### 1

#### Genocidal settlement is a structure, not an event meaning ontological logic of elimination is an everyday manifestation that defines settler identity.

**Rifkin 14**, Mark. Settler common sense: Queerness and everyday colonialism in the American renaissance. U of Minnesota Press, 2014. (Associate Professor of English & WGS at UNC-Greensboro)//Elmer

If nineteenth-century American literary studies tends to focus on the ways Indians enter the narrative frame and the kinds of meanings and associa- tions they bear, recent attempts to theorize settler colonialism have sought to shift attention from its effects on Indigenous subjects to its implications for nonnative political attachments, forms of inhabitance, and modes of being, illuminating and tracking the pervasive operation of settlement as a system. In Settler Colonialism and the Transformation of Anthropology, Patrick Wolfe argues, “Settler colonies were (are) premised on the elimination of native societies. The split tensing reflects a determinate feature of settler colonization. The colonizers come to stay—invasion is a structure not an event” (2).6 He suggests that a “logic of elimination” drives settler governance and sociality, describing “the settler-colonial will” as “a historical force that ultimately derives from the primal drive to expansion that is generally glossed as capitalism” (167), and in “Settler Colonialism and the Elimination of the Native,” he observes that “elimination is an organizing principle of settler-colonial society rather than a one-off (and superceded) occurrence” (388). Rather than being superseded after an initial moment/ period of conquest, colonization persists since “the logic of elimination marks a return whereby the native repressed continues to structure settler- colonial society” (390). In Aileen Moreton-Robinson’s work, whiteness func- tions as the central way of understanding the domination and displacement of Indigenous peoples by nonnatives.7 In “Writing Off Indigenous Sover- eignty,” she argues, “As a regime of power, patriarchal white sovereignty operates ideologically, materially and discursively to reproduce and main- tain its investment in the nation as a white possession” (88), and in “Writ- ing Off Treaties,” she suggests, “At an ontological level the structure of subjective possession occurs through the imposition of one’s will-to-be on the thing which is perceived to lack will, thus it is open to being possessed,” such that “possession . . . forms part of the ontological structure of white subjectivity” (83–84). For Jodi Byrd, the deployment of Indianness as a mobile figure works as the principal mode of U.S. settler colonialism. She observes that “colonization and racialization . . . have often been conflated,” in ways that “tend to be sited along the axis of inclusion/exclusion” and that “misdirect and cloud attention from the underlying structures of settler colonialism” (xxiii, xvii). She argues that settlement works through the translation of indigeneity as Indianness, casting place-based political collec- tivities as (racialized) populations subject to U.S. jurisdiction and manage- ment: “the Indian is left nowhere and everywhere within the ontological premises through which U.S. empire orients, imagines, and critiques itself ”; “ideas of Indians and Indianness have served as the ontological ground through which U.S. settler colonialism enacts itself ” (xix).

#### That results in land exploitation and ecocide – specifically manifests in knowledge institutions making forefronting Settler Colonialism a prior question.

**Paperson 17** la paperson or K. Wayne Yang, June 2017, “A Third University is Possible” (an associate professor of ethnic studies at the University of California, San Diego)//Elmer

Land is the prime concern of settler colonialism, contexts in which the colonizer comes to a “new” place not only to seize and exploit but to stay, making that “new” place his permanent home. Settler colonialism thus complicates the center–periphery model that was classically used to describe colonialism, wherein an imperial center, the “metropole,” dominates distant colonies, the “periphery.” Typically, one thinks of European colonization of Africa, India, the Caribbean, the Pacific Islands, in terms of external colonialism, also called exploitation colonialism, where land and human beings are recast as natural resources for primitive accumulation: coltan, petroleum, diamonds, water, salt, seeds, genetic material, chattel. Theories named as “settler colonial studies” had a resurgence beginning around 2006.[2] However, the analysis of settler colonialism is actually not new, only often ignored within Western critiques of empire.[3] The critical literatures of the colonized have long positioned the violence of settlement as a prime feature in colonial life as well as in global arrangements of power. We can see this in Franz Fanon’s foundational critiques of colonialism. Whereas Fanon’s work is often generalized for its diagnoses of anti/colonial violence and the racialized psychoses of colonization upon colonized and colonizer, Fanon is also talking about settlement as the particular feature of French colonization in Algeria. For Fanon, the violence of French colonization in Algeria arises from settlement as a spatial immediacy of empire: the geospatial collapse of metropole and colony into the same time and place. On the “selfsame land” are spatialized white immunity and racialized violation, non-Native desires for freedom, Black life, and Indigenous relations.[4] Settler colonialism is too often thought of as “what happened” to Indigenous people. This kind of thinking confines the experiences of Indigenous people, their critiques of settler colonialism, their decolonial imaginations, to an unwarranted historicizing parochialism, as if settler colonialism were a past event that “happened to” Native peoples and not generalizable to non-Natives. Actually, settler colonialism is something that “happened for” settlers. Indeed, it is happening for them/us right now. Wa Thiong’o’s question of how instead of why directs us to think of land tenancy laws, debt, and the privatization of land as settler colonial technologies that enable the “eventful” history of plunder and disappearance. Property law is a settler colonial technology. The weapons that enforce it, the knowledge institutions that legitimize it, the financial institutions that operationalize it, are also technologies. Like all technologies, they evolve and spread. Recasting land as property means severing Indigenous peoples from land. This separation, what Hortense Spillers describes as “the loss of Indigenous name/land**”** for Africans-turned-chattel, recasts Black Indigenous people as black bodies for biopolitical disposal: who will be moved where, who will be murdered how, who will be machinery for what, and who will be made property for whom.[5] In the alienation of land from life, alienable rights are produced: the right to own (property), the right to law (protection through legitimated violence), the right to govern (supremacist sovereignty), the right to have rights (humanity). In a word, what is produced is whiteness. Moreover, it is not just human beings who are refigured in the schism. Land and nonhumans become alienable properties, a move that first alienates land from its own sovereign life. Thus we can speak of the various technologies required to create and maintain these separations, these alienations: Black from Indigenous, human from nonhuman, land from life.[6] “How?” is a question you ask if you are concerned with the mechanisms, not just the motives, of colonization. Instead of settler colonialism as an ideology, or as a history, you might consider settler colonialism as a set of technologies —a frame that could help you to forecast colonial next operations and to plot decolonial directions. This chapter proceeds with the following insights. (1) The settler–native– slave triad does not describe identities. The triad—an analytic mainstay of settler colonial studies—digs a pitfall of identity that not only chills collaborations but also implies that the racial will be the solution. (2) Technologies are trafficked. Technologies generate patterns of social relations to land. Technologies mutate, and so do these relationships. Colonial technologies travel. In tracing technologies’ past and future trajectories, we can connect how settler colonial and antiblack technologies circulate in transnational arenas. (3) Land—not just people—is the biopolitical target.[7] The examples are many: fracking, biopiracy, damming of rivers and flooding of valleys, the carcasses of pigs that die from the feed additive ractopamine and are allowable for harvest by the U.S. Food and Drug Administration. The subjugation of land and nonhuman life to deathlike states in order to support “human” life is a “biopolitics” well beyond the Foucauldian conception of biopolitical as governmentality or the neoliberal disciplining of modern, bourgeois, “human” subject. (4) (Y)our task is to theorize in the break, that is, to refuse the master narrative that technology is loyal to the master, that (y)our theory has a Eurocentric origin. Black studies, Indigenous studies, and Othered studies have already made their breaks with Foucault (over biopolitics), with Deleuze and Guatarri (over assemblages and machines), and with Marx (over life and primitive accumulation). (5) Even when they are dangerous, understanding technologies provides us some pathways for decolonizing work. We can identify projects of collaboration on decolonial technologies. Colonizing mechanisms are evolving into new forms, and they might be subverted toward decolonizing operations. The Settler–Native–Slave Triad Does Not Describe Identities One of the main interventions of settler colonial studies has been to insist that the patterning of social relations is shaped by colonialism’s thirst for land and thus is shaped to fit modes of empire. Because colonialism is a perverted affair, our relationships are also warped into complicitous arrangements of violation, trespass, and collusion with its mechanisms. For Fanon, the psychosis of colonialism arises from the patterning of violence into the binary relationship between the immune humanity of the white settler and the impugned humanity of the native. For Fanon, the supremacist “right” to create settler space that is immune from violence, and the “right” to abuse the body of the Native to maintain white immunity, this is the spatial and fleshy immediacy of settler colonialism. Furthermore, the “humanity” of the settler is constructed upon his agency over the land and nature. As Maldonado- Torres explains, “I think, therefore I am” is actually an articulation of “I conquer, therefore I am,” a sense of identity posited upon the harnessing of nature and its “natural” people.[8] This creates a host of post+colonial problems that have come to define modernity. Because the humanity of the settler is predicated on his ability to “write the world,” to make history upon and over the natural world, the colonized is instructed to make her claim to humanity by similarly acting on the world or, more precisely, acting in his. Indeed, for Fanon, it is the perverse ontology of settler becomings—becoming landowner or becoming property, becoming killable or becoming a killer—and the mutual implication of tortured and torturer that mark the psychosis of colonialism. This problem of modernity and colonial psychosis is echoed in Jack Forbes’s writings: Columbus was a wétiko. He was mentally ill or insane, the carrier of a terribly contagious psychological disease, the wétiko psychosis. . . . The wétiko psychosis, and the problems it creates, have inspired many resistance movements and efforts at reform or revolution. Unfortunately, most of these efforts have failed because they have never diagnosed the wétiko.[9] Under Western modernity, becoming “free” means becoming a colonizer, and because of this, “the central contradiction of modernity is freedom.”[10] Critiques of settler colonialism, therefore, do not offer just another “type” of colonialism to add to the literature but a mode of analysis that has repercussions for any diagnosis of coloniality and for understanding the modern conditions of freedom. By modern conditions of freedom, I mean that Western freedom is a product of colonial modernity, and I mean that such freedom comes with conditions, with strings attached, most manifest as terms of unfreedom for nonhumans. As Cindi Mayweather says, “your freedom’s in a bind.”[11]

