### 1NC – Th

#### Interp: The aff must have a unified solvency advocate who advocates for the plan for the same advantages the aff gives.

#### Violation: They have reasons IP is independently bad for the two advantages but not an advocate who deliniates a reduction measure and its two separate advocates not a unified one.

#### Lack of a solvency advocate is a reason to vote neg – it proves there’s no grounding in the literature and wrecks mutual engagement and topic ed – links to fairness since debaters come up with obscure advocacies that have no reciprocal neg ground. It also explodes limits because affs can Frankenstein advantages together making predictable neg prep impossible.

### 1NC – Th

#### Interpretation: The affirmative must specify to what degree they reduce intellectual property protections.

#### Reduce requires quantification.

Passarello 13 – J.D. Candidate, Duke University School of Law, 2013. (Nicholas, NOTE: THE ITEM VETO AND THE THREAT OF APPROPRIATIONS BUNDLING IN ALASKA, 30 Alaska L. Rev. 125, Lexis)//BB

With respect to the item veto power, the question in the case was whether or not the governor could strike descriptive language without affecting the rest of the appropriation. The state constitution clearly guarantees the power to "strike or reduce items in appropriations bills." 61 To determine what exactly it is that the governor may strike, the Alaska Supreme Court here addressed the meaning of "item" for the first time. 62 The court concluded that "item" means "a sum of money dedicated to a particular purpose." 63 This holding rested on five lines of analysis, all of which indicate that the amount of an appropriation is the object affected by the item veto power. First, the court noted that the word "item" implies "a notion of unity between two essential elements of an appropriation: the amount and the purpose." 64 Altering the amount of an item is expressly allowed in the Constitution via the reduction power, 65 but to alter the purpose would destroy that unity by fundamentally changing the item into something else not enacted by the legislature. 66 Second, the use of the word "reduce" implies a quantitative effect**,** and the drafters likely intended the companion word "strike" to [\*136] have the same type of effect as well. 67 Third, "**reduce**" and "strike" **describe** the same **action applied to different extents:** **when an amount is "reduced**" **to the point where it is lessened to nothing**, **it is effectively "struck."** 68 **Thus, the object** of the "strike" **must be associated with an amount** of money **to the extent** **that it can be lessened**. 69 Fourth, the historical purpose of the item veto was to curtail the amount of state spending by mitigating the effects of log-rolling, a purpose most closely directed at the amount of the appropriation. 70 Fifth, "public policy disfavors a reading of "item' that would permit the executive branch to substantively alter the legislature's appropriation bills, resulting in appropriations passed without the protection our constitution contemplates." 71 For these reasons, the court concluded that the power to "strike" only refers to completely diminishing the amount of an appropriations item, not the descriptive language accompanying it.

#### 2] Violation: they don’t

#### Vote neg for shiftiness – vague plan wording wrecks Neg Ground since it’s impossible to know which DAs link or which CPs are competitive since different IP’s have different implications – absent 1AC specification, the 1AR can squirrel out of links by saying they don’t effect a certain protection or they don’t reduce IP enough to trigger the link.

#### Independently vote Negative on Presumption since the Aff gets struck down for being void-for-vagueness since they don’t have an explanation of what is reduced or remaining after the Plan.

#### Fairness and education are voters – debate’s a game that needs rules to evaluate it and education gives us portable skills for life like research and thinking.

#### Drop the debater – a) they have a 7-6 rebuttal advantage and the 2ar to make args I can’t respond to, b) it deters future abuse and sets a positive norm.

#### Use competing interps – a) reasonability invites arbitrary judge intervention since we don’t know your bs meter, b) collapses to competing interps – we justify 2 brightlines under an offense defense paradigm just like 2 interps.

#### Give me 30 speaker points – speaker points are endlessly arbitrary so 30s are key to avoid 4-2 screws especially at this tournament where there might be one.

#### No RVIs – a) illogical – you shouldn’t win for being fair – it’s a litmus test for engaging in substance, b) norming – I can’t concede the counterinterp if I realize I’m wrong which forces me to argue for bad norms, c) baiting – incentivizes good debaters to be abusive, bait theory, then collapse to the 1AR RVI

### 1NC – CP

#### CP: The member nations of the World Trade Organization should enter into a prior and binding consultation with the World Health Organization over whether to reduce IP protections for medicines. Member nations should support the proposal and adopt the results of consultation.

