justified as working against ‘piracy’. The rhetoric of ‘piracy’ makes expansion a moral imperative and the processes of making this imperative come to life connect back to racial capitalism. This will be explored in the following section.

TRIPS as an agreement is about more than patents: it sets minimum standards in copyright, trade marks, geographical indications, industrial designs, and lay-out designs of integrated circuits. It was the first stage in ensuring that the morality of expansion reproduces globally as the intellectual property standards in TRIPS obligate all members of the WTO (Drahos and Braithwaite 2002, 10). For Big Pharma, TRIPS will ensure the enclosure of biotechnology through patents and trade secret law. It also functions as an important vehicle for accumulation by dispossession through the forcing open of world markets, exactly like India: a country labelled as a notorious ‘pirate’ for making generics a fundamental part of their national pharmaceutical industry. Indeed, as a combination of a market-opener and a globalisation of the morality of accumulation, TRIPS can be seen as a cog in the engine wheels of “the motor of accumulation” (Harvey 2003, 182).

TRIPS has been effective since 1995 and was negotiated during the Uruguay Round of the General Agreement on Tariffs and Trade (GATT). Those missing from the important negotiation meetings and tables are easily identifiable: African, Asian, South American countries were repeatedly denied entry into spheres in which they might have the power to object and derail TRIPS. Alongside this came a system of coercion and blindsiding in which Third World countries were threatened through trade sanctions, and were also unprepared for the level of capital that had been sunk into intellectual property lawyers and infrastructure. India was the last stand against TRIPS. When finally having to sign during the Final Act of Marrakesh in April 1994, a number of Indian parliamentarians and members of the judiciary delivered rousing speeches about the recolonisation of India (Drahos and Braithwaite 2002, 146). However, the Indian pharmaceutical industry, along with every other member of the WTO was now forced to play by intellectual property rules set in Washington and New York (Drahos and Braithwaite 2002). In the aptly named TRIPS Was Never Enough, Sell says, “Despite the fact that a TRIPS advocate triumphantly exclaimed, “we got 95% of what we wanted,” that 5% has always mattered, and 95% was never enough. While many countries believed that they were negotiating a ceiling on intellectual property rules, they quickly discovered they actually had negotiated only a floor.” (Sell 2011, 448). After TRIPS came TRIPS-plus, U.S.-plus, and ACTA-plus, making TRIPS look like a walk in the park in comparison to the stringency that these initiatives have brought (Sell 2011, 448). TRIPS-plus in particular targets the import of generic medicines and the logics of expansion and accumulation present themselves again.

A crucial aspect of primitive accumulation, accumulation by dispossession, and racial capitalism is extraction. Within the context of pharmaceutical intellectual property practice and TRIPS, three important kinds of extraction take place: the forcing open of markets through the obligation of building intellectual property infrastructure (Drahos and Braithwaite 2002); the theft from the collective knowledge of indigenous peoples (Olufunmilayo 2006; Drahos and Braithwaite 2002); and the outsourcing of clinical trials to the Third World while producing drugs for a Western market (Drahos and Braithwaite 2002; Fassin 2007; Lurie and Wolfe 1997; Angell 1997).

Minds and Bodies for Extraction

In the world of intellectual property, those who hold the webs of patents, patent lawyers, and the capital to keep it all spinning, are lords of the knowledge economy and thus, knowledge exporters. Those who are knowledge poor, like South Africa and other Third World countries, are also knowledge importers (Drahos and Braithwaite 2002). TRIPS ensures that not only will knowledge poor countries have to standardise themselves to Western intellectual property rights, but they will have to pay dearly for the privilege. The message of the discourse around piracy has been that governments of other countries are stealing from the minds of U.S. inventors by not following patent protection. This narrative is connected with larger processes of the world order. In the 1950s, pharmaceutical corporations, particularly Pfizer International, made sweeping overseas sales figures. Due to recently independent post-colonial nations trying to rebuild themselves politically and economically, national pharmaceutical industries were nascent or non-existent. Drugs had to be imported and Pfizer profited. Countries like India and China were at first long-term prospects of profit. As their national pharmaceutical industries grew, they quickly became dangers to an established global system of branded medicine, one rooted in colonialism and imperialism (Drahos and Braithwaite 2002). The avid extension and proliferation of the intellectual property regime, particularly in regards to pharmaceuticals, can thus be seen as a legal disciplinary mechanism for those countries daring to circumvent Big Pharma. By pouring resources into an infrastructure to support intellectual property rights, (Drahos and Braithwaite 2002) lower income countries (primarily post-colonies) are being pulled away from investing in basic human rights needs, such as access to medicines. Here we see Harvey’s accumulation by dispossession clearly.

Though Harvey is less particular about the racial aspect of the extraction, Alexander, Legassick and Hemson, Tutu, and even Mbeki make very clear that there is a power imbalance between extractors and those extracted from. Drahos and Braithwaite (2002) point to the ways in which racist narratives of the ‘East’ were mobilised for the movement of the U.S. government to put in place sanctions against Asian countries who did not yet follow patent protection laws in the 1980s and 1990s, forcing them to behave. Indeed, this example of a racial and imperial attitude seems to form a stubborn undercurrent not just through TRIPS but through Big Pharma’s more specific practices in the Third World. For example, Western intellectual property rights did not recognise the rights of indigenous peoples. By the time evidence proved individual pharmaceutical corporations were stealing indigenous peoples’ collective knowledge, TRIPS had been set into stone (Drahos and Braithwaite 2002, 71). Unethical clinical trials are another striking example. Lurie and Wolfe (1997) describe the deaths of hundreds of infants in the Third World who were needlessly unethically infected in trials of interventions to reduce perinatal transmission of HIV. Even trials that are ‘ethical’, however, are often conducted within vulnerable populations in Third World countries, creating a cheap clinical trial pool for pharmaceutical corporations to test drugs on (Fassin 2007; Lurie and Wolfe 1997; Angell 1997). Informant C, a doctor, tells me they feel that there have been so many conspiracy theories about the HIV/AIDS crisis in South Africa that they feel almost reluctant saying what they think out loud. Yet when I ask about their opinion of Big Pharma’s role in Africa, they tell me with a sigh:

South Africa and Africa is like, what’s the word? a testing ground. I hate saying that but I sometimes do feel. I hate saying that because it’s putting the conspiracy theories, the cynicism into something. I guess, that it’s my feeling: it’s subjective rather than objective. When I say conspiracy theory, I mean it’s something that you don’t want to believe is happening but you know that there is probably truth in it.

Their hesitation comes with high stakes: the only reason their partner is able to get treatment for skin cancer is due to access to a clinical trial. Otherwise, the treatment costs R95, 000 every three weeks for two years. “They are doing some good work out there,” they tell me. Big Pharma’s moral location in South Africa is nebulous and uneven, as is the ‘global apartheid’ of neoliberalism. Indeed, their practices follow the same logic of racial capitalism: the bodies of colonial subjects that propped up the Empire have become the bodies of post-colonial subjects who prop up a much more diffuse, abstract corporate Empire. The lines between conspiracy and controversy are just as thin across the world as they are in South Africa.

#### The 1AC’s fetishism of the public domain, demonstrated by their embrace of generic medicine, is a form of neocolonial domination that papers over inequalities and information feudalism. The public domain is a structure of white supremacy that erases the 1AC’s complicity.