#### Expansion of medical access is a form of settler colonial biomedical onslaught – humanitarian promotions of health proliferate genocidal assimilation.

**Klausen 13,** Jimmy Casas. "Reservations on hospitality: contact and vulnerability in Kant and indigenous action." Hospitality and World Politics. Palgrave Macmillan, London, 2013. 197-221. (Associate Professor in the Instituto de Relações Internacionais at the Pontifícia Universidade Católica do Rio de Janeiro)//Elmer

On the other hand and by contrast, the governmental reach of public health initiatives that would effect the improvement of isolated indigenous populations’ health accords with Kantian philanthropy – with all the risks of violated freedom and smothered life that entails. Public health advocates would repair the disadvantaged morbidity profile of isolated indigenous groups through a policy of initiating contact supported by the provision of modern biomedical health care services to ameliorate the epidemiological effects of contact. State-initiated contact without attendant health care has proved disastrous. Into the 1970s, FUNAI attempted to make friendly contact with isolated Indians. By relying on hired expert indigenous trackers, government contact expeditions located isolated groups and – demonstrating their interest in seeking commerce – enticed the latter with gifts of machetes and blankets. One FUNAI expedition to contact the Matis in 1978 resulted in high morbidity from pneumonia and other infectious diseases and killed one of every two Matis. 60 To correct such devastating policies, anthropologists Magdalena Hurtado, Kim Hill, Hillard Kaplan and Jane Lancaster have elaborated the following argument: Many anthropologists and indigenous-rights activists believe that uncontacted Indians should be left alone. These people are well-meaning, but they are wrong because they base their position on three incorrect assumptions. First, they assume that the Indians have chosen to remain isolated . . . . Those who oppose contact also assume that the Indians will inevitably be decimated by virgin-soil epidemics . . . . Finally, opponents of contact assume that isolated native groups will survive if not contacted. 61 However, even correcting for the fatal infelicities of past policy-driven, state-initiated contacts such as FUNAI’s, the preponderantly disadvantaged morbidity profile of such virgin-soil populations cannot be reduced by greater hospitality in the form of redoubled and more expert interventionary contacts. Although public health efforts like those advocated by Hurtado et al. might reduce mortality, highly disease-vulnerable persons will still sicken and will do so through means that would pretend to foster life by actively disregarding how the people subject to these external machinations might determine their own needs and value their own health. Isolated indigenes’ biological lives would be simultaneously fostered and risked, while their free personhood would count as nothing morally–culturally. In short, there are serious political costs to be weighed in such an intervention. Because of – and not in spite of – their philanthropy, public health interventions of the type that Hurtado et al. advocate extend the reach of governmentality much more intrusively than land rights policies. Besides deciding on behalf of peoples in regard to the interpretation of their acts of self-quarantine, the advocated public health policies surgically insert apparatuses of biomedicine directly into the contacted peoples’ living being. Such policies thereby displace indigenous norms of health and native cultural strategies of living on with the norms and overall strategy embedded in the culture of scientific and clinical biomedicine. Though the pretence is that such acts demonstrate the hospitality of the wider national or global society, such health policy interventions cannot simply make a presentation for possible society; rather, qua philanthropy they initiate contact, which, because of the high degree of vulnerability of those contacted, must needs lead to the proliferation of contacts. It is not a hospitable policy of fostering life that Hurtado et al. support, not merely possible commerce but an obsessive philanthropy of biomedical life support and literally unavoidable onslaught of commerce, possibly forevermore. Most startlingly, such public health interventions presume as universal a standard of life that could certainly vary while retaining meaning and value. The anthropologist Tess Lea describes this universalising interventionary compulsion in withering words: When you are a helping bureau-professional, the compulsion to do something to fix the problems of target populations – those deemed as suffering from unequal and preventable conditions – exceeds all other impulses . . . . ‘They’ need our greater commitment. The idea that life might be lived differently with value and meaning or that ‘need’ might be conceived differently from the way in which we calculate it through our interventionary lens, becomes impossible to imagine. 62 Hurtado et al. assume that health professionals and policy makers must hospitably confer biomedically acquired immunity on heretofore isolated and now contacted virgin soil populations. Fostering indigenous lives by imposing an alien conception of immunity, they would inhospitably destroy alternate strategies of living on. Seeing through their interventionary lens, Hurtado et al. themselves become arbiters of successful and unsuccessful forms of life: they presume that self-quarantine cannot itself serve as an effective cultural strategy to immunise living bodies. Thus, ironically perhaps, these anthropologists choose biology above culture by seeing each from a standpoint authorised by the culture of biomedicine. From their interventionary lens and against Canguilhem’s admonition above, self-quarantine appears to be a failed strategy for living on because the immunity it would confer is imperfect or incomplete. Likewise, condoning self-isolation is imperfect or incomplete hospitality as against their more perfect interventionary hospitality in the name of life. Authorising themselves to make these judgements, they enact an altogether different collapse of morality into nature than the Kantian collapse I reconstruct above. Whereas Kant’s collapse of minimalism into abstentionism and moral duty into nature’s constraints opens hospitality and therefore strategies for living on, this other collapse binds moralising conceptions of ‘health’ to the biomedically conceived body. Yet if, according to Canguilhem, for humans especially, ‘health is precisely a certain latitude, a certain play in the norms of life and behavior’, 63 then it seems that the ‘health’ that supposedly hospitable, though strictly philanthropic, ‘life’-fostering interventionary contact would impose on the exuberance of self-quarantining indigenous peoples is a sickness unto that other perpetual peace Kant mentions: death.