#### WHO says yes – it supports increasing the availability of generics and limiting TRIPS

Hoen 03 [(Ellen T., researcher at the University Medical Centre at the University of Groningen, The Netherlands who has been listed as one of the 50 most influential people in intellectual property by the journal Managing Intellectual Property, PhD from the University of Groningen) “TRIPS, Pharmaceutical Patents and Access to Essential Medicines: Seattle, Doha and Beyond,” Chicago Journal of International Law, 2003] JL

However, subsequent resolutions of the World Health Assembly have strengthened the WHO’s mandate in the trade arena. In 2001, the World Health Assembly adopted two resolutions in particular that had a bearing on the debate over TRIPS [30]. The resolutions addressed:

– the need to strengthen policies to increase the availability of generic drugs;

– and the need to evaluate the impact of TRIPS on access to drugs, local manufacturing capacity, and the development of new drugs

#### Consultation boosts strong leadership, authority, and cohesion among member states – key to WHO legitimacy

Gostin et al 15 [(Lawrence O., Linda D. & Timothy J. O’Neill Professor of Global Health Law at Georgetown University, Faculty Director of the O’Neill Institute for National & Global Health Law, Director of the World Health Organization Collaborating Center on Public Health Law & Human Rights, JD from Duke University) “The Normative Authority of the World Health Organization,” Georgetown University Law Center, 5/2/2015] JL

Members want the WHO to exert leadership, harmonize disparate activities, and set priorities. Yet they resist intrusions into their sovereignty, and want to exert control. In other words, ‘everyone desires coordination, but no one wants to be coordinated.’ States often ardently defend their geostrategic interests. As the Indonesian virus-sharing episode illustrates, the WHO is pulled between power blocs, with North America and Europe (the primary funders) on one side and emerging economies such as Brazil, China, and India on the other. An inherent tension exists between richer ‘net contributor’ states and poorer ‘net recipient’ states, with the former seeking smaller WHO budgets and the latter larger budgets.

Overall, national politics drive self-interest, with states resisting externally imposed obligations for funding and action. Some political leaders express antipathy to, even distrust of, UN institutions, viewing them as bureaucratic and inefficient. In this political environment, it is unsurprising that members fail to act as shareholders. Ebola placed into stark relief the failure of the international community to increase capacities as required by the IHR. Guinea, Liberia and Sierra Leone had some of the world's weakest health systems, with little capacity to either monitor or respond to the Ebola epidemic.20 This caused enormous suffering in West Africa and placed countries throughout the region e and the world e at risk. Member states should recognize that the health of their citizens depends on strengthening others' capacity. The WHO has a central role in creating systems to facilitate and encourage such cooperation.

The WHO cannot succeed unless members act as shareholders, foregoing a measure of sovereignty for the global common good. It is in all states' interests to have a strong global health leader, safeguarding health security, building health systems, and reducing health inequalities. But that will not happen unless members fund the Organization generously, grant it authority and flexibility, and hold it accountable.

#### WHO is critical to disease prevention – it is the only international institution that can disperse information, standardize global public health, and facilitate public-private cooperation

Murtugudde 20 [(Raghu, professor of atmospheric and oceanic science at the University of Maryland, PhD in mechanical engineering from Columbia University) “Why We Need the World Health Organization Now More Than Ever,” Science, 4/19/2020] JL

WHO continues to play an indispensable role during the current COVID-19 outbreak itself. In November 2018, the US National Academies of Sciences, Engineering and Medicine organised a workshop to explore lessons from past influenza outbreaks and so develop recommendations for pandemic preparedness for 2030. The salient findings serve well to underscore the critical role of WHO for humankind.

The world’s influenza burden has only increased in the last two decades, a period in which there have also been 30 new zoonotic diseases. A warming world with increasing humidity, lost habitats and industrial livestock/poultry farming has many opportunities for pathogens to move from animals and birds to humans. Increasing global connectivity simply catalyses this process, as much as it catalyses economic growth.

WHO coordinates health research, clinical trials, drug safety, vaccine development, surveillance, virus sharing, etc. The importance of WHO’s work on immunisation across the globe, especially with HIV, can hardly be overstated. It has a rich track record of collaborating with private-sector organisations to advance research and development of health solutions and improving their access in the global south.

It discharges its duties while maintaining a dynamic equilibrium between such diverse and powerful forces as national securities, economic interests, human rights and ethics. COVID-19 has highlighted how political calculations can hamper data-sharing and mitigation efforts within and across national borders, and WHO often simply becomes a convenient political scapegoat in such situations.

International Health Regulations, a 2005 agreement between 196 countries to work together for global health security, focuses on detection, assessment and reporting of public health events, and also includes non-pharmaceutical interventions such as travel and trade restrictions. WHO coordinates and helps build capacity to implement IHR.

#### WHO diplomacy solves great power conflict

Murphy 20 [(Chris, U.S. senator from Connecticut serving on the U.S. Senate Foreign Relations Committee) “The Answer is to Empower, Not Attack, the World Health Organization,” War on the Rocks, 4/21/2020] JL

The World Health Organization is critical to stopping disease outbreaks and strengthening public health systems in developing countries, where COVID-19 is starting to appear. Yemen announced its first infection earlier this month, and other countries in Africa, Asia and the Middle East are at severe risk. Millions of refugees rely on the World Health Organization for their health care, and millions of children rely on the WHO and UNICEF to access vaccines.