Vats and Keller ‘18 [Anjali Vats; Assistant Professor of Communication and African and African Diaspora Studies at Boston College and Assistant Professor of Law at Boston College Law School; Deirdré A. Keller; Professor of Law at Ohio Northern University, Claude W. Pettit College of Law; 2018; “Critical Race IP”; Cardozo Arts & Ent. LJ; https://www.cardozoaelj.com/wp-content/uploads/2018/10/VATS-KELLER-ARTICLE.pdf; Accessed 08-29-2021] AK

3. The Public Domain

Critical Race IP scholarship, like intellectual property scholarship generally, is concerned with the public domain. However, unlike their law and economics counterparts, Race IP Crits are concerned with the racial and social justice dimensions of the management of the public domain, especially in ways that refuse to recognize property rights in existing traditional knowledge and hinder access to knowledge. Recent cases such as Eldred v. Ashcroft206 and Golan v. Holder207 have extended the term and scope of intellectual property rights, posing considerable problems for marginalized groups, particularly with respect to A2K. Unsurprisingly, as per claims of the rise of information feudalism, such transfers of information often unfold along (neo)colonial axes, with the developing world paying the price for the privatization and increasing scope of copyright, patent, and trademark law.208 Intellectual property maximalism in copyright and patent results in a “shrinking” public domain by restricting access to knowledge along distinctly racial lines.209 James Boyle210 and Michael Brown211 offer in- depth accounts of this process, while Sunder and Chander highlight the need to read the public domain as not simply the opposite of intellectual property but also as a space for (neo)colonial ownership claims to traditional knowledge.212 “The romance of the public domain” refers to the fetishistic desire to embrace the public domain as an alternative to intellectual property maximalism without adequate consideration of its underlying inequalities.213 Meanwhile, as the expansion of trademark law threatened and threatens to make the brand all-powerful, both as a legal and cultural form, it too erodes equal access to the public domain, particularly for those who were racially stereotyped. Jane Gaines and Rosemary Coombe trace this process, demonstrating the increasing value and significance of ownership of the brand as well as resistance to that ownership, particularly when racial symbols are invoked.214

As information feudalism has grown more intense in the 2000s, calls for equal access have become more commonplace. Chon, for instance, argues for wide access to educational materials,215 one which was borne out in the Delhi University copyright case in which the Indian Supreme Court determined that the policy interest in access to knowledge outweighed the monopoly afforded to publishers.216 In contexts such as access to copyrighted materials or access to pharmaceuticals, the public domain is not a universal concept but one that must be situationally redefined to account for the states of development and growth trajectories of nations in the Global South.217 While we take up some of these examples in the sections that follow, we observe generally that the public domain is not an unqualified good, nor is its designation as the opposite of property without complications. It is instead a social construction which often erases intellectual property law’s protection of white supremacy and denies A2K to the world’s most vulnerable populations. The regulation of the public domain and the scope of its contents, therefore, remain important questions for scholars of race and intellectual property.

**Neoliberal capitalism will produce extinction – the system reproduces crises that depoliticize the left, undermine futural thought, and postpone its demise – the impacts are environmental collapse, endless war, and the rise of fascism**

Shaviro ‘15 (Steven Shaviro is an American academic, philosopher and cultural critic whose areas of interest include film theory, time, science fiction, panpsychism, capitalism, affect and subjectivity. He earned a PhD from Yale in 1981. “No Speed Limit: Three Essays on Accelerationism” <https://track5.mixtape.moe/qdkkdt.pdf> rvs)

The problem may be summarized as follows. Capitalism has indeed created the conditions for general prosperity and therefore for its own supersession. But it has also blocked, and continues to block, any hope of realizing this transformation. We cannot wait for capitalism to transform on its own, but we also cannot hope to progress by appealing to some radical Outside or by fashioning ourselves as militants faithful to some “event” that (as Badiou has it) would mark a radical and complete break with the given “situation” of capitalism. Accelerationism rather demands a movement against and outside capitalism—but on the basis of tendencies and technologies that are intrinsic to capitalism. Audre Lord famously argued that “the master’s tools will never dismantle the master’s house.” But what if the master’s tools are the only ones available? Accelerationism grapples with this dilemma. What is the appeal of accelerationism today? It can be understood as a response to the particular social and political situation in which we currently seem to be trapped: that of a long-term, slow-motion catastrophe**. Global warming, and environmental pollution and degradation, threaten to undermine our whole mode of life.** And this mode of life is itself increasingly stressful and precarious, due to the depredations of neoliberal capitalism. As Fredric Jameson puts it, the world today is characterized by “heightened polarization, increasing unemployment, [and] the ever more desperate search for new investments and new markets.” These are all general features of capitalism identified by Marx, but in neoliberal society we encounter them in a particularly pure and virulent form. I want to be as specific as possible in my use of the term “neoliberalism” in order to describe this situation. I define neoliberalism as a specific mode of capitalist production (Marx), and form of governmentality (Foucault), that is characterized by the following specific factors: 1. The dominating influence of financial institutions, which facilitate transfers of wealth from everybody else to the already extremely wealthy (the “One Percent” or even the top one hundredth of one percent). 2. The privatization and commodification of what used to be common or public goods (resources like water and green space, as well as public services like education, communication, sewage and garbage disposal, and transportation). 3. The extraction, by banks and other large corporations, of a surplus from all social activities: not only from production (as in the classical Marxist model of capitalism) but from circulation and consumption as well. Capital accumulation proceeds not only by direct exploitation but also by rent-seeking, by debt collection, and by outright expropriation (“primitive accumulation”). 4. The subjection of all aspects of life to the so-called discipline of the market. This is equivalent, in more traditional Marxist terms, to the “real subsumption” by capital of all aspects of life: leisure as well as labor. Even our sleep is now organized in accordance with the imperatives of production and capital accumulation. 5. The redefinition of human beings as private owners of their own “human capital.” Each person is thereby, as Michel Foucault puts it, forced to become “an entrepreneur of himself.” In such circumstances, we are continually obliged to market ourselves, to “brand” ourselves, to maximize the return on our “investment” in ourselves. There is never enough: like the Red Queen, we always need to keep running, just to stay in the same place. Precarity is the fundamental condition of our lives. All of these processes work on a global scale; they extend far beyond the level of immediate individual experience. My life is precarious, at every moment, but I cannot apprehend the forces that make it so. I know how little money is left from my last paycheck, but I cannot grasp, in concrete terms, how “the economy” works. I directly experience the daily weather, but I do not directly experience the climate. Global warming and worldwide financial networks are examples of what the ecological theorist Timothy Morton calls hyperobjects. They are phenomena that actually exist but that “stretch our ideas of time and space, since they far outlast most human time scales, or they’re massively distributed in terrestrial space and so are unavailable to immediate experience.” Hyperobjects affect everything that we do, but we cannot point to them in specific instances. The chains of causality are far too complicated and intermeshed for us to follow. In order to make sense of our condition, we are forced to deal with difficult abstractions. We have to rely upon data that are gathered in massive quantities by scientific instruments and then collated through mathematical and statistical formulas but that are not directly accessible to our senses. We find ourselves, as Mark Hansen puts it, entangled “within networks of media technologies that operate predominantly, if not almost entirely, outside the scope of human modes of awareness (consciousness, attention, sense perception, etc.).” We cannot imagine such circumstances in any direct or naturalistic way, but only through the extrapolating lens of science fiction. Subject to these conditions, we live under relentless environmental and financial assault. We continually find ourselves in what might well be called a state of crisis. However, this involves a paradox. A crisis—whether economic, ecological, or political—is a turning point, a sudden rupture, a sharp and immediate moment of reckoning. But for us today, crisis has become a chronic and seemingly permanent condition. We live, oxymoronically, in a state of perpetual, but never resolved, convulsion and contradiction. Crises never come to a culmination; instead, they are endlessly and indefinitely deferred. For instance, after the economic collapse of 2008, the big banks were bailed out by the United States government. This allowed them to resume the very practices—the creation of arcane financial instruments, in order to enable relentless rent-seeking—**that led to the breakdown of the economic system in the first place.** The functioning of the system is restored, but only in such a way as to guarantee the renewal of the same crisis, on a greater scale, further down the road. Marx rightly noted that crises are endemic to capitalism. But far from threatening the system as Marx hoped, today these crises actually help it to renew itself. As David Harvey puts it, it is precisely “through the destruction of the achievements of preceding eras by way of war, the devaluation of assets, the degradation of productive capacity, abandonment and other forms of ‘creative destruction’” that capitalism creates “a new basis for profit-making and surplus absorption.” What lurks behind this analysis is the frustrating sense of an impasse. Among its other accomplishments, neoliberal capitalism has also robbed us of the future. For it turns everything into an eternal present. The highest values of our society—as preached in the business schools—are novelty, innovation, and creativity. And yet these always only result in more of the same. How often have we been told that a minor software update “changes everything”? Our society seems to function, as Ernst Bloch once put it, in a state of “sheer aimless infinity and incessant changeability; where everything ought to be constantly new, everything remains just as it was.” This is because, in our current state of affairs, the future exists only in order to be colonized and made into an investment opportunity. John Maynard Keynes sought to distinguish between risk and genuine uncertainty. Risk is calculable in terms of probability, but genuine uncertainty is not. Uncertain events are irreducible to probabilistic analysis, because “there is no scientific basis on which to form any calculable probability whatever.” Keynes’s discussion of uncertainty has strong affinities with Quentin Meillassoux’s account of hyperchaos. For Meillassoux, there is no “totality of cases,” no closed set of all possible states of the universe. Therefore, there is no way to assign fixed probabilities to these states. This is not just an empirical matter of insufficient information; uncertainty exists in principle. For Meillassoux and Keynes alike, there comes a point where “we simply do not know.” But today, Keynes’s distinction is entirely ignored. The Black-Scholes Formula and the Efficient Market Hypothesis both conceive the future entirely in probabilistic terms. In these theories, as in the actual financial trading that is guided by them (or at least rationalized by them), the genuine unknowability of the future is transformed into a matter of calculable, manageable risk. True novelty is excluded, because all possible outcomes have already been calculated and paid for in terms of the present. While this belief in the calculability of the future is delusional, it nonetheless determines the way that financial markets actually work. We might therefore say that speculative finance is the inverse—and the complement—of the “affirmative speculation” that takes place in science fiction. Financial speculation seeks to capture, and shut down, the very same extreme potentialities that science fiction explores. Science fiction is the narration of open, unaccountable futures; derivatives trading claims to have accounted for, and discounted, all these futures already. The “market”—nearly deified in neoliberal doctrine—thus works preemptively, as a global practice of what Richard Grusin calls premediation. It seeks to deplete the future in advance. Its relentless functioning makes it nearly impossible for us to conceive of any alternative to the global capitalist world order. Such is the condition that Mark Fisher calls capitalist realism. As Fisher puts it, channeling both Jameson and Žižek, “it’s easier to imagine the end of the world than the end of capitalism.”