#### Biomedicine itself is invested in colonial exploitation through testing done on indigenous communities to biopiracy and stealing indigenous knowledge.

**Lift Mode 17** 3-10-2017 "Pharmaceutical Colonialism” <https://medium.com/@liftmode/pharmaceutical-colonialism-3-ways-that-western-medicine-takes-from-indigenous-communities-3a9339b4f24f> (We at Liftmode.com are a team of professionals from a variety of backgrounds, dedicated to the mission of providing the highest quality and highest purity nutritional health supplements on the market. We look specifically for the latest and most promising research in the fields of cognition enhancement, neuroscience and alternative health supplements, and develop commercial strategies to bring these technologies to the marketplace.)//Elmer

Does modern medicine take from rural communities? At first, this seems outrageous. However, on closer inspection, we find three main methods of poaching: stealing indigenous knowledge, ‘biopiracy’, and the sale of pharmaceuticals at exorbitant prices. Another example includes using developing countries and rural populations as test subjects in unethical clinical trials — for example on AIDS patients in South Africa.[1] This article examines three methods that Western medicine takes from rural communities. We also examine the emerging new forms of medicine and how many people are beginning to appreciate the medical knowledge of different cultures around the world. Traditional knowledge and culture is threatened by the expansive natural of the pharmaceutical industry 1. Pharmaceutical colonialism: Stealing Indigenous Knowledge First and foremost, what has been taken from indigenous communities for the last roughly 600 years is traditional knowledge about medicinal plants. It is interesting that the major advancements in Western medicine coincide very closely to escalating global colonialism by Western countries. It’s difficult to estimate the exact percentage of modern drugs that were originally based on traditional plant sources, because of the complex evolution of Western laboratory-made medicine. However, this percentage is known to be very high. In fact, a 2006 paper by Dr. A Gurib-Fakim states: “Natural products and their derivatives represent more than 50% of all the drugs in clinical use in the world. Higher plants contribute no less than 25% of the total.”[2] The extent to which traditional knowledge permeates through Western medicine is too broad to explain fully in a small article like this. We’d need to write an entire book to cover the full content! So, we will just take a look at one example below. How the West takes Indigenous knowledge: Anti-Malaria Drugs Mosquitoes are, by far, the world’s most dangerous animals, spreading a number of diseases including Dengue fever, Zika virus, and malaria. According to the World Health Organization, nearly half of the world’s population is at risk of malaria. In 2015, over 210 million people became infected with malaria, and a staggering 429 000 people died from the blood parasite.[3] To combat the infectious disease, scientists have developed two major classes of anti-malarial drugs. These are both based on indigenous knowledge of plant medicine: Mosquitos kill more people than any other animal every year 1. Quinine Quinine is extracted from the bark of the cinchona tree, native to South America. Contrary to propaganda by the Spanish inquisitors, which is still used in modern medicine today, Westerners did not ‘discover’ the cinchona tree. Indigenous Peruvian cultures had been using the bark of the cinchona tree for hundreds, possibly thousands, of years before the arrival of the colonial forces from the North. They crushed it up and mixed it with water to ‘relieve shivering’ — a major sign of the feverish symptoms of malaria.[4] Unlike traditional Chinese knowledge, which has survived until modern times, the ancient knowledge of South America cultures was almost completely destroyed by colonial forces. This makes tracing the historical use of the cinchona tree more difficult.[5] After the inquisition of most traditional cultures in South America, the cinchona bark was brought back to Western Europe and was hailed as one of the most exciting discoveries of modern medicine. The success of cinchona bark in Europe created a massive industry, initially run by the Spanish, but which was later overtaken by French and English industrialists.[6] It’s important to know that the ‘traditional’ use of cinchona bark in 18th century Europe was in exactly the same method as its original use in indigenous societies: crushing up the barking and mixing it with water. The chemical compound quinine was first extracted from cinchona bark in 1820 by two Frenchmen: Pierre Joseph Pelletier and Joseph Caventou. This allowed purified quinine to replace traditional cinchona extracts.[7] Interestingly, Western scientists have since discovered that cinchona bark actually contains several active components, which function in a synergistic relationship to kill the malaria parasite.[8] In modern times, a number of quinine-based drugs have been developed, with varying success. The issue becomes complex here because, while these drugs were developed by Western scientists using modern technological laboratories, if it hadn’t been for the original indigenous knowledge, these compounds could not have been developed at all. The quinine derivatives include Chloroquine, Pyrimethamine, and Mefloquine. Chloroquine was used as a spray along with DDT in the WHO’s malaria eradication plan (the efficacy and usefulness of this are still under debate: numerous countries that were sprayed with these chemicals soon developed strains of malaria that were resistant to the drugs).[9] 60411828 - workers are fogging for dengue control. mosquito borne diseases of zika virus. Quinine-based drugs were used in sprays to combat malaria around the world 2. Artemisinin Artemisinin is an active compound found in traditional Chinese medicine called Qinghao Su (sweet wormwood). This traditional Chinese medicine has been used to treat fevers for over a thousand years. It is currently still extracted from plant sources, the majority of which are grown in China, Vietnam and East Africa. Once the full-grown plants are harvested, the chemical is extracted, leaving the pure artemisinin at a highly variable market price of between $120 — $1200 per kilogram.[10] It’s interesting that the artemisinin-based drug combinations (ACTs) are the most expensive anti-malarial treatments available. This is despite the fact that it is one of the few malarial medications that are still mostly plant-based. However, Western pharmaceutical companies are now developing synthetic forms of artemisinin. The new forms of artemsinin are genetically engineered and have intellectual property rights attached, potentially bringing in big revenues for the companies involved. The proponents of the synthetic form of artemisinin claim that the synthetic form will be able to be sold for cheaper than the natural form. However, the average import price of natural artemsisin to India over the last ten years was around $370 per kilo — a fair amount cheaper than the price that the pharmaceutical companies are pushing for.[11] Artemisinin farming sustains the livelihoods of an estimated 100’000 farmers. With synthetic derivatives being developed this puts the livelihoods of the farmers and their families at risk of poverty (estimated to be around 3–5 times the number of people as the farmers themselves).[12] The ironic and disturbing thing about the whole situation is that the artemisinin farmers themselves are the ones who are most at risk of contracting malaria. In effect, they stand to not only have their incomes stripped by Western pharmaceutical companies but also to become physically dependent on the products of those very companies. [13] 16118463 - portrait of a burmese woman with thanaka powdered face working in farm Farmers livelihoods are threatened by the use of synthetic chemicals 2. ‘Biopiracy’ — stealing natural resources and plants The idea that modern medicine might be a form of colonialism seems at first to be quite outrageous! However, on closer inspection, it’s quite clear that a few nations continue to play the role of ‘missionary’, helping to save people in the ‘developing world’.[14] In some cases, though, the role of the ‘missionary’ becomes a little less clear. The second way that Western medicine takes from indigenous communities is something called ‘Biopiracy’. This is similar to the method we described above, however, in this case, what is taken is not knowledge but the actual plants and resources themselves. In biopiracy actions, plants and natural resources are stolen entirely from indigenous communities and are then used to develop drugs and medicines in the West. The indigenous communities benefit nothing from the theft of their resources. Medicines developed from stolen materials are often sold back to the very people from whom the original plant-sources were stolen — at exorbitant prices. Examples of medications that face biopiracy charges include: A drug for diabetes developed in the UK from a Libyan plant, Artemisia judaica A medicine for immunosuppression developed by GlaxoSmithKline which is derived from a chemical found in termite hills in Gambia An HIV treatment taken from bacteria found in central Uganda Antibiotic drugs developed from amoebas found in Mauritius and Venezuela Anti-diarrhea vaccines developed from Egyptian bacteria [15] According to Beth Burrows, president of Washington-based Edmond’s Institute: “Times have changed. It is no longer acceptable for the great white explorer to trawl across Africa or South America taking what they want for their own commercial benefit. It is no more than a new form of colonial pillaging. As there are internationally recognized rights for oil, so there should be for indigenous plants and knowledge.”[16] In an ideal world, knowledge and resources would be shared equitably. Both the indigenous cultures and the modern world would benefit from the sharing of knowledge and medicinal plants, which could leave the world a much better place. However, this is not the case in today’s world. More and more, we see evidence of pharmaceutical companies using rural communities as customers and guinea-pigs for medicine that was originally sourced from local knowledge.[17] Traditional medicine is pushed off the market and indigenous knowledge is ‘dumbed down’ through development programs. This forces the majority of the world to have to work through cartel-like pharmaceutical corporations who extract unbelievably large sums of money from people, which we’ll look at below.[18] 21736635 - shanty house in bangkok water canals along the river bank, thailand Those who benefit the least from pharmaceutical colonialism are the ones who need healthcare the most