The World Health Organization is not perfect, but its team of doctors and public health experts have had major successes. Their most impressive claim to fame is the eradication of smallpox – no small feat. More recently, the World Health Organization has led an effort to rid the world of two of the three strains of polio, and they are close to completing the trifecta.

These investments are not just the right thing to do; they benefit the United States. Improving health outcomes abroad provides greater political and economic stability, increasing demand for U.S. exports. And, as we are all learning now, it is in America’s national security interest for countries to effectively detect and respond to potential pandemics before they reach our shores.

As the United States looks to develop a new global system of pandemic prevention, there is absolutely no way to do that job without the World Health Organization. Uniquely, it puts traditional adversaries – like Russia and the United States, India and Pakistan, or Iran and Saudi Arabia – all around the same big table to take on global health challenges. It has relationships with the public health leaders of every nation, decades of experience in tackling viruses and diseases, and the ability to bring countries together to tackle big projects. This ability to bridge divides and work across borders cannot be torn down and recreated – not in today’s environment of major power competition – and so there is simply no way to build an effective international anti-pandemic infrastructure without the World Health Organization at the center.

#### Ought means should

Merriam Webster n.d. – Merriam Webster’s Learner’s Dictionary, “ought”, <http://www.learnersdictionary.com/definition/ought>  
ought /ˈɑːt/ verb  
Learner's definition of OUGHT [modal verb] 1 ◊ Ought is almost always followed by to and the infinitive form of a verb. The phrase ought to has the same meaning as should and is used in the same ways, but it is less common and somewhat more formal. The negative forms ought not and oughtn't are often used without a following to. — used to indicate what is expected They ought to be here by now. You ought to be able to read this book. There ought to be a gas station on the way. 2 — used to say or suggest what should be done You ought to get some rest. That leak ought to be fixed. You ought to do your homework.

#### Should means must and is immediate

Summers 94 (Justice – Oklahoma Supreme Court, “Kelsey v. Dollarsaver Food Warehouse of Durant”, 1994 OK 123, 11-8, http://www.oscn.net/applications/oscn/DeliverDocument.asp?CiteID=20287#marker3fn13)

¶4 The legal question to be resolved by the court is whether the word "should"[13](http://www.oscn.net/applications/oscn/DeliverDocument.asp?CiteID=20287#marker3fn13) in the May 18 order connotes futurity or may be deemed a ruling in praesenti.[14](http://www.oscn.net/applications/oscn/DeliverDocument.asp?CiteID=20287#marker3fn14) The answer to this query is not to be divined from rules of grammar;[15](http://www.oscn.net/applications/oscn/DeliverDocument.asp?CiteID=20287#marker3fn15) it must be governed by the age-old practice culture of legal professionals and its immemorial language usage. To determine if the omission (from the critical May 18 entry) of the turgid phrase, "and the same hereby is", (1) makes it an in futuro ruling - i.e., an expression of what the judge will or would do at a later stage - or (2) constitutes an in in praesenti resolution of a disputed law issue, the trial judge's intent must be garnered from the four corners of the entire record.[16](http://www.oscn.net/applications/oscn/DeliverDocument.asp?CiteID=20287#marker3fn16) [CONTINUES – TO FOOTNOTE] [13](http://www.oscn.net/applications/oscn/DeliverDocument.asp?CiteID=20287#marker2fn13) "*Should*" not only is used as a "present indicative" synonymous with *ought* but also is the past tense of "shall" with various shades of meaning not always easy to analyze. See 57 C.J. Shall § 9, Judgments § 121 (1932). O. JESPERSEN, GROWTH AND STRUCTURE OF THE ENGLISH LANGUAGE (1984); St. Louis & S.F.R. Co. v. Brown, 45 Okl. 143, 144 P. 1075, 1080-81 (1914). For a more detailed explanation, see the Partridge quotation infra note 15. Certain contexts mandate a construction of the term "should" as more than merely indicating preference or desirability. Brown, supra at 1080-81 (jury instructions stating that jurors "should" reduce the amount of damages in proportion to the amount of contributory negligence of the plaintiff was held to imply an *obligation* *and to be more than advisory*); Carrigan v. California Horse Racing Board, 60 Wash. App. 79, [802 P.2d 813](http://www.oscn.net/applications/oscn/deliverdocument.asp?box1=802&box2=P.2D&box3=813) (1990) (one of the Rules of Appellate Procedure requiring that a party "should devote a section of the brief to the request for the fee or expenses" was interpreted to mean that a party is under an *obligation* to include the requested segment); State v. Rack, 318 S.W.2d 211, 215 (Mo. 1958) ("should" would mean the same as "shall" or "must" when used in an instruction to the jury which tells the triers they "should disregard false testimony"). [14](http://www.oscn.net/applications/oscn/DeliverDocument.asp?CiteID=20287#marker2fn14) In praesenti means literally "at the present time." BLACK'S LAW DICTIONARY 792 (6th Ed. 1990). In legal parlance the phrase denotes that which in law is presently or immediately effective, as opposed to something that will or would become effective in the future *[in futurol*]. See Van Wyck v. Knevals, [106 U.S. 360](http://www.oscn.net/applications/oscn/deliverdocument.asp?box1=106&box2=U.S.&box3=360), 365, 1 S.Ct. 336, 337, 27 L.Ed. 201 (1882).