#### The alternative is Black Marxism. Their opposition to IP protections fails because it starts at the wrong place. This radical Black tradition disrupts the terms of ownership and turns Marxism inside out. The alt generates Black kinship and social life outside of the university, rebuilding the IP system from the ground up to solve the aff.

Moten ‘13 (Fred Moten, Moten is professor of performance studies at New York University and has taught previously at University of California, Riverside, Duke University, Brown University, and the University of Iowa, 3 July 2013, “The Subprime and the beautiful”, African Identities Volume 11, 2013 - Issue 2, <https://www.tandfonline.com/doi/abs/10.1080/14725843.2013.797289>) \\EGott

In a recent review of Fredric Jameson’s Valences of the Dialectic, Kunkel (2010) writes: It’s tempting to propose a period ...stretching from about 1983 (when Thatcher, having won a war, and Reagan, having survived a recession, consolidated their popularity) to 2008 (when the neoliberal programme launched by Reagan and Thatcher was set back by the worst economic crisis since the Depression). During this period of neoliberal ascendancy – an era of deregulation, financialization, industrial decline, demoralization of the working class, the collapse of Communism and so on – it often seemed easier to spot the contradictions of Marxism than the more famous contradictions of capitalism ... (p. 12) The year that marks the beginning of the period Kunkel proposes – which is characterized by ‘the peculiar condition of an economic theory that had turned out to flourish above all as a mode of cultural analysis, a mass movement that had become the province of an academic “elite,” and an intellectual tradition that had arrived at some sort of culmination right at the point of apparent extinction’ – is also the year of the publication of Cedric Robinson’s Black Marxism: The Making of the Black Radical Tradition, a book that could be said to have announced the impasse Kunkel describes precisely in its fugitive refusal of it (Kunkel 2010, p. 12; Robinson 2000). If the culmination of the Marxian intellectual tradition coincides with the moment in which Jameson begins magisterially to gather and direct all of its resources toward the description and theorization of what most clear-eyed folks agree is the deflated, defeated spirit of the present age, Robinson’s project has been to alert us to the radical resources that lie before that tradition, where ‘before’ indicates both what precedes and what awaits, animating our times with fierce urgency. One of the fundamental contradictions of capitalism is that it establishes conditions for its own critique (which anticipates a collapse whose increasing imminence increasingly seems to take the form of endless deferral); that those very conditions seem to render that critique incomplete insofar as it will have always failed to consider capitalism’s racial determination is, in turn, a contradiction fundamental to Marxism. While Black Marxism emphatically exposes these contradictions, it is not reducible to such exposure. Rather, in elucidating an already given investigation of the specificities of Marxism’s founding, antifoundational embarrassment, which bears the massive internal threat of critique becoming an end in itself while operating in the service of the renovation, rather than the overturning, of already existing social and intellectual structures, Robinson understands the Marxian tradition as part of the ongoing history of racial capitalism. This is not dismissal; indeed, it echoes the deepest and richest sounds of Marx’s own blackness. It does, however, sanction the question in which I am interested today: what made Robinson’s critique – and, more importantly, that which, in Robinson’s work (and in Marx’s), exceeds critique – possible? The answer, or at least the possibility for a more precise rendering of the question, is also to be found in Black Marxism, in which critique is interrupted by its own eruptive condition of possibility roughly at the book’s rich, dense, but simultaneously, open and capacious center, a chapter called ‘The Nature of the Black Radical Tradition’. Robinson’s critical discovery of racial capitalism depends upon and extends the preservation of what he calls ‘the ontological totality’. In describing this integrated totality’s character, Robinson notes how preservation impossibly proceeds within the confines of ‘a metaphysical system that had never allowed for property in either the physical, philosophical, temporal, legal, social or psychic senses’. It’s motive force is ‘the renunciation of actual being for historical being’, out of which emerges a ‘revolutionary consciousness’ that is structured by but underived from ‘the social formations of capitalist slavery, or the relations of production of colonialism’ (Robinson 2000, pp. 243–244, 246). It is not just that absolutist formulations of a kind of being-fabricated are here understood themselves to be fabrications; it is also that renunciation will have ultimately only become intelligible as a general disruption of ownership and of the proper when the ontological totality that black people claim and preserve is understood to be given only in this more general giving. The emergence and preservation of blackness, as the ontological totality, the revolutionary consciousness that black people hold and pass, is possible only by way of the renunciation of actual being and the ongoing conferral of historical being – the gift of historicity as claimed, performed dispossession. Blackness, which is to say, black radicalism, is not the property of black people. All that we have (and are) is what we hold in our outstretched hands. This open collective being is blackness – (racial) difference mobilized against the racist determination it calls into existence in every moment of the ongoing endangerment of ‘actual being’, of subjects who are supposed to know and own. It makes a claim upon us even as it is that upon which we all can make a claim, precisely because it – and its origins – are not originary. That claim, which is not just one among others because it is always one þ more among others, however much it is made under the most extreme modes of duress, in an enabling exhaustion that is, in Stanley Cavell’s word, unowned, takes the form, in Edouard Glissant’s word, of consent (Cavell 1995, p. 101; Glissant & Diawara, 2011, p. 5). ‘To consent not to be a single being’, which is the anoriginal, anoriginary constitution of blackness as radical force – as historical, paraontological totality – is, for Robinson, the existential and logical necessity that turns the history of racial capitalism, which is also to say the Marxist tradition, inside out. What cannot be understood within, or as a function of, the deprivation that is the context of its genesis, can only be understood as the ongoing present of a common refusal.1 This oldnew kind of transcendental aesthetic, off and out in its immanence as the scientific productivity of such immanence projects, is the unowned, differential, and differentiated thing itself that we hold out to one another, in the bottom, under our skin, for the general kin, at the rendezvous of victory. To say that we have something (only insofar as we relinquish it) is to say that we come from somewhere (only insofar as we leave that place behind). Genesis is dispersion; somewhere is everywhere and nowhere as the radical dislocation we enact, where we stay and keep on going, before the beginning, before every beginning, and all belonging, in undercommon variance, in arrivance and propulsion, in the flexed load of an evangelical bridge, passed on this surrepetitious vamp, here. If you need some, come on, get some. We come from nothing, which is something misunderstood. It’s not that blackness is not statelessness; it’s just that statelessness is an open set of social lives whose animaterialized exhaustion remains as irreducible chance. Statelessness is our terribly beautiful open secret, the unnatural habitat, and habitus of analytic engines with synthetic capacities. Preservation is conditional branching, undone computation (tuned, forked, tongued), improvisation and, what it forges, digital speculation beyond the analogical or representational or calculative reserve. Critique – for example, the deciphering of the fundamental discursive structures that (de)form Western civilization – is part of its repertoire but it must always be kept in mind that cryptanalytic assertion has a cryptographic condition of possibility. Robinson’s movement within and elucidation of the open secret has been a kind of open secret all its own. For a long time, before its republication in 2000, Black Marxism circulated underground, as a recurrent seismic event on the edge or over the edge of the university, for those of us who valorized being on or over that edge even if we had been relegated to it. There, at least, we could get together and talk about the bomb that had gone off in our heads. Otherwise we carried around its out, dispersive potenza as contraband, buried under the goods that legitimate parties to exchange can value, until we could get it to the black market, where (the) license has no weight, and hand it around out of a suitcase or over a kitchen table or from behind a makeshift counter. Like Pryor (1994) said: ‘I got some shit, too ... you respect my shit and I’ll respect yours’. Maybe there is some shit in the back of our cars that we don’t even know about. Certainly, this smuggled cargo would be cause for optimism, even against the grain of our constant, clear-eyed vigilance, even against the general interdiction – the intellectual state of emergency – enforced when we emphysemically authorize ourselves to speak of the spirit of the age. That spirit marks the scene in which the etiolation of black studies in the name of critique is carried out by way of our serial flirtation with forgetting our own animation, the collective being that is more precisely understood as being-in-collection insofar as the latter term denotes a debt that is not only incalculable but also subprime. Therefore, by way of the brilliant black light in Frank B. Wilderson’s Afro-pessimistic sound – which materializes, in an investigation of black being, the most rigorous instance of this fatal but necessary proximity to oblivion – I’d like to consider what it is (again and again) to lose a home. This is Wilderson (2007): Slavery is the great leveler of the black subject’s positionality. The black American subject does not generate historical categories of entitlement, sovereignty, and immigration for the record. We are ‘off the map’ with respect to the cartography that charts civil society’s semiotics; we have a past but not a heritage. To the data-generating demands of the Historical Axis, we present a virtual blank, much like that which the Khosian presented to the Anthropological Axis. This places us in a structurally impossible position, one that is outside the articulations of hegemony. However, it also places hegemony in a structurally impossible position because – and this is key – our presence works back on the grammar of hegemony and threatens it with incoherence. If every subject – even the most massacred among them, Indians – is required to have analogs within the nation’s structuring narrative, and the experience of one subject on whom the nation’s order of wealth was built is without analog, then that subject’s presence destabilizes all other analogs (p. 31).