#### Vote negative to endorse a cartography of refusal

**Day 15** Iyko, Associate Professor of English. Chair, Critical Social Thought. “Being or Nothingness: Indigeneity, Antiblackness, and Settler Colonial Critique.” Source: Critical Ethnic Studies, Vol. 1, No. 2 (Fall 2015), pp. 102-121 //Elmer

And so the potential relations that Wilderson sets up through a critique of sovereignty are at best irrelevant or at worse false in Sexton’s absolute claim that slavery stands alone as the “threshold of the political world.”45 I suggest that this wavering relation/nonrelation of antiblackness and Indigeneity exhibited in Wilderson’s and Sexton’s work reveal the problem in any totalizing approach to the heterogeneous constitution of racial difference in settler colonies. Beyond this inconsistency, the liberal multiculturalist agenda that Wilderson and Sexton project into Indigenous sovereignty willfully evacuates any Indigenous refusal of a colonial politics of recognition. Among other broad strokes, Sexton states, “as a rule, Native Studies reproduces the dominant liberal political narrative of emancipation and enfranchisement.”46 This provides a basis for Wilderson’s assertion that Indigenous sovereignty engages in a liberal politics of state legitimation through recognition because “treaties are forms of articulation” that buttress “the interlocutory life of America as a coherent (albeit genocidal) idea.”47 But such a depoliticized liberal project is frankly incompatible with Indigenous activism and scholarship that emerges from Native studies in North America. The main argument in Glen Sean Coulthard’s book Red Skin, White Masks is to categorically reject “the liberal recognition-based approach to Indigenous selfdetermination.”48 This is not a politics of legitimizing Indigenous nations through state recognition but rather one of refusal, a refusal to be recognized and thus interpellated by the settler colonial nation-state. Drawing on Fanon, Coulthard describes the “necessity on the part of the oppressed to ‘turn away’ from their other-oriented master-dependency, and to instead struggle for freedom on their own terms and in accordance with their own values.”49 It is also difficult to reconcile the depoliticized narrative of “resurgence and recovery” that Wilderson and Sexton attribute to Indigenous sovereignty in the face of Idle No More, the anticapitalist Indigenous sovereignty movement in Canada whose national railway and highway blockades have seriously destabilized the expropriation of natural resources for the global market. These are examples that Coulthard describes as “direct action” rather tjhan negotiation—in other words, antagonism, not conflict resolution: The [blockades] are a crucial act of negation insofar as they seek to impede or block the flow of resources currently being transported to international markets from oil and gas fields, refineries, lumber mills, mining operations, and hydroelectric facilities located on the dispossessed lands of Indigenous nations. These modes of direct action . . . seek to have a negative impact on the economic infrastructure that is core to the colonial accumulation of capital in settler-political economies like Canada’s.50 These tactics are part of what Audra Simpson calls a “cartography of refusal” that “negates the authority of the other’s gaze.”51 It is impossible to frame the blockade movement, which has become the greatest threat to Canada’s resource agenda,52 as a struggle for “enfranchisement.” Idle No More is not in “conflict” with the Canadian nation-state; it is in a struggle against the very premise of settler colonial capitalism that requires the elimination of Indigenous peoples. As Coulthard states unambiguously, “For Indigenous nations to live, capitalism must die.”

#### Reject Reformism or Plan Focus - Challenging the 1AC’s colonialist framework of interpretation is a prior question to whether or not the Aff is a good idea

Deloria Jr. 99 – Member of the Standing Rock Sioux Tribe and Professor at University of Colorado Boulder  
(Vine, also Former Executive Director for the National Congress of American Indians and former Professor of Political Science and Law at the University of Arizona, For This Land: Writing on Religion in America, p. 101-7)//Elmer  
If there were any serious concern about liberation, we would see thousands of people simply walk away from the vast economic, political, and intellectual machine we call Western civilization and refuse to be enticed to participate in it any longer. Liberation is not a difficult task when one no longer finds value in a set of institutions or beliefs. We are liberated from the burden of Santa Claus and the moral demand to be "good" when, as maturing adolescents, we reject the concept of Santa Claus. Thereafter we have no sense of guilt in late November that we have not behaved properly during the year, and no fear that a lump of coal rather than a gift will await us Christmas morning. In the same manner, we are freed and liberated once we realize the insanity and fantasy of the present manner of interpreting our experiences in the world. Liberation, in its most fundamental sense, requires a **rejection of everything we have been taught** and its replacement by only those things we have experienced as having values. But this replacement only begins the task of liberation. For the history of Western thinking in the past eight centuries **has been one of replacement of ideas** within a framework that has remained **basically unchanged** for nearly two millenia. Challenging this framework of interpretation means a rearrangement of our **manner of perceiving the world**, and it involves a reexamination of the body of human knowledge and its structural reconstruction into a new format, Such a task appears to be far from the struggles of the present. It seems abstract and meaningless in the face of contemporary suffering. And it suggests that people can be made to change their oppressive activity by intellectual reorientation alone. All these questions arise, however, because of the fundamental orientation of Western peoples toward the world. We assume that we know the structure of reality and must only make certain minor adjustments in the machinery that operates it in order to bring our institutions into line. Immediate suffering is thus placed in juxtaposition with abstract metaphysical conceptions of the world and, because we can see immediate suffering, **we feel impelled to change conditions quickly** to relieve tensions, never coming to **understand how the basic attitude toward life** and its derivative attitudes toward minority groups **continues to dominate** the goals and activities that appear designed to create reforms, Numerous examples can be cited to show that **our efforts to bring justice** into the world **have been short-circuited** by the passage of events, and that those efforts are unsuccessful because we have failed to consider the **basic framework within which we pose questions, analyze alternatives, and suggest solutions**. Consider the examples from our immediate past. In the early sixties college application forms included **a blank line** on which all prospective students were required **to indicate** their **race**. Such information was used to discriminate against those of a minority background, and so **reformers demanded** that the **question be dropped**. By the time all colleges had been forced to eliminate questions concerning the race of applicants, the Civil Rights Movement had so sensitized those involved in higher education that scholarships were made available in great numbers to people of minority races. **There was no way,** however, **to allocate** such **scholarships** **because college officials could no longer determine the racial background** of students on the basis of their applications for admission. Much of the impetus for **low-cost housing** in the cities was based upon the premise that in the twentieth century people should not have to live in hovels but that adequate housing should be constructed for them. Yet in the course of **tearing down** slums and building new housing projects, low-income housing areas were eliminated. The **construction cost** of the new projects **made** it necessary to charge hi**gher rentals**. **Former residents** of the lowincome areas **could not afford to live** in the new housing, so they moved to other parts of the city and created exactly the same conditions that had originally provoked the demand for low-rent housing. Government schools had a very difficult time teaching American Indian children the English language. (One reason was the assumption of teachers that all languages had Latin roots, and their inability to adapt the programs when they discovered that Indian languages were not so derived.) Hence programs in bilingual teaching methods were authorized that would use the native language to teach the children English, an underhanded way of eliminating the native language. Between the time that bilingual programs were conceived and the time that they were finally funded, other programs that concentrated on adequate housing had an unexpected effect on the educational process. Hundreds of new houses were built in agency towns, and Indians moved from remote areas of the different reservations into those towns where they could get good housing. Since they were primarily younger couples with young children, the housing development meant that most Indian children were now growing up in the agency communities and were learning English as a first language. Thus the bilingual programs, which began as a means of teaching English as a second language, became the method designed to preserve the native vernacular by teaching it as a second language to students who had grown up speaking English. Example after example could be cited, each testifying to the devastating effect of a general attitude toward the world that underlies the Western approach to human knowledge. The basis of this attitude is the assumption that the world operates in certain predetermined ways, that it operates continuously under certain natural laws, and that the nature of every species is homogeneous, with few real deviations.