### 1NC – K

#### Genocidal settlement is not a one-off event, but a structuring logic of elimination manifested in the reiteration of spatial inhabitance and modes of being that create complicity in genocide. The role of the ballot is to center indigenous scholarship and resistance.

Mark Rifkin 14 [Associate Professor of English & WGS @ UNC-Greensboro] ‘Settler Common Sense: Queerness and Everyday Colonialism in the American Renaissance,’ pp. 7-10, 2014.

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).

#### The aff’s *gnaritas nullius* assumption that knowledge belongs to the public is incompatible with indigenous autonomy. Shifting medicine from intellectual property to the public domain reconfigures the Western system of IPR and stands in direct contradiction with native sovereignty.

Younging 10 “Intergovernmental Committee On Intellectual Property And Genetic Resources Traditional Knowledge And Folklore” Seventeenth Session Geneva, December 6-10, 2010 Wipo Indigenous Panel On The Role Of The Public Domain Concept: Experiences In The Fields Of Genetic Resources, Traditional Knowledge And Traditional Cultural Expressions: Experiences From Canada Document prepared by Mr. Gregory Younging [Creative Rights Alliance, Kelowna, Canada, Opaskwayak Cree Nation-Canada] <https://www.wipo.int/edocs/mdocs/tk/en/wipo_grtkf_ic_17/wipo_grtkf_ic_17_inf_5_a.pdf> SM

Under the IPR system, knowledge and creative ideas that are not “protected” are in the Public

Domain (i.e. accessible by the public). Generally, Indigenous peoples have not used IPRs to protect their knowledge; and so TK is often treated as if it is in the Public Domain – without regard for Customary Laws. Another key problem for TK is that the IPR system’s concept of the Public Domain is based on the premise that the author/creator deserves recognition and compensation for his/her work because it is the product of his/her genius; but that all of society must eventually be able to benefit from that genius. Therefore, according to this aspect of IPR theory, all knowledge and creative ideas must eventually enter the Public Domain. Under IPR theory, this is the reasoning behind the time period limitations associated with copyright, patents and trademarks.

The precept that all Intellectual Property, including TK, is intended to eventually enter the Public Domain is a problem for Indigenous peoples because Customary Law dictates that certain aspects of TK are not intended for external access and use in any form. As a response to this, there have been circumstances where indigenous people have argued that some knowledge should be withdrawn from circulation and that for specific kinds of knowledge, protection should be granted in perpetuity. 29 Examples of this include, sacred ceremonial masks, songs and dances, various forms of shamanic art, sacred stories, prayers, songs, ceremonies, art objects with strong spiritual significance such as scrolls, petroglyphs, and decorated staffs, rattles, blankets, medicine bundles and clothing adornments, and various sacred symbols, designs, crests, medicines and motifs. However, the present reality is that TK is, or will be, in the Public Domain (i.e., the IPR system overrides Customary Law.)

Certain aspects of TK should not enter the public domain (as deemed under Customary Law) and should remain protected as such into perpetuity, which could be expressed as a form of “Indigenous private domain.” (Younging 2007). Indigenous peoples’ historical exclusion from the broad category of ‘public’ feeds part of the differences in objectives. Indigenous peoples also present different perceptions of knowledge, the cultural and political contexts from which knowledge emerges, and the availability, or perceived benefits of the availability, of all kinds of cultural knowledge. 30

Copyright Case Study: The Cameron Case

In 1985 the Euro-Canadian author Anne Cameron began publishing a series of children’s books though Harbour Publications based on Westcoast Indigenous traditional stories. These books include: The Raven, Raven and Snipe, Keeper of the River, How the Loon Lost Her Voice, Orca’s Song, Raven Returns the Water, Spider Woman, Lazy Boy and Raven Goes Berrypicking. Cameron had been told the traditional stories by Indigenous storytellers and/or had been present at occasions where the stories were recited. The original printing of the books granted Anne Cameron sole authorship, copyright and royalty beneficiary, and gave no credit to the Indigenous origins of the stories. As the discourse around Indigenous cultural appropriation emerged in the 1990s, Cameron’s books came under severe Indigenous criticism; not only on the grounds of cultural appropriation, but the Indigenous TK holders asserted that some of the stories and aspects of the stories were incorrect.