#### The ROJ is to engage in a project of mapping property. Both property and rhetorical spaces like debate perpetuate IP as whiteness, sustaining racial capitalism and reinforcing an exclusionary praxis. Only the K engages in strategies to fight racial capitalism inside and outside debate.

Vats ‘19 [Anjali Vats, JD, PhD; Associate Professor of Law at the University of Pittsburgh School of Law with a secondary appointment in the Communication Department at the University of Pittsburgh; 10-02-2019; “Mapping property”; Quarterly Journal of Speech, Vol. 105, No. 4, 508–526; DOI: 10.1080/00335630.2019.1666347; Accessed 08-29-2021] AK

Rhetorically mapping property

The insights that the books that I have discussed here provide are important ones for thinking about future directions for rhetoric and rhetorical studies. For a field at a crossroads in terms of its investments in subjects and methods, the rich possibilities for studying (intellectual) property, particularly by way of the rhetorical strategies, cultural practices, and institutional structures that ensure its continued existence as a tool for normalizing racial orders and racial capitalism, can offer direction for scholars. Property implicitly structures the all too familiar “available means of persuasion,” in Aristotle’s words, in which individuals exist, often without notice. Returning to the notion of mapping property, then, can aid rhetorical scholars in thinking about how the field can contribute to studies of (intellectual) property, whether by breaking ground around new objects of study or deepening existing analyses around topics such as the ones that I have described. The property turn in the humanities, however, makes it clear that studying persuasion without an understanding of property as a set of rules for subject-subject relationalities that materially constrain rhetorical situations is ill-advised. Property provides nuanced explanations for material realities that other theories may not.

Bhandar, Karuka, Sunder Rajan, and Eng and Han highlight multiple, multimodal strategies through which property is incorporated, constructed, and decolonized. They show that discursive and material choices are pivotal in the outcome in property cases. In their canonical essay on the separate but equal doctrine, Marouf Hasian, Celeste Condit, and John Lucaites argue that law is dependent on rhetorical culture. They write that: “A rhetorical culture is ... power-in-action, and the meaning of the law necessarily derives from the forms available in rhetorical culture.”20 The books I have reviewed certainly showcase the complex relationships between law and rhetorical culture. However, they also demonstrate that studying rhetorical culture is impossible without sustained attention to political economy, institutional structures, and interpersonal dynamics,

among other issues. Rhetoric without materiality simply misses the ways that property and power exist in multiple forms, including deeds, railroads, prescription drugs, and therapeutic exchanges, among others.

There is perhaps no more immediate example in the discipline of rhetoric through which to demonstrate the ubiquity and urgency of (intellectual) property problems than the controversy that erupted in the summer of 2019, when Dr. Martin Medhurst decided to pen an editorial for publication in Rhetoric & Public Affairs on the topic of the long-brewing controversy over the process for selecting the Distinguished Scholars of the National Communication Association. In less than a week, over 1,500 scholars mobilized to express their outrage at Dr. Medhurst’s sentiments – and those in a letter signed by nearly all the living Distinguished Scholars as well. Without belaboring the details or histories of the event, I want to very briefly note some of the ways that property, rhetorical and otherwise, came to the fore, particularly in forms that the authors here would presumably highlight as examples of property’s exclusions.

For instance, editorships, awards, and other markers of disciplinary prowess confer status property on particular individuals for “improving” the discipline. As in the examples that Bhandar highlights, that status property is deeply intertwined with narrow, Euro-American conceptions of (white) romantic scholarship, which I have written about at length elsewhere. Further, the infrastructures of the discipline are built to reinforce whiteness as (intellectual) property. Karuka’s argument is, fundamentally, one about the manner in which material infrastructures have operated through racialized labor to entrench white racial power, even through hegemonic struggle. In the discipline of rhetoric, graduate programs are the metaphorical infrastructure through which (racial) capitalism operates to destroy healthy modes of relationship, all too often replacing them with competitive, patronage-based ones. Additionally, the field is a site for the management of multiple, competing understandings of (rhetorical) knowledge. Sunder Rajan highlights how cultures, nations, and institutions conceptualize value differently, in his case in the context of human health. The emergence of the methodological distinction between close reading and critical rhetoric showcases how such disparate values emerge in spaces that are purportedly attempting to achieve the same ends. Finally, the underdevelopment of critical race studies within rhetoric highlights the exclusionary praxis of the field. If #CommunicationSoWhite and #RhetoricSoWhite have demonstrated anything, it is that the disciplines of communication and rhetoric have, as of yet, not enacted the theory and praxis that can achieve stated goals of diversity, equity, and inclusion.21 More intersectional work remains to be done around race and property.