#### The Aff relegates indigenous possibility to reservation, accelerating death-making – only an orientation of refusal as generative can solve. This the ROTB is to reject systems of settler colonialism.

King 17, Tiffany Lethabo. "Humans involved: Lurking in the lines of posthumanist flight." Critical Ethnic Studies 3.1 (2017): 162-185. (Assistant Professor of Women’s, Gender and Sexuality Studies at Georgia State)//GZ but re-cut by Elmer

Within Native feminist theorizing, ethnographic refusal can be traced to Audra Simpson’s 2007 article, “On Ethnographic Refusal.” In this seminal work, Simpson reflects on and gains inspiration from the tradition of refusal practiced by the people of Kahnawake.14 Simpson shares that Kahnawake refusals are at the core and spirit of her own ethnographic and ethical practices of refusal. I was interested in the larger picture, in the discursive, material and moral territory that was simultaneously historical and contemporary (this “national” space) and the ways in which *Kahnawakero:non*, the “people of Kahnawake,” had *refused* the authority of the state at almost every turn. The ways in which their formation of the initial membership code (now replaced by a lineage code and board of elders to implement the code and determine cases) was refused; the ways in which their interactions with border guards at the international boundary line were predicated upon a refusal; how refusal worked in everyday encounters to enunciate repeatedly to ourselves and to outsiders that “this is who we are, this is who you are, these are my rights.”15 Because Simpson was concerned with applying the political and everyday modes of Kahnawake refusal, she attended to the “collective limit” established by her and her Kahnawake participants.16 The collective limit was relationally and ethically determined by what was shared but more importantly by what was not shared. Simpson’s ability to discern the collective limit could only be achieved through a form of relational knowledge production that regards and cares for the other. Simpson recounts how one of her participants forced her to recognize a collective limit. Approaching and then arriving at the limit, Simpson experiences the following: And although I pushed him, hoping that there might be something explicit said from the space of his exclusion— or more explicit than he gave me— it was enough that he said what he said. “Enough” is certainly enough. “Enough,” I realised, was when I reached the limit of my own return and our collective arrival. Can I do this and still come home; what am I revealing here and why? Where will this get us? Who benefits from this and why? And “enough” was when they shut down (or told me to turn off the recorder), or told me outright funny things like “nobody seems to know”— when everybody *does* know and talks about it *all the time*. Dominion then has to be exercised over these representations, and that was determined when enough was said. The ethnographic limit then, was reached not just when it would cause harm (or extreme discomfort)—the limit was arrived at when the representation would bite all of us and compromise the *representational* territory that we have gained for ourselves in the past 100 years.17 Extending her discussion of ethnographic refusal beyond the bounds of ethnographic concerns, Simpson also ponders whether this enactment of refusal can be applied to theoretical work. Simpson outright poses a question: “What is theoretically generative about these refusals?”18 The question that Simpson asks in 2007 is clarified by Eve Tuck and K. Wayne Yang in the 2014 essay “R- Words: Refusing Research.” Arguing that modes of refusal extended into the theoretical and methodological terrains of knowledge production are productive and necessary, Tuck and Yang state: For the purposes of our discussion, the most important insight to draw from Simpson’s article is her emphasis that refusals are not subtractive, but are theoretically generative, expansive. Refusal is not just a “no,” but a redirection to ideas otherwise unacknowledged or unquestioned. Unlike a settler colonial configuration of knowledge that is petulantly exasperated and resentful of limits, a methodology of refusal regards limits on knowledge as productive, as indeed a good thing.19 In line with Simpson’s intervention, Tuck and Yang posit that “refusal itself could be developed into both method and theory.”20 For Tuck and Yang, a generative practice of refusal and a decolonial and abolitionist tradition is making Western thought “turn back upon itself as settler colonial knowledge, as opposed to universal, liberal, or neutral knowledge without horizon.”21 In fact, the coauthors suggest “making the settler colonial metanarrative the object of . . . research.”22 What this move effectively does is question the uninterrogated assumptions and exposes the violent particularities of the metanarrative. Scrutiny as a practice of refusal also slows down or perhaps halts the momentum of the machinery that allows, as Tuck and Yang argue, “knowledge to facilitate interdictions on Indigenous and Black life.”23

### UV

### Fw

#### Top-Level on Util:

#### 1] Framing Issue – If we win our reps are good and that our ethical orientations come apriori, that means that we just have to win a risk of a link to prove that the plan is unethical.

#### 2] Equality – Util is bad and not neutral.

Mignolo 7, Walter D. "The de-colonial option and the meaning of identity in politics." (2007). (Professor at Duke)//Elmer

The rhetoric of modernity (from the Christian mission since the sixteenth century, to the secular Civilizing mission, to development and modernization after WWII) occluded—under its triumphant rhetoric of salvation and the good life for all—**the perpetuation of** the logic of **coloniality**, that is, of massive appropriation of land (and today of natural resources), massive exploitation of labor (from open slavery from the sixteenth to the eighteenth century, to disguised slavery, up to the twenty first century), and the dispensability of human livesfrom the massive killing of people in the Inca and Aztec domains to the twenty million plus people from Saint Petersburg to the Ukraine during WWII killed in the so called Eastern Front.4 Unfortunately, not all the massive killings have been recorded with the same value and the same visibility. The unspoken criteria for the value of human lives is an obvious sign (from a de-colonial interpretation) of the hidden imperial identity politics: that is, the value of human lives to which the life of the enunciator belongs becomes the measuring stick to evaluate other human lives who do not have the intellectual option and institutional power to tell the story and to classify events according to a ranking of human lives; that is, according to a racist classification.5

#### 3] Calculability – Settler Colonialism is unable to be calculated on a utilitarian or a consequentialist metric – it is both a spiritual and cultural genocide that leads to a psychological and emotional genocide that can’t be accounted for by body count.