This led to a major confrontation with Indigenous women authors at a women writer’s conference in Montreal in 1990. At the end of the confrontation Cameron agreed not to publish any more Indigenous stories in the series: however, she did not keep her word and the books continued to be reprinted and new books in the series continued to be published (Armstrong and Maracle1992). Some minor concessions have been made in subsequent reprints of books in the series and new additions. Reprints of the books that were produced after around 1993/94 contained the disclaimer: “When I was growing up on Vancouver Island I met a woman who was a storyteller. She shared many stories with me and later gave me permission to share them with others… the woman’s name was Klopimum.” However, Cameron continued to maintain sole author credit, copyright and royalties payments. In a further concession, the 1998 new addition to the series T’aal: the One Who Takes Bad Children is co-authored by Anne Cameron and the Indigenous Elder/storyteller Sue Pielle who also shares copyright and royalties.

Patent Case Study: The Igloolik Case

An example of the failure of the Patent Act In Canada to respond to Inuit designs is the Igloolik Floe Edge Boat Case.31 A floe edge boat is a traditional Inuit boat used to retrieve seals shot at the floe edge (the edge of the ice floe), to set fishing nets in summer, to protect possessions on sled when travelling by snowmobile or wet spring ice, and to store hunting or fishing equipment. In the late 1980’s the Canadian government sponsored the Eastern Arctic Scientific Research Center to initiate a project to develop a floe edge boat that combined the traditional design with modern materials and technologies. In 1988 the Igloolik Business Association (IBA) sought to obtain a patent for the boats. The IBA thought that manufactured boats using the floe edge design would have great potential in the outdoor recreation market. To assist the IBA with its patent application the agency, the Canadian Patents and Developments Limited (CPDL) initiated a pre-project patent search that found patents were already held by a non-Inuit company for boats with similar structures. The CPDL letter to the IBA concluded that it was difficult for the CPDL to inventively distinguish the design from previous patents and, therefore, the IBA patent would not be granted. The option of challenging the pre-existing patent was considered by the IBA, however, it was decided that it would not likely be successful due to the high financial cost and risk involved in litigation.

Trademark Case: The Snumeymux Case

As most Indigenous communities are far behind in terms of establishing businesses most trademarking of TK involves a non-Indigenous corporation trademarking an Indigenous symbol, design or name. Again, many cases could have been examined in this section but only two have been chosen: one case involving the Snumeymux Band trade marking petroglyphs through the Canadian Patent Office, and one involving an international corporation’s patent licence being the subject of an intense international Indigenous lobbying effort.

The Snumeymux people have several ancient petroglyphs located off their reserve lands near False Narrows on Gabriola Island, BC. In the early 1990s non-Indigenous residents of Gabriola Island began using some of the petroglyph images in coffee shops and various other business logos. In the mid-1990s the Island’s music festival named itself after what had become the local name of the most well known petroglyph image, the dancing man. The Dancing Man Music Festival then adopted the image of the dancing man as the festival logo and used it on brochures, posters, advertisements and T-shirts.

The Snuneymux Band first made unsuccessful appeals to the festival, buisnesses and the Gabriola community to stop using the petroglyph symbols. In 1998 the Snuneymux Band hired Murry Brown as legal counsel to seek protection of the petroglyphs (Manson-2003). At a 1998 meeting with Brown, Snuneymux Elders and community members on the matter, The Dancing Man Festival and Gabriola business’ and community representatives were still defiant that they had a right to use the images from the petroglyphs (Brown-2003).

On the advice of Murry Brown, The Snuneymux Band filed for a Section 91(n) Public Authority Trademark for eight petroglyphs and was awarded the trademark in October of 1998 (Brown2003). The trademark protects the petrogylphs from “all uses” by non-Snuneymux people and, therefore the Dancing Man Festival and Gabriola Island business and community representatives were forced to stop using images derived from the petroglyphs. In the Snuneymux case the petroglyphs were trademarked for “defensive” purposes. The Snuneymux case represents an innovative use of the IPR system that negotiated within the systems limitations and found a way to make it work to protect TK.