Indeed, CRT-Net and the Facebook Group “Communication Scholars for Transformation” have demonstrated that many white scholars have not hesitated to invoke the “cultural logics of white racial grievance”22 in order to protect whiteness as (intellectual) property. As scholars in rhetoric take up questions of (intellectual) property in this kairotic moment, they would be well served to begin by interrogating the spaces closest to them. Rhetoric itself is built on the edifices of the regimes that scholars such as Bhandar, Karuka, Sunder Rajan, Eng and Han describe. As with whiteness, the machinations of property frequently goes unnoticed, at considerable cost to those who do not benefit from them.23 Whiteness as (intellectual) property has been normalized for far too long in communication and rhetoric. Turning inward to consider how rhetoric, specifically, is mired in problems of (intellectual) property will not only aid the field in becoming more just but also in thinking with more depth about problems of property in the world.

## Case

### Solvency

#### TRIPs waiver doesn’t solve- it doesn’t obligate countries to do anything, just makes it legal.

Mercurio 21 [Bryan; Professor of Law, The Chinese University of Hong Kong; "The IP Waiver for COVID-19: Bad Policy, Bad Precedent," 2021; 1-6. International Review of Intellectual Property and Competition Law.] Justin

It is not only the length of time which is an issue but also the ultimate impact of the waiver. A waiver simply means that a WTO Member would not be in violation of its WTO obligations if it does not protect and enforce the COVID-19-related IPRs for the duration of the waiver. The waiver would thus allow Members to deviate from their international obligations but not obligate Members to suspend protection and enforcement of the IPRs. Members like the US who support the waiver may not implement the necessary domestic legislation to waive IPRs within the jurisdiction. It is questionable whether the US could even legally implement the waiver given that IPRs are a matter of constitutional law.17

#### 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.

### C1

#### Evergreening is a myth – this card ends the debate.

Lietzan 20 [Erika; Professor of Law, University of Missouri School of Law, Research interests in Pharmaceutical Regulation, Device Regulation, Intellectual Property; “The Evergreening Myth Claims that drug innovators extend their patents obscure a radical policy‐​making goal.,” Cato Institute; Fall 2020; <https://www.cato.org/regulation/fall-2020/evergreening-myth>/] Justin

In recent years, U.S. policymakers have considered proposals intended to prevent — or at least reduce — “evergreening” by pharmaceutical companies. Some proposals would change the antitrust enforcement landscape, others the intellectual property landscape, and still others the regulatory framework that governs new medicines. Some proposals — such as those creating new causes of action under the antitrust laws or limiting the availability of patents for discoveries — are profound and their proponents cite a body of academic and policy literature that decries supposed “evergreening” by companies to justify their ideas.

The term “evergreening” is a metaphor, meant to remind audiences of evergreen trees, which have green foliage year‐​round. It implies that something has been extended, and users of the metaphor view this extension as improper or undesirable. When offering descriptions and examples of evergreening, they focus on drug companies continuing to innovate after first introducing a new molecule, and on the broader marketplace for medicines after subsequent innovations have been introduced to the market. But proponents are frustratingly inconsistent and unclear about what, exactly, has been “extended” in these situations. A close look at the regulatory landscape in which continuing pharmaceutical innovation occurs shows that arguments for reform are grounded in myths, such as the myth that pharmaceutical companies continuing to innovate somehow “extend” their patents.

Once the myths of “evergreening” are laid bare, it becomes apparent that proponents of these proposals really want for the government to limit medical innovators to one medical product in the marketplace for each useful new molecule discovered. They are arguing that an innovator should not enjoy an exclusive market — and the resulting advantageous pricing — for innovations that, though discrete and independently satisfying the standard for a patent under U.S. law, stem in some fashion from an earlier innovation for which that innovator separately enjoyed exclusivity and the resulting pricing advantages. Or, at least, that drug innovators should not. This is a radical proposal that merits careful reflection and discussion, and it is not ripe for action. Understanding that this is the true policymaking objective requires unpacking the regulatory landscape and market more carefully, and paying closer attention to word choice, than proponents of reform often do. The Evergreening Allegation In the United States, every new medicinal product requires premarket approval from the Food and Drug Administration. The drug statute refers to approval of a “new drug,” and ambiguity in the term “drug” provides fertile ground for confusion and rhetorical mischief, as discussed later in this article. A firm that wants to market a new drug must prove to the FDA that the drug is safe and effective. Generating this information takes years, beginning with work in the laboratory and on animals, and progressing through several rounds of “clinical” testing in humans. For new molecules, the clinical portion of this research and development program averages six years. The process is also expensive: the Tufts Center for the Study of Drug Development now estimates the average cost of developing a new molecular entity at $2.6 billion. That figure includes average out‐​of‐​pocket costs of $1.4 billion and reflects the cost of unsuccessful projects. Most research and development programs fail. When new drugs are first launched by innovators, they tend to be sold under brand names and protected by patents as well as statutory rights in the data that supported FDA approval (known as “data exclusivity”). Although the pricing of these products may reflect competitive pressure from other branded products, it also reflects the fact that patent rights and statutory data exclusivity delay the launch of cheaper copies. But no more than five years later, and often earlier, the innovator’s competitors may file applications seeking approval of their own products based on the innovator’s research, rather than performing their own. They file what are known as “abbreviated applications” — abbreviated because they omit some, or all, of the research needed to prove safety and effectiveness. Abbreviated applications are much less expensive and time‐​consuming to assemble, and the competitors’ drugs correspondingly much less expensive than the original drugs they copy. When a competitor seeks to market an exact copy through an abbreviated application, we call its drug a “generic” drug. Pharmacists usually dispense generic copies even when doctors prescribe the corresponding branded products by name. Some people use the “evergreening” label when an innovator holds more than one patent protecting its product, especially if some patents expire later than others. More often, though, these people use the label when an innovator introduces a newer version of its own product that is already on the market. These newer products tend to be sold under brand names and protected by their own patents and statutory data exclusivity. Sometimes the innovator also stops selling its older product. If purchasers shift to the innovator’s newer product rather than purchasing cheap copies of the innovator’s older product, some say the innovator has engaged in evergreening. Although the term “evergreening” is a metaphor and signifies an extension of something, proponents of reform proposals do not agree on the particulars of the term’s use. Some say the company has evergreened its invention, its drug, or its product. Others say the company has evergreened the drug’s patent or patent life, or its exclusivity. Some say it has extended the drug’s patents, or the drug’s patent coverage or patent life, or the drug’s exclusivity period. Some say the company has evergreened the drug’s price, or its own profits or monopoly, or the company has extended its market power. Many argue that through evergreening — whatever the term means — the innovator has improperly blocked other firms from competing with it. On this basis, they seek government intervention. For instance, one recent proposal would allow the Federal Trade Commission to bring antitrust actions against innovators who introduced newer products to replace their older products. Three Myths of Evergreening The circumstances that trigger the “evergreening” label occur at the intersection of several complex bodies of law: the federal framework requiring premarket approval of new medicines and their copies, federal intellectual property laws, federal and state laws governing promotion of medicines, and federal laws and practices and state laws relating to prescribing and dispensing medicines. Many who propose aggressive government intervention because of evergreening give short shrift to this landscape, which allows the perpetuation of three myths that distort policymaking discussions. Before reviewing the myths, it will help to understand two points about the framework in which innovators compete with the companies that submit abbreviated applications. First, the FDA approves products, not active ingredients. And second, patents protect inventions, not products. Federal law states that every “new drug” requires an approved application. But at the FDA the term “drug” has more than one meaning. It includes a medicine’s active ingredient, to be sure. But it also includes drug products. A drug product is a medicine in its finished form, meaning the form that will be sold in the market and administered to patients. And the FDA approves a particular product described in a particular application — the specific combination of active and inactive ingredients (often called a drug’s “formulation”), in a particular dosage form (such as capsule or tablet), for a particular route of administration (such as oral or topical), at a particular strength, for particular medical uses (also known as the product’s “indications”), manufactured as described in the application, and accompanied by labeling written for prescribers based on the data in the application. Federal law allows a patent to issue for any new, useful, non‐​obvious invention, including a process, a composition of matter, and an improvement to an existing process or composition of matter. The patent usually expires 20 years after its application date. For any particular drug product approved by the FDA, the innovator might own patents on various types of inventions. The innovator usually owns a patent claiming the product’s active ingredient, and because the innovator generally files this patent before starting clinical trials, it is usually the first to expire. Other inventions protected by patent might include the product’s formulation or a dosage form and dosage of the active ingredient (or formulation). These inventions may emerge later in the premarket development process. If the resulting patent applications refer to the active ingredient patent, the patents will expire when the active ingredient patent expires, but otherwise they will expire later. The innovator may also own other patents claiming inventions embodied in the product, such as a patent claiming methods of using or administering the product, a patent claiming the manufacturing process, or a patent claiming a metabolite of the active ingredient. These, too, could expire later than the first patent — sometimes much later. These two points work together. A single active ingredient associated with a single brand name might be the subject of a half dozen, dozen, or more discrete products. Suppose an active ingredient was formulated into tablets and the innovator sold six strengths. Suppose the innovator also formulated an injectable version, which it sold in two strengths. Suppose it also developed a disintegrating tablet for oral administration, which it sold in four strengths. This innovator would sell 12 discrete products with the same active ingredient and probably (though not necessarily) the same brand name. And because a single product might incorporate many discrete inventions, the patents relevant to one product might differ from the patents relevant to another. Failure to realize this — and its regulatory significance — leads to three myths, as follows.