#### 4] Psychiatric Colonialism – Native Bodies are scientifically considered to have “dampened pain and pain signaling” meaning their pain is considered and evaluated differently to justify colonial actions that “won’t hurt as much” – means their starting point is violent.

#### 5] Ontology Outweighs - They can’t win any of their impacts in a word where they have conceded the libidinal economy and ontology which serves as a filter for their impacts.

#### 6] Extinction Rhetoric is a tactical securing of life for infinite futurist progression in opposition to the backward savage – the impact is endless violence.

Schotten 16 C. Heike Schotten 3-4-2016 “Queering Sovereignty, Decolonizing Desire” Spatializing Sovereignty organized by The Society for Radical Geography, Spatial Theory, and Everyday Life, Transcribed by Tabatha R. at rev.com. http://www.ustream.tv/recorded/84081898. 8:07 - 19:56 (associate professor of political science at UMass)//Elmer

Assumes if we act now we can secure the world for the future

Preomptive

Is a logic of futurism

Okay so in the state of nature, which Hobbes defines as a place where there's **no security**, there **is**, in Edelman's terms, **no future**. This is true not only because we are responsible solely for our own survival, an endeavor we cannot possibly succeed at on our own, but it is also because given this radical insecurity, we are incapable of imagining any other moment or time than now. Hobbes himself acknowledges there is no "accounting of time" in the state of nature, which of course makes sense; in a condition of perpetual war, the future is unimaginable because it is so tenuous. As well, the past becomes effectively irrelevant, hence **the institution of sovereignty** in Hobbes' version **secures** our **physical preservation** and I’m arguing that it does so **by** bringing **temporality** itself into existence and **producing a future**. Okay, so that's the first point. The second point is that, in this act, **the sovereign establishes the very meaning and content of life itself**. For understood temporally, there is a way in which there is no distinction between life and death in the state of nature, in so far as there is no way to tell present from future. The state of nature's enduring present entails that life there is a kind of limbo-like existence, a suspension of living or perpetual near-death experience wherein we can never be certain of anything. This may be why it is so important to Hobbes to establish the commonwealth in the first place: Not simply to preserve life, as he explicitly suggests, but actually more primarily to definitively demarcate life as life and differentiate it from death. I mean, there's a normative enterprise going on here, right? Indeed, although the sovereign is the beacon of peace, war and death are just as must a byproduct of the institution of sovereignty as life and peace are. So what I take from this is that sovereignty, in short, is the definitive bio-political regime, in so far as it constitutes and determines life as such, distinguishing it from what only becomes subsequently recognizable as death. The third point is that sovereignty institutes this life-death distinction via a moralized logic that relegates life to the domain of civilization and value, and death to the domain of savagery and nihilism. This becomes clear in the conflicted and confusing ways Hobbes characterizes the state of nature as simultaneously a time, a place, and a condition. Now as I just argued that the state of nature is a time — like if it is an era or an epoch — it's a time with no time, a moment that is completely timeless, an era lacking any dynamism or principle of change. If the state of nature is instead a condition, which he also claims, he is clear that it is one of savagery, writing "It may peradventure be thought there never was such a time nor condition of war as this; and I believe it was never generally so over all the world, but there are many places where they live so now," and he cites as an example, "the savage people in many places of America." Bolstering the view that the state of nature is a story about humanity's pre-history, Hobbes here rehearses the enlightenment trope of indigenous peoples as European humanity's ancestors and/or pre-modern childhood. Savagery is, therefore, associated with solid temporality, timelessness, and the failure of forward movement or progress. Conclusively, when referencing a geographical location, the state of nature is America, and the 17th-century European notion of the new world, an empty land ripe for exploration and conquest. These specifications of the state of nature in Hobbes make clear that establishment of sovereignty imposes a clear distinction not simply between peace and war, life and death, but also between modernity and backwardness, civilization and savagery. Each of these categorical pairs functions as a surrogate for the others. Taken together, they suggest the deep implications of the categories of life and death with colonization and conquest for European politics and political theory. The fourth point is that the commonwealth, or sovereign or sovereignty, can't actually solve the problem Hobbes says it does. So if there's no state and we're all going to murder each other, the solution is obviously a really big bad, coercive state, right? And that's going to solve the problem? It can't solve the problem, and that's because it can't solve the problem of desire, which has **futurism** built into its very structure. Hobbes actually gets short shrift as a psychologist. He actually talks quite a bit about desire and affect. So desire, according to Hobbes, is a voluntary motion of the body, whose aim, regardless of object, is attainment — possession, consumption, enjoyment. Yet this attainment poses a dilemma, for as he says, **the aim of desire is "not** to enjoy once only and for **one instant** of time, **but** **to assure forever** the way of one's future desire." According to Hobbes, in other words, desire seeks perpetuity of enjoyment. It aims at a consumption that can never fully completed. The fifth point — we're almost done — is that Hobbes asserts, therefore, that human beings are perpetual power-seekers, not because we want more and more, but because we want to preserve what we have now forever. His claim is that mere maintenance of the present **requires** **accumulation**, **undertaking a perpetual reference to an unknown future**. Thus, even despite the security from physical violence the sovereign provides, he cannot alleviate the anxiety that runs apace with desire. Everything we do today is undertaken for the sake of a future, which, if we're successful, will be no different from the present. But the sovereign can't guarantee that, right? Sixth then, and finally, this means that Hobbes' colonial story of the emergence of life and death from the state of nature is based on an underlying logic of desire that **explains** why settler colonial societies transform into expansionist security states. Hobbes' understanding of desire and its dilemmas elaborates George W. **Bush's** doctrine of **preemptive warfare**, the logic of **Israeli self-defense** in the face of so-called "existential threats," and the rationale behind **stand-your-ground laws** that exonerated the murderer of Trayvon Martin. The fact of this logic's hegemony in economics and political science as rational-choice theory or in international relations as Big R Realism make clear that **futurist temporality is the** unquestioned philosophical **foundation of the U.S.** economic and political **order**, as well as the obviously imperial investments of these economic disciplines. In short, it is the temporalization of desire itself that explains both the settler colonial foundations of survival, life and the value of life, as well as its transformation into an expansionist imperial project. Okay, that was part one. Part two: settlement and the global war on terror. So how does this reading of Hobbes through Edelman help us understand the emergence of empire? Lorenzo Veracini has argued that settler colonialism is distinct from other types of colonialism in so far as it seeks to erase itself as settler colonialism. Following Patrick Wolf's argument that settler colonialism pursues a logic of elimination, whereby settlers seek to replace the native and indigenize themselves post-facto, Veracini argues that because it aims at the elimination of the native, settler colonization necessarily aims at its own elimination. The truly successful settler colonial project, then, would therefore efface the native entirely, whether through genocide or assimilation or some other form of disappearance, the politics of recognition as Glen Coulthard has recently argued. Unless and until elimination is accomplished, settler states will engage in all sort of contortions, both political and ideological, to obscure the native in order to naturalize the conquest. Veracini represents this future of settler colonialism as either conceptually embedded its definition or else as a kind of bad faith on settlers' part, potentially implying that a guilty conscience somehow seeks to ward off complicity with conquest. I think that Edelman's understanding of futurism, however, helps explicate just how and why this anxious, reiterative, and reactionary veiling impulse is definitive of bio-political sovereignty. Hobbes' narratization of the drive of the state of nature is, like any other narratization of the drive, an imposition and thus an explicitly ideological move that serves a particular political agenda. It is the specifically futurist character of this imposition that destines it for failure and thus explains its anxious and recursive structure. Edelman regards this narrative movement toward a viable political future as fundamentally fantasmatic, not to mention conservative and ideological. Futurism, in other words – and these are his words — "perpetuates the fantasy of meaning's eventual realization," a realization that is by definition impossible, in so far as it is always only ever to come. Right? That's what the future is: It's beyond our grasp, it's always just out of reach. Built into Hobbes' understanding of desire, in other words, is the failed tautology of futurism, which as Edelman instructs, is fundamentally and futilely political. My contention is that this constitutive failure of futurism can be understood as the **dynamic content of conquest** in settler societies, as the original **civilizationist imposition of temporality,** an act that explains their subsequent transmogrification into expansionist security states. So, rather than face the violence that brought peace and life itself into being, Hobbes instead naturalizes this founding act by declaring it to be a "general inclination of all mankind" to engage in what he calls a "perpetual and restless desire of power after power that ceases only in death." In other words, he both institutes life and pushes it forward via a futurist narrativization of the drive into an insatiable, cumulative desire. Yet while desire **may push us** ever **forward**, ever beyond the initial moment of settlement, **it cannot erase that settlement** or relieve settlers' sovereignty of conquest. This is neither because of settler colonialist theoretical definition nor because settlers secretly feel guilty, but rather because the **impossibility of fulfilling** **futurism's** fantastical **promises** **requires** some **other way** of meeting the needs it manufactures if settler sovereignty is to maintain itself and it polity in tact. Settler societies resort to any number of destructive forms of managing futurism's failing, from transfer and removal to **outright extermination through war, massacre, starvation, and disease**. Yet this anxious reiterative activity is wholly predicable from an Edelmanian perspective and ineliminable from the structure of settler sovereignty because the **futurist narrativization** of the drive has **rendered** settlers beholden to an **unsustainable temporality that must produce** queerness or **death in order to continue to produce meaning**, survival, and civilization for itself. Settler sovereignty, thus, cannot do without the death native it brings into being. The **native as death must exist** in order to purchase life and survival for the settler. And yet, as Veracini and Wolf argue, the native cannot exist if the settler is to indigenize herself as native to the land she has expropriated, **hence the production of new enemies**, new queers, **new deathly threats to settlement and its civilization and its way of life**. The settler colonial foundation of bio-political sovereignty gives way to an expansionist imperial security state that finds new enemies abroad and new obstacles to its endless expansion, thereby solving, albeit only ever partially and temporarily, the problem of futurist failure that constituted settlement to begin with.