Case Studies Summary

The case studies have shown that serious conflicts exist between the IPR and TK systems and lead to the conclusion that it constitutes a major problem which Indigenous peoples must work out with the modern states they are within and the international community. In contrast to Eurocentric thought, almost all Indigenous thought asserts that property is a sacred ecological order and manifestations of that order should not be treated as commodities.32 It is clear that there are pressing problems in the regulation of TK. It is also clear that IPR system and other Eurocentric concepts do not offer a solution to some of the problems. There have been cases of Indigenous people using the IPR system to protect their TK. However, the reality is that there are many more cases of non-Indigenous people using the IPR system to take ownership over TK using copyright, trademark, patents and the Public Domain. In many such cases this had created a ridiculous situation whereby Indigenous peoples cannot legally access their own knowledge. A study undertaken on behalf of the Intellectual Property Policy Directorate (IPPD) of Industry Canada and the Canadian Working Group on Article 8(j) concluded: “There is little in the cases found to suggest that the IP system has adapted very much to the unique aspects of Indigenous knowledge or heritage. Rather, Indigenous peoples have been required to conform to the legislation that was designed for other contexts and purposes, namely western practices and circumstances. At the same time, there is little evidence that these changes have been promoted within the system, i.e., from failed efforts to use it that have been challenged” (IPPD-2002). Such conclusions, along with other conclusions being drawn in other countries and international forums, and the case study examples discussed, appear to support the argument that new systems of protection need to be developed. Sui Generis models based on and/or incorporating Customary Laws have been proposed and developed in many countries and are being discussed in the WIPO IGC.

Gnaritas Nullius (Nobody’s Knowledge)

Just as Indigenous territories were declared as Terra Nullius in the colonization process, so too has TK been treated as Gnaritas Nullius (Nobody’s Knowledge) by the IPR system and consequently flowed into the public domain along with Western knowledge. This has occurred despite widespread Indigenous claims of ownership and breech of Customary Law. The problem is that advocates for the public domain seem to see knowledge as the same concept across cultures, and impose the liberal ideals of freedom and equality to Indigenous peoples knowledge systems. Not all knowledge has the same role and significance within diverse epistemologies, nor do diverse worldviews all necessarily incorporate a principle that knowledge can be universally accessed. Neither can all knowledge fit into a Western paradigms and legal regimes. A central dimension of Indigenous knowledge systems is that knowledge is shared according to developed rules and expectations for behavior within frameworks that have been developed and practiced over centuries and millennium. Arguments for a public domain of Indigenous knowledge again reduces the capacity for Indigenous control and decision making (Anderson 2010) and can not be reasonably made outside the problematic frameworks of the colonization of TK and Gnaritas Nullius.

#### Representations of extinction are fabricated by the logic of elimination - settlers have a psychological investment in imagining the end of the world to create a sense of white vulnerability at the expense of enacting decolonization.

Dalley 16

(Hamish Dalley received his Ph.D. from the Australian National University in 2013, and is now an Assistant Professor of English at Daemen College, Amherst, New York, where he is responsible for teaching in World and Postcolonial Literatures., (2016): The deaths of settler colonialism: extinction as a metaphor of decolonization in contemporary settler literature, Settler Colonial Studies, DOI: 10.1080/2201473X.2016.1238160, JKS)