Myth of evergreening patents / The first myth is that innovators extend their patents. This is legally impossible. In the United States, a patent expires 20 years after its application date.

There are only two ways a patent’s expiration date can shift later in time: (1) When it issues a patent, the U.S. Patent and Trademark Office (PTO) adjusts the expiry date later to compensate for routine delays at the PTO. And (2), if the marketing application proposed a new active ingredient, then if the company asks the PTO for a patent term extension within 60 days of FDA approval, the PTO will use a statutory formula to extend one patent claiming the product to compensate partially for the lapse of patent life during premarket testing and regulatory review. There is no other mechanism by which a patent might be extended. In particular, a patent on one invention — no matter when it expires — does not extend the patent on another invention.

Myth of blocked competitors / The second myth is that when an innovator holds patents that expire after its active ingredient patent, or when it introduces newer products to market, it can prevent its competitors from bringing their copies to market. Instead, once the initial patent and (if applicable) statutory exclusivity on the innovator’s active ingredient have expired, its competitors have substantial freedom to operate. This freedom reflects two facts that are often overlooked.

First, the innovator’s competitor does not have to propose an exact copy. Federal law permits the competitor to rely on the innovator’s research but propose competing products that are not identical. To be sure, a competitor may submit an ANDA for a product that essentially duplicates the innovator’s product — that is, a generic. Ordinarily, the company shows in the ANDA that its product has the same active ingredient, route of administration, dosage form, strength, and labeling as the innovator’s product. The generic must also be “bioequivalent” to the original drug that it references, meaning that its active ingredient must reach the site of action in the body to the same extent and at the same rate as the active ingredient of the referenced product. But even a generic can be a little different. For example, it usually does not need the same inactive ingredients in the same quantities. And the generic competitor need not use the same manufacturing process.

If a competitor wants to offer a different route of administration, dosage form, or strength — for instance, to avoid infringing a patent — it may still be able to use the generic drug approval pathway. It simply files a “suitability petition” asking the FDA’s permission. The agency will approve the petition unless more data are needed to establish the proposed product’s safety and effectiveness. And at this point, the competitor may file an ANDA. More significantly, though, a competitor can always use a different abbreviated application pathway: a “505(b)(2)” application for a product that differs more substantially from the innovator’s product. Although the changes proposed in this hybrid application must be supported by new data, the competitor otherwise relies on the innovator’s data, avoiding the expensive and time‐​consuming research and development process the innovator went through. In addition to using this mechanism to propose modifications that avoid a patent, a competitor might use the mechanism to propose innovations that will offer an advantage in the market — such as changes to the active ingredient and new medical uses.

Second, an abbreviated application cites a specific innovative product, not the active ingredient or brand writ large. The competitor selects one innovative product as the reference product on which it relies — for instance, one of the 12 products in the hypothetical above. Its regulatory burden is tied to that specific product alone. The requirement to show sameness and bioequivalence (for an ANDA) and, critically, the obligation to contend with patents and wait for statutory exclusivity to expire are linked to the one specific product, alone. (In rare circumstances, when filing a hybrid application, a competitor might cite two innovative products, but the same point applies.)

To be sure, the patents associated with the cited innovative product affect when the FDA may approve the abbreviated application. Whether it files an ANDA or a hybrid application, a competitor must address the unexpired patents listed in the FDA’s “Orange Book” for the specific innovative product it has chosen to cite. For each listed patent, it has two choices, and its selection dictates the timing of FDA approval as far as that patent is concerned. The competitor may state the date on which the patent will expire, signaling that it does not plan to market its product until expiry. This precludes final approval of its product until patent expiry. Or it may assert that the patent is invalid or will not be infringed by its product, notifying the innovator of this position. If the innovator sues within 45 days, the drug statute stays final approval of its abbreviated application for 30 months. Under changes to the law made in 2003, though, unless the competitor changes its position on a patent after filing its abbreviated application, approval of its application is stayed only once. At the end of the 30 months, the FDA must approve the abbreviated application if the approval standard is met, even if there is ongoing patent litigation.

Although a competitor using the abbreviated application pathway must contend with the innovator’s patents and approval of its product may be delayed because of those patents, this is true of only the patents associated with the specific product that it references. The competitor does not have to contend with patents associated with other products that happen to contain the same active ingredient or bear the same brand name. Similarly, the competing applicant grapples with only the statutory exclusivity associated with the product it references. The drug statute provides five years of exclusivity in the data supporting new chemical entities and three years of exclusivity for most new products that are not new chemical entities. Separately, if an innovator introduces what the FDA calls a new “condition of approval” — such as a new strength or dosage form — the drug statute may provide three years of exclusivity. This delays approval of abbreviated applications proposing products with the same active ingredient for the same condition of approval. But a competitor that proposed a different strength or dosage form — or that cited a product with a different strength or dosage form (such as the innovator’s original product) — would not need to grapple with that exclusivity.

This debunks the myth that an innovator with later‐​expiring patents and an innovator that introduces newer products can prevent its competitors from bringing copies to market. Instead, competitors have several options. For instance, empirical studies show that competitors file abbreviated applications as early as the law permits them to do so, arguing that the innovator’s patents are invalid or, if applicable, not infringed by the new drug. They tend to lose these arguments when the active ingredient patent is at issue, but they tend to win if a formulation patent is at issue. If a competitor believed it would infringe a patent or feared it would lose the patent infringement suit brought by the innovator, it could seek a license. Settlements of patent litigation between innovators and competitors seeking to market generic copies usually include a license allowing the competitor to bring its product to market earlier than the date of patent expiry. There are also other options.

Once the patent on the active ingredient expires, a competitor can use the ingredient in its own product and file an abbreviated application, relying on the research performed and submitted by the innovator. Even in an ANDA, a true generic application, only the active ingredient must be the same. A competitor may be able to design around patents claiming other aspects of the innovator’s product (such as its strength and route of administration) and still file a true generic application. The competitor would simply file a suitability petition and, upon approval of that petition, a generic application proposing the difference that allowed it to avoid patent infringement. Then it would assert non‐​infringement in its application. If it could not file a generic application (for instance, because the FDA requested data to support the changes made), it could always file a hybrid application. It would still rely on the innovator’s research and it would similarly assert non‐​infringement in its application. In either case, the innovator might not sue if the competitor clearly avoided its patents.

It is thus misleading for advocates of intervention to complain about the number of “patents” associated with a “drug.” A competitor filing an abbreviated application does not copy a “drug” in the broad sense of the term. Accurately describing a company’s freedom to operate in the market would require focusing on discrete products that can serve as references for abbreviated applications and on the number, scope, and breadth of the patent claims held by the innovator for those products. This would tell policymakers more about the market effects of a firm’s innovation and patenting practices than the number of patents associated with a particular brand name or the number of patents associated with the many finished products containing a particular active ingredient.