## Adv 1

### 1NC – AT: Evergreening Top-Level

#### Secondary and Follow-on patents are key.

IP Watch 18 9-21-2018 "Inside Views: Why Follow-On Pharmaceutical Innovations Should Be Eligible For Patent Protection" <https://www.ip-watch.org/2018/09/21/follow-pharmaceutical-innovations-eligible-patent-protection/> (a non-profit independent news service that provides professional coverage of global policymaking on intellectual property and innovation.)//Elmer

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 would have been no patent incentive to invest in the development of the drug, and without that incentive AZT might have languished on the shelf as simply one more failed drug candidate. Other examples of important drugs that likely never would have been made available to patients without the availability of a “secondary” patent include **Evista** (raloxifene, used in the treatment of osteoporosis and to reduce the risk of invasive breast cancer), **Zyprexa** (olanzapine, used in the treatment of schizophrenia), and an orally-administrable formulation of the antibiotic cefuroxime. **Pharmaceutical development** **is prolonged and unpredictable**, and frequently **a safe and effective drug** **occurs only as a result of** **follow-on innovation** occurring **long** **after the initial synthesis** and characterization of a pharmaceutically interesting chemical compound. The inventions protected by secondary patents can be just as critical to the development of drugs as a patent on the active ingredient itself. 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 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 is an incoherent concept AND anti-trust solves it

IP Watch 18 9-21-2018 "Inside Views: Why Follow-On Pharmaceutical Innovations Should Be Eligible For Patent Protection" <https://www.ip-watch.org/2018/09/21/follow-pharmaceutical-innovations-eligible-patent-protection/> (a non-profit independent news service that provides professional coverage of global policymaking on intellectual property and innovation.)//Elmer

“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.

#### 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.

#### Aff gets circumvented- powerful countries use bilateral agreements to force other countries to accept their IPR protections- its empirically proven

DC = developing country

NIT = Net Importers of Technology (this references developing countries)

NET = Net Exporters of Technology (countries with advanced economies)

Marcellin 16 Marcellin, Sherry (Professor, London School of Economics). The political economy of pharmaceutical patents: US sectional interests and the African Group at the WTO. Routledge, 2016./SJKS

In July 1988, prior to the Montreal Mid-Term Review, DCs had sensed that the approach being proposed by industrialised countries was desirable on the grounds that the alternative would be a proliferation of unilateral or bilateral actions (MTN.GNG/NG11/8: 31). These NITs maintained that acceptance of such an approach would be tantamount to creating a licence to force, in the name of trade, modifications in standards for the protection of IP in a way that had not been found acceptable or possible so far in WIPO (ibid). Brazil subsequently informed the Group that on October 20, 1988, unilateral restrictions had been applied by the US to Brazilian exports as a retaliatory measure in connection with an IP issue; that this type of action seriously inhibited Brazil’s participation in the work of the Group, since ‘no country could be expected to participate in negotiations while experiencing pressures on the substance of its position’ (MTN.GNG/NG11/10: 27). The Brazilian delegate maintained that such action by the US constituted a blatant infringement of GATT rules and was contrary to the Standstill commitment of the Punta del Este Declaration. ‘The United States action was an attempt to coerce Brazil to change its intellectual property legislation, and furthermore represented an attempt by the United States to improve its negotiating position in the Uruguay Round’ (ibid). A US delegate countered that the measures had been taken with regret and as a last resort after all alternative ways of defending legitimate US interests had been exhausted, and that the US further believed that the adoption of effective patent protection was in Brazil’s own interest (ibid: 28). The US had therefore applied its strategy of coercive unilateralism against one of the two most important players championing the cause of the South in the TRIPS negotiations, the other being India. Apprehensive about the resistance of this dominant Southern duo, the United States sought to utilise its market size as a bargaining tool to secure changes to national IP regimes. It therefore decided to impact the more powerful of the two at the time, thereby indirectly admonishing India and the entire coalition against strengthened IP rules, as well as their domestic export constituencies who would be affected by US decisions to restrict imports. Moreover, because Brazil and India appeared to be collaborating extensively in maintaining a united front, a resulting strain on Brazil’s economy would likely affect their co-operation. However, since market opening and closure have been treated as the currency of trade negotiations in the post-war period (Steinberg 2002: 347), the move to place restrictions on Brazilian exports by the largest consumer market in the GPE should not have been entirely unanticipated. Brazil was also the regional leader in South America and disciplining it would send an unequivocal warning to other South American countries (Drahos and Braithwaite 2002: 136), including Argentina, Chile and Peru who were also active participants in the negotiations. This would mark the start of a series of coercive strategies aimed at compliance with the US private-sector envisioned GATT IPP.

#### 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.

## Adv 2

### 1NC – IP not Key [Generic]

#### Alt Causes to lack of generics thump Aff solvency to zero – pay-for-delay, citizen petitions, authorized generics, and testing sample access – this is terminal since they’d just shift tactics to non-patent strategies.