Settlers love to contemplate the possibility of their own extinction; to read many contemporary literary representations of settler colonialism is to find settlers strangely satisfied in dreaming of ends that never come. This tendency is widely prevalent in English-language representations of settler colonialism produced since the 1980s: the possibility of an ending – the likelihood that the settler race will one day die out – is a common theme in literary and pop culture considerations of colonialism’s future. Yet it has barely been remarked how surprising it is that this theme is so present. For settlers, of all people, to obsessively ruminate on their own finitude is counterintuitive, for few modern social formations have been more resistant to change than settler colonialism. With a few excep- tions (French Algeria being the largest), the settler societies established in the last 300 years in the Americas, Australasia, and Southern Africa have all retained the basic features that define them as settler states – namely, the structural privileging of settlers at the expense of indigenous peoples, and the normalization of whiteness as the marker of pol- itical agency and rights – and they have done so notwithstanding the sustained resistance¶ that has been mounted whenever such an order has been built. Settlers think all the time that they might one day end, even though (perhaps because) that ending seems unlikely ever to happen. The significance of this paradox for settler-colonial literature is the subject of this article.¶ Considering the problem of futurity offers a useful foil to traditional analyses of settler- colonial narrative, which typically examine settlers’ attitudes towards history in order to highlight a constitutive anxiety about the past – about origins. Settler colonialism, the argument goes, has a problem with historical narration that arises from a contradiction in its founding mythology. In Stephen Turner’s formulation, the settler subject is by definition one who comes from elsewhere but who strives to make this place home. The settlement narrative must explain how this gap – which is at once geographical, historical, and existential – has been bridged, and the settler transformed from outsider into indigene. Yet the transformation must remain constitutively incomplete, because the desire to be at home necessarily invokes the spectre of the native, whose existence (which cannot be disavowed completely because it is needed to define the settler’s difference, superior- ity, and hence claim to the land) inscribes the settler’s foreignness, thus reinstating the gap between settler and colony that the narrative was meant to efface.1 Settler-colonial narrative is thus shaped around its need to erase and evoke the native, to make the indigene both invisible and present in a contradictory pattern that prevents settlers from ever moving on from the moment of colonization.2 As evidence of this constitutive contradiction, critics have identified in settler-colonial discourse symptoms of psychic distress such as disavowal, inversion, and repression.3 Indeed, the frozen temporality of settler-colonial narrative, fixated on the moment of the frontier, recalls nothing so much as Freud’s description of the ‘repetition compulsion’ attending trauma.4 As Lorenzo Veracini puts it, because:¶ ‘settler society’ can thus be seen as a fantasy where a perception of a constant struggle is juxtaposed against an ideal of ‘peace’ that can never be reached, settler projects embrace and reject violence at the same time. The settler colonial situation is thus a circumstance where the tension between contradictory impulses produces long-lasting psychic conflicts and a number of associated psychopathologies.5¶ Current scholarship has thus focused primarily on settler-colonial narrative’s view of the past, asking how such a contradictory and troubled relationship to history might affect present-day ideological formations. Critics have rarely considered what such narratological tensions might produce when the settler gaze is turned to the future. Few social formations are more stubbornly resistant to change than settlement, suggesting that a future beyond settler colonialism might be simply unthinkable. Veracini, indeed, suggests that settler-colonial narrative can never contemplate an ending: that settler decolonization is inconceivable because settlers lack the metaphorical tools to imagine their own demise.6 This article outlines why I partly disagree with that view. I argue that the narratological paradox that defines settler-colonial narrative does make the future a problematic object of contemplation. But that does not make settler decolonization unthinkable per se; as I will show, settlers do often try to imagine their demise – but they do so in a way that reasserts the paradoxes of their founding ideology, with the result that the radical potentiality of decolonization is undone even as it is invoked.¶ I argue that, notwithstanding Veracini’s analysis, there is a metaphor via which the end of settler colonialism unspools – the quasi-biological concept of extinction, which, when deployed as a narrative trope, offers settlers a chance to consider and disavow their demise, just as they consider and then disavow the violence of their origins. This article traces the importance of the trope of extinction for contemporary settler-colonial litera- ture, with a focus on South Africa, Canada, and Australia. It explores variations in how the death of settler colonialism is conceptualized, drawing a distinction between his- torio-civilizational narratives of the rise and fall of empires, and a species-oriented notion of extinction that draws force from public anxiety about climate change – an invocation that adds another level of ambivalence by drawing on ‘rational’ fears for the future (because climate change may well render the planet uninhabitable to humans) in order to narrativize a form of social death that, strictly speaking, belongs to a different order of knowledge altogether. As such, my analysis is intended to draw the attention of settler- colonial studies toward futurity and the ambivalence of settler paranoia, while highlighting a potential point of cross-fertilization between settler-colonial and eco-critical approaches to contemporary literature.¶ That ‘extinction’ should be a key word in the settler-colonial lexicon is no surprise. In Patrick Wolfe’s phrase,7 settler colonialism is predicated on a ‘logic of elimination’ that tends towards the extermination – by one means or another – of indigenous peoples.8 This logic is apparent in archetypal settler narratives like James Fenimore Cooper’s The Last of the Mohicans (1826), a historical novel whose very title blends the melancholia and triumph that demarcate settlers’ affective responses to the supposed inevitability of indigenous extinction. Concepts like ‘stadial development’ – by which societies progress through stages, progressively eliminating earlier social forms – and ‘fatal impact’ – which names the biological inevitability of strong peoples supplanting weak – all contribute to the notion that settler colonialism is a kind of ‘ecological process’ that necessitates the extinction of inferior races. What is surprising, though, is how often the trope of extinction also appears with reference to settlers themselves; it makes sense for settlers to narrate how their presence entails others’ destruction, but it is less clear why their attempts to imagine futures should presume extinction to be their own logical end as well.