Myth that automatic substitution is critical / The final myth of evergreening is that continuing innovation — especially when an innovator introduces a newer version of its product and stops selling its old version — precludes uptake of less expensive medicines by interfering with automatic pharmacy substitution under state pharmacy law. This myth reflects an assumption that competitors who file abbreviated applications depend on automatic pharmacy substitution — rather than the ordinary rough and tumble of a competitive marketplace — to obtain market share. The truth may be more complicated.

Automatic pharmacy substitution arises through a combination of longstanding FDA practices and state pharmacy law. Once the agency has approved two products with the same active ingredient, it assesses whether they are “therapeutically equivalent.” Designating two as therapeutically equivalent means that they have the same clinical profile and that they can be “substituted”: either can be dispensed instead of the other. A true generic drug, an exact copy of the innovator’s product approved based on an ANDA, will be deemed therapeutically equivalent. Every state either permits or requires pharmacists to dispense a therapeutically equivalent generic drug when a doctor prescribes an innovator’s drug by its brand name, unless the doctor has said not to. The notion advanced by critics of alleged “evergreening” is that once an innovator introduces a newer version of its branded product, doctors will prescribe the newer version. And because the generic company instead copied the older version, pharmacists will not — cannot under state law — substitute the generic product when the patient presents a prescription for the newer innovator product.

The problem with this argument is that actual dispensing decisions probably reflect a more complex interaction of prescriber decisions, payer preferences, and state law. To begin with, a doctor may specify either branded drugs or generic drugs. A doctor could write the brand name, to be sure, but the doctor could also simply identify the active ingredient, which will usually lead the pharmacist to dispense one of the available generic drugs. In theory, the doctor could even identify a particular generic company’s drug containing a particular active ingredient. And while drugmakers rarely promote generic drugs to doctors and patients, nothing prevents them from doing so. They do promote their therapeutically equivalent generic drugs to pharmacies and payers, focusing on the lower prices they offer. And a company that filed a hybrid application for a product that differed from the innovator’s product might brand its product and promote the distinguishing features, or (depending on the reason it filed the hybrid application) position the product as a near‐​duplicate of the more expensive branded alternatives and promote it as such.

In short, an innovator’s newer product creates a new choice for doctors and payers. To be sure, if doctors select this product, pharmacists will dispense it rather than generic copies of the innovator’s older product. Doctors might shift their prescribing to the newer product for many reasons, including persuasive advertising and promotion — meaning they come to believe (based on advertising that, per FDA rules, must be truthful and not misleading) that there are benefits to the newer product. They might shift for other reasons, including experience treating patients with the two options. But companies may advertise and promote generic products to doctors and patients as well, and based on this advertising (or for other reasons, such as experience with the older innovative product that the competitor copied) doctors might not select the innovator’s newer product. They might specify the innovator’s older product (which would lead to automatic substitution, even if the innovator no longer markets the product) or, again, a generic product itself.

Generic companies will be able to introduce copies of the innovator’s first product and they may or may not enjoy sales depending on the choices they make and the choices made by others in the market.

The assumption that competing companies depend on automatic substitution for market share may be simplistic. Only a minority of states require substitution; most instead have permissive laws. In these states, if a generic product is therapeutically equivalent to the prescribed product and the payer requires its use, the permissive state pharmacy law makes it possible for a pharmacist to substitute, in accordance with the patient’s insurance, without consulting the physician. In these cases, the patient’s insurance drives the product selection. State law just makes it possible to comply with the insurance without contacting the doctor. If a payer perceives the innovator’s new product as less cost effective than available generic drugs containing the same active ingredient, it may decline to cover the product. A rational payer will adopt strategies that steer doctors and patients to less expensive products that are equally or adequately effective — not only those that are therapeutically equivalent, but also those that are not. In these cases, even if a doctor specifies a branded product, the patient’s insurance might prompt a conversation among the doctor, pharmacist, and patient, ultimately leading to modification of the prescription and dispensing of the cheaper copy of the innovator’s first‐​version product.

In short, when an innovator introduces a new product into the market, generic companies will be able to introduce copies of the innovator’s first product and they may or may not enjoy sales depending on the choices they make and the choices made by others in the market. In this scenario, products compete for the business of rational payers based on their comparative benefits and cost. Substitution may play almost no true role, and whether the innovator still markets its older branded product may be irrelevant.

#### The aff takes too long – we read green.

1AC FDA 21 [https://www.fda.gov/drugs/news-events-human-drugs/generic-drug-approval-process]

#### It depends on the complexity of the drug product and the completeness of the application. Some generic versions of priority drugs – drugs that CDER has determined to potentially provide a significant advance in medical care -- have been approved in six months or less. Other times it may take years before FDA’s scientific and medical team is 100 percent confident in an approval decision. It often takes several rounds of communication between FDA and the generic drug company before the product is shown to be safe, effective, high quality, and substitutable for the brand name counterpart. Some generic drugs are never approved, because the company is unable to meet FDA’s rigorous standards for approval.

### C2

#### Generic medicine is dangerous—contamination and unsanitary manufacturing conditions.

White 19 [(C. Micheal, Professor and Head of the Department of Pharmacy Practice, University of Connecticut) “Why your generic drugs may not be safe and the FDA may be too lax” The Conversation, 12/4/19. <https://theconversation.com/why-your-generic-drugs-may-not-be-safe-and-the-fda-may-be-too-lax-125529>] RR

This leads to a vital question: Are generics safe? If drug manufacturers followed the FDA’s strict regulations, the answer would be a resounding yes. Unfortunately for those who turn to generics to save money, the FDA relies heavily on the honor system with foreign manufacturers, and U.S. consumers get burned. Eighty percent of the active ingredients and 40% of the finished generic drugs used in the U.S. are manufactured overseas.

As a pharmacist, I know that the safety of prescription medications is vital. My research, recently published in the “Annals of Pharmacotherapy,” raises alarming concerns about our vulnerabilities.

Do experts have something to add to public debate?

Where are your drugs being made?

A pharmacist at a drug plant outside Mumbai in 2012, shortly after a change in patent law allowed production of a generic cancer drug. Rafiq Mugbool/AP Photo

Generic drug manufacturers either make bulk powders with the active ingredient in them or buy those active ingredients from other companies and turn them into pills, ointments or injectable products.

In 2010, 64% of foreign manufacturing plants, predominantly in India and China, had never been inspected by the FDA. By 2015, 33% remained uninspected.

In addition, companies in other countries are informed before an inspection, giving them time to clean up a mess. Domestic inspections are unannounced.

Faking results

The FDA informs manufacturing plants in other countries when it plans to inspect their plants. Andrew Harnik/AP Photo

As I detail in my paper, when announced foreign FDA inspections began to occur in earnest between 2010 and 2015, numerous manufacturing plants were subsequently barred from shipping drugs to the U.S. after the inspections uncovered shady activities or serious quality defects.

Unscrupulous foreign producers shredded documents shortly before FDA visits, hid documents offsite, altered or manipulated safety or quality data or utilized unsanitary manufacturing conditions. Ranbaxy Corporation pleaded guilty in 2013 to shipping substandard drugs to the U.S. and making intentionally false statements. The company had to withdraw 73 million pills from circulation, and the company paid a $500 million fine.

These quality and safety issues can be deadly. In 2008, 100 patients in the U.S. died after receiving generic heparin products from foreign manufacturers. Heparin is an anticoagulant used to prevent or treat blood clots in about 10 million hospitalized patients a year and is extracted from pig intestines.

Some of the heparin was fraudulently replaced with chondroitin, a dietary supplement for joint aches, that had sulphur groups added to the molecule to make it look like heparin.

One of the heparin manufacturers inspected by the FDA received a warning letter after it was found to have used raw material from uncertified farms, used storage equipment with unidentified material adhering to it and had insufficient testing for impurities.