Fox 17, Erin. "How pharma companies game the system to keep drugs expensive." Harvard Business Review (April 6, 2017), https://hbr. org/2017/04/how-pharma-companies-game-the-system-to-keep-drugs-expensive (last visited on November 22, 2019) (2017). (director of Drug Information at University of Utah Health)//Elmer

The ways companies stop generics One of the ways branded drug manufacturers prevent competition is simple: cash. In so-called “pay for delay” agreements, a brand drug company simply pays a generic company not to launch a version of a drug. The Federal Trade Commission estimates these pacts cost U.S. consumers and taxpayers $3.5 billion in higher drug costs each year. “Citizen petitions” offer drug companies another way to delay generics from being approved. These ask the Food and Drug Administration to delay action on a pending generic drug application. By law, the FDA is required to prioritize these petitions. However, the citizens filing concerns are not individuals, they’re corporations. The FDA recently said branded drug manufacturers submitted 92% of all citizen petitions. Many of these petitions are filed near the date of patent expiration, effectively limiting potential competition for another 150 days. “Authorized generics” are another tactic to limit competition. These aren’t really generic products at all; they are the same product sold under a generic name by the company that sells the branded drug. Why? By law, the first generic company to market a drug gets an exclusivity period of 180 days. During this time, no other companies can market a generic product. But the company with the expiring patent is not barred from launching an “authorized generic.” By selling a drug they’re already making under a different name, pharmaceutical firms are effectively extending their monopoly for another six months. Another way pharmaceutical firms are thwarting generics is by restricting access to samples for testing. Generic drug makers need to be able to purchase a sample of a brand-name product to conduct bioequivalence testing. That’s because they have to prove they can make a bioequivalent product following the current good manufacturing practices (CGMP) standard. These manufacturers don’t need to conduct clinical trials like the original drug company did. But the original drug developer often declines to sell drug samples to generics manufacturers by citing “FDA requirements,” by which they mean the agency’s Risk Evaluation and Mitigation Strategies program. The idea behind this program is a good one: give access to patients who will benefit from these personalized medicines, and bar access for patients who won’t benefit and could be seriously harmed. However, brand drug makers are citing these requirements for the sole purpose of keeping generics from coming to market.

#### Petitions to the FDA swamp and deter generics.

Feldman 17 Robin Feldman 6-16-2017 "Pharma companies fight behind-the-scenes wars over generic drugs" <https://www.statnews.com/2017/06/16/generic-drugs-biosimilars-pharma/> (Arthur J. Goldberg Distinguished Professor of Law and Director of the Center for Innovation.)//Elmer

One tactic that my colleague Evan Frondorf and I describe in our book, “Drug Wars: How Big Pharma Raises Prices and Keeps Generics Off the Market,” involves petitions to the Food and Drug Administration asking that the agency not give the green light to generic versions of a drug. Our research on 12 years of FDA data shows that in some years nearly 1 out of every 5 petitions filed on any topic — including food, tobacco, dietary supplements, and devices — was related to delaying generic entry. The FDA denies 80 percent of these petitions, but the process takes time, even for silly petitions, such as one asking the FDA to declare that a generic must provide information that the regulations already require. The time it takes to respond to these petitions delays the entry of the generic.

#### Authorized Generics decimate competition.

Sipkoff 4 Martin Sipkoff 8-4-2004 "Big Pharma uses effective strategies to battle generic competitors" <https://www.drugtopics.com/view/big-pharma-uses-effective-strategies-battle-generic-competitors> (Healthcare Writer)//Elmer

But, according to Cutting Edge, brand-name pharmaceutical companies have begun flanking generics in an inventive way: They enter into manufacturing and distribution agreements with a generic company before a patent is about to expire, attempting to preempt market share. "A typical agreement specifies that the generic company will serve as a distributor of the nonbranded, generic form of the drug, which will continue to be produced in the branded drug company's manufacturing facilities," said Hess. "It's an increasingly popular strategy, often stemming from out-of-court patent lawsuit settlements." A successful flanking strategy can be beneficial to a generic manufacturer because it saves on capital outlay by not having to build or modify manufacturing facilities. "The brand-name pharmaceutical company benefits because the partnership enables it to continue to operate its manufacturing lines and turn a profit, thereby recouping more of its R&D investment in the drug and more of its capital investment in the manufacturing plant," said Hess. Here's an example of effective flanking: Generic drugmaker Apotex launched a version of GlaxoSmithKline's blockbuster drug Paxil in September 2003, threatening to significantly dent GSK's $3.2 billion-a-year bestseller. In response to Apotex's entry into the market, GSK struck a licensing agreement with another generic drugmaker, Par Pharmaceutical, in April 2003. The agreement specifies that GSK will supply Par with generic Paxil, in immediate-release form. The tablets are made by a GSK subsidiary, and Parwhich pays a royalty to GSK on salesdistributes them in the United States. "The royalty payments help GSK capture a small segment of the generic Paxil market, which offsets the losses of its branded Paxil sales following the drug's patent expiration," said Hess. Flanking is very controversial because it virtually derails competition. In fact, some generic manufacturers say it's illegal. It's very similar to what the Generic Pharmaceutical Association and others regard as the illegitimate strategy of "authorized generics." "It's an easy concept to describe," said Robert Reznick, a partner with the national law firm Hughes Hubbard & Reed. He chairs the firm's Pharmaceutical and Healthcare Practice Group and has written about the legality of authorized generics. "An authorized generic is like any other generic in that it is deemed equivalent to a brand-name drug," he said. "But rather than being made by an independent generic drug manufacturer pursuant to an Abbreviated New Drug Application, it is either made by or under a license from the New Drug Application holder itself. It may be marketed by an affiliate of the brand-name manufacturer or by a third party." In a white paper titled "Are Authorized Generics Lawful?" Reznick and his colleagues recently concluded that agreements between brand and generic manufacturers to create authorized generics may be legal under antitrust law, but the issue has yet to be fully settled.

#### Generic companies are just incompetent – means even without patents, they wouldn’t be able to produce.

Fox 17, Erin. "How pharma companies game the system to keep drugs expensive." Harvard Business Review (April 6, 2017), https://hbr. org/2017/04/how-pharma-companies-game-the-system-to-keep-drugs-expensive (last visited on November 22, 2019) (2017). (director of Drug Information at University of Utah Health)//Elmer

Problems with generic drug makers Although makers of a branded drug are using a variety of tactics to create barriers to healthy competition, generic drug companies are often not helping their own case. In 2015, there were 267 recalls of generic drug products—more than one every other day. These recalls are for quality issues such as products not dissolving properly, becoming contaminated, or even being outright counterfeits. A few high-profile recalls have shaken the belief that generic drugs are truly the same. In 2014, the FDA withdrew approval of Budeprion XL 300 — Teva’s generic version of GlaxoSmithKline’s Wellbutrin XL. Testing showed the drug did not properly release its key ingredient, substantiating consumers’ claims that the generic was not equivalent. In addition, concerns about contaminated generic Lipitor caused the FDA to launch a $20 million initiative to test generic products to ensure they are truly therapeutically equivalent. In some cases, patent law also collides with the FDA’s manufacturing rules. For example, the Novartis patent for Diovan expired in 2012. Ranbaxy received exclusivity for 180 days for the first generic product. However, due to poor quality manufacturing, Ranbaxy couldn’t obtain final FDA approval for its generic version. The FDA banned shipments of Ranbaxy products to the United States. Ranbaxy ended up paying a $500 million fine, the largest penalty paid by a generic firm for violations. Due to these protracted problems with the company that had won exclusivity, a generic product did not become available until 2014. The two-year delay cost Medicare and Medicaid at least $900 million. Ranbaxy’s poor-quality manufacturing also delayed other key generic products like Valcyte and Nexium. Ironically, it was Mylan—involved in its own drug pricing scandal over its EpiPen allergy-reaction injector—that filed the first lawsuit to have the FDA strip Ranbaxy of its exclusivity. Mylan made multiple attempts to produce generic products but was overruled in the courts.