These issues continue to this day. Dozens of blood-pressure and anti-ulcer drugs were recalled in 2018 and 2019 due to contamination with the potentially carcinogenic compounds N-nitrosodimethylamine or N-nitrosodiethylamine.

One of the major producers of these active ingredient powders used by multiple generic manufacturers was inspected in 2017. The FDA found that the company fraudulently omitted failing test results and replaced them with passing scores.

This raises a critical question: How many more violations would occur with inspections occurring as frequently as they do in the U.S., and more importantly, if they were unannounced? Relatively speaking, the number of drugs proved to be tainted or substandard has been small, and the FDA has made some progress since 2010. But the potential for harm is still great.

### C3

**No solvency and reject "empirical" claims -- vaccines require complex infrastructure to manufacture, not just patents**

**Hotez 5/10** [Peter J. Hotez, Maria Elena Bottazzi, and Prashant Yadav. "Producing a Vaccine Requires More Than a Patent," Foreign Affairs, 5-10-2021, accessed 8-8-2021, https://www.foreignaffairs.com/articles/united-states/2021-05-10/producing-vaccine-requires-more-patent] HWIC

On May 5, President Joe Biden announced that the United States would support an international bid to waive intellectual property rights to vaccines for the duration of the coronavirus pandemic, thereby ostensibly allowing other countries to ramp up production even of the sophisticated technology behind the Pfizer-BioNTech and Moderna vaccines against COVID-19. Many in the global health community and developing world welcomed the decision as a victory for greater equity in vaccine distribution, in which middle- and low-income countries are lagging far behind wealthy ones. But the jubilation may be premature. The drive for intellectual property waivers originates in part from the world’s experience fighting the last war, against HIV/AIDS. Patent pools, intellectual property waivers, and other liberalizing mechanisms were urgent in assuring equity of access to lifesaving drugs during that epidemic. But these tools are better suited to medicines and other pharmaceuticals than to vaccines. Producing vaccines—particularly those as technologically complex as the messenger RNA (mRNA) inoculations against COVID-19—requires not only patents but an entire infrastructure that cannot be transferred overnight. The sharing of patents is an important and welcome development for the long term, but it may not even be the most pressing first step. JUST OPEN THE SPIGOT At the turn of the millennium, multinational pharmaceutical companies were charging $10,000 per patient for a daily drug regimen that could keep those infected with HIV/AIDS alive. Those in low- and middle-income countries in Africa and elsewhere could access this cocktail only under limited circumstances. Then, in 2001, the Indian drug manufacturer Cipla Limited began producing versions of a triple antiretroviral drug cocktail for a mere $350. Cipla, in collaboration with Médecins Sans Frontières (Doctors Without Borders), helped usher in a new era of global access to essential medicines—one that justified relaxing or even ignoring international patents and other property rights to produce and distribute an important and lifesaving drug as a generic. Since that time, global health advocacy organizations have found increasingly sophisticated ways to work with multinationals in ensuring access to essential medicines for low- and middle-income countries. In the 2010s, the global health initiative Unitaid helped create a Medicines Patent Pool, in which pharmaceutical companies from all over the world offered antiretroviral drug licenses, thereby creating a path for developing generic versions so long as the patent holders received royalties. The mechanism supplied voluntary licenses to new producers even while protecting the legal rights of the drugs’ original manufacturers. Companies such as Gilead, for example, have supplied voluntary licenses for their antivirals directly to generic manufacturers, allowing for tiered pricing across countries. Barely any COVID-19 vaccines have been administered in the African continent or in low- or middle-income countries in Asia and Latin America. Global health professionals have understandably sought to ascertain whether a similar approach could help make the distribution of COVID-19 vaccines less lopsided. More than one billion vaccine doses have now been administered—but overwhelmingly to people living in just a few countries. More than half have been administered in the United States (250 million) and China (290 million) alone, followed by India (160 million), the United Kingdom (51 million), and Germany (32 million). In contrast, for all practical purposes, barely any COVID-19 vaccines have been [administered](https://www.nytimes.com/interactive/2021/world/covid-vaccinations-tracker.html) in the African continent or in low- or middle-income countries in Asia and Latin America. Global health advocates have responded to this inequity by seeking to apply the lessons they learned from antiretroviral drugs and demanding patent pools or other intellectual property waivers for COVID-19 vaccines. In March 2021, Médecins Sans Frontières organized protests at the World Trade Organization (WTO) headquarters in Geneva, unfurling a banner that read, “No COVID Monopolies—Wealthy Countries Stop Blocking TRIPS Waiver,” referring to the organization’s Agreement on Trade-Related Aspects of Intellectual Property Rights. The assumption underlying such demands is that intellectual property

is a crucial barrier blocking vaccine developers, especially in low- and middle-income countries, from producing COVID-19 vaccines to scale—particularly the high-performing mRNA vaccines that Pfizer-BioNTech and Moderna currently produce. These vaccines elicit more than 90 percent protective immunity against both symptomatic illness and documented infection, including asymptomatic infection, with COVID-19. They are successfully driving the recovery of the United States, Israel, and other nations. But so far, mRNA vaccines are mostly invisible to Africa, Latin America, and low- and middle-income countries in other regions. The hope of those pushing for TRIPS waivers and patent pools is that these will unleash the technology to make the recovery global. IT TAKES A WHOLE ECOSYSTEM Intellectual property sharing may be helpful in the long term. But producing complicated biologics, especially innovative ones such as mRNA or adenovirus-vectored vaccines, is not solely a matter of patent access. Small-molecule antiviral drugs are comparatively straightforward: the multistep chemical processes through which they are synthesized are often fully detailed in published patents or scientific papers. Chemists and formulation experts can often synthesize and scale up production just from knowing the drug structure. But vaccines are different. Producing and manufacturing lipid-encased mRNA molecules, recombinant adenoviruses, or even the proteins or whole inactivated viruses used in older-generation vaccines requires a far higher level of sophistication than is needed for producing small-molecule drugs. Moreover, vaccine production must meet stringent requirements for quality control, quality assurance, and regulatory oversight. The **effective transfer of such complex technology requires a receiving ecosystem that can take years, sometimes decades, to build**. Countries seeking to ramp up vaccine production will need to train staff scientists and technicians. They will also need scientific administrators versed not only in basic research and development but also in detailed record keeping, including specific documentation practices such as batch production records. Moreover, they will need strong quality control systems and regulatory guardrails. Building such an infrastructure requires intensive training and often considerable financial investment and risk. It also takes time—by some estimates, vaccine development requires at least 11 years, and even then the probability that such efforts will result in bringing a vaccine to market is less than ten percent. Consider that the COVID-19 vaccines were themselves the outcome of decades of research and development. Few nations are prepared to take such risks. Only a handful of low- or middle-income countries currently have the capacity to produce new vaccines. Only a handful of low- or middle-income countries currently have the capacity to produce new vaccines. The most notable and largest is India, which currently makes the adenovirus-vectored vaccines developed by Janssen and by Oxford and AstraZeneca, as well as an older-technology recombinant protein vaccine and a whole inactivated virus vaccine. Manufacturers in Brazil, Cuba, and some Southeast Asian countries have experience producing childhood vaccines and may be able to develop the capacity to make COVID-19 vaccines as well. Other possibilities may develop elsewhere, including in the Middle East and Africa. But in the near term, such manufacturers will require financing, access to very large amounts of raw materials and supplies (possibly including relaxation of export controls), and some technical expertise in manufacturing and quality control if they are to produce the existing vaccines against COVID-19. Vaccinating India alone will require almost two billion doses, and more than 12 billion doses will be required to vaccinate the world. The emergence of new variants and the need for booster doses may increase demand even further. Whether mRNA vaccine technology can be scaled to produce billions of doses in 2021, or even by early 2022, remains entirely unknown, but the goal is worth pursuing. To this end, some kind of patent relaxation may be necessary, but far from sufficient. Would-be producers will need technical know-how, regulatory controls, and components that are currently in very short supply, such as nucleotides and lipids.