¶ The idea appears repeatedly in English-language literary treatments of settler colonial- ism. Consider, for instance, the following rumination on the future of South African settler society, from Olive Schreiner’s 1883 Story of an African Farm:¶ It was one of them, one of those wild old Bushmen, that painted those pictures there. He did not know why he painted but he wanted to make something, so he made these. [...] Now the Boers have shot them all, so that we never see a yellow face peeping out among the stones. [...] And the wild bucks have gone, and those days, and we are here. But we will be gone soon, and only the stones will lie on, looking at everything like they look now.10¶ In this example, the narrating settler character, Waldo, recognizes prior indigenous inha- bitation but his knowledge comes freighted with an expected sense of biological super- iority, made apparent by his description of the ‘Bushman’s’ ‘yellow face’, and lack of mental self-awareness. What is not clear is why Waldo’s contemplation of colonial geno- cide should turn immediately to the assumption that a similar fate awaits his people as well. A similar presumption of racial vulnerability permeates other late nineteenth- century novels from the imperial metropole, such as Dracula and War of the Worlds,¶ which are plotted around the prospect of invasions that would see the extinction of British imperialism, and, in the process, the human species.¶ Such anxieties draw energy from a pattern of settler defensiveness that can be observed across numerous settler-colonial contexts. Marilyn Lake’s and Henry Reynold’s account of the emergence of transnational ‘whiteness’ highlights the paradoxical fact that while white male settlers have been arguably the most privileged class in history, they have routinely perceived themselves to be ‘under siege’, threatened with destruction to the extent that their very identity of ‘whiteness was born in the apprehension of immi- nent loss’.11 The fear of looming annihilation serves a powerful ideological function in settler communities, working to foster racial solidarity, suppress dissent, and legitimate violence against indigenous populations who, by any objective measure, are far more at risk of extermination than the settlers who fear them. Ann Curthoys and Dirk Moses have traced this pattern in Australia and Israel-Palestine, respectively.12 This scholarship suggests that narratives of settler extinction are acts of ideological mystification, obscuring the brutal inequalities of the frontier behind a mask of white vulnerability – an argument with which I sympathize. However, this article shows how there is more to settler-colonial extinction narratives than bad faith. I argue that we need a more nuanced understanding of how they encode a specifically settler-colonial framework for imagining the future, one that has implications for how we understand contemporary literatures from settler societies, and which allows us to see extinction as a genuine, if flawed, attempt to envisage social change.¶ In the remainder of this paper I consider extinction’s function as a metaphor of decolonization. I use this phrase to invoke, without completely endorsing, Tuck and Yang’s argu- ment that to treat decolonization figuratively, as I argue extinction narratives do, is necessarily to preclude radical change, creating opportunities for settler ‘moves to innocence’ that re-legitimate racial inequality.13 The counterview to this pessimistic perspec- tive is offered by Veracini, who suggests that progressive change to settler-colonial relationships will only happen if narratives can be found that make decolonization think- able.14 This article enters the debate between these two perspectives by asking what it means for settler writers to imagine the future via the trope of extinction. Does extinction offer a meaningful way to think about ending settler colonialism, or does it re-activate settler-colonial patterns of thought that allow exclusionary social structures to persist?¶ I explore this question with reference to examples of contemporary literary treatments of extinction from select English-speaking settler-colonial contexts: South Africa, Australia, and Canada.15 The next section of this article traces key elements of extinction narrative in a range of settler-colonial texts, while the section that follows offers a detailed reading of one of the best examples of a sustained literary exploration of human finitude, Margaret Atwood’s Maddaddam trilogy (2003–2013). I advance four specific arguments. First, extinction narratives take at least two forms depending on whether the ‘end’ of settler society is framed primarily in historical-civilizational terms or in a stronger, biological sense; the key question is whether the ‘thing’ that is going extinct is a society or a species. Second, biologically oriented extinction narratives rely on a more or less conscious slippage between ‘the settler’ and ‘the human’. Third, this slippage is ideologically ambivalent: on the one hand, it contains a radical charge that invokes environmentalist discourse and climate-change anxiety to imagine social forms that re-write settler-colonial dynamics; on the other, it replicates a core aspect of imperialist ideology by normalizing whiteness as¶ equivalent to humanity. Fourth, these ideological effects are mediated by gender, insofar as extinction narratives invoke issues of biological reproduction, community protection, and violence that function to differentiate and reify masculine and feminine roles in the putative de-colonial future. Overall, my central claim is that extinction is a core trope through which settler futurity emerges, one with crucial narrative and ideological effects that shape much of the contemporary literature emerging from white colonial settings.

#### The aff’s understanding of public knowledge also requires an alternative – vote negative for a sui generis moral rights framework that emphasizing guardianship over ownership. The link turn assumes a settler notion of personhood which proves our argument.

Vézina 20 “Ensuring Respect for Indigenous Cultures A Moral Rights Approach” Brigitte Vézina [fellow at the Canadian think tank Centre for International Governance Innovation. She holds a bachelor’s degree in law from the Université de Montréal and a master’s in law from Georgetown University], Centre for International Governance Innovation Papers No. 243 — May 2020, <https://www.cigionline.org/static/documents/documents/vezina-paper_1.pdf> SM

Features of a Sui Generis Moral Rights-type Framework

Subject Matter and Beneficiaries

TCEs that maintain a current and significant relationship with the Indigenous peoples who hold them would be protected. As long as a community, as a whole and by virtue of its own internal cultural rules, identifies with a specific form of expression and can establish a particular relationship with it, it can claim protection over it. As Susy Frankel points out, the key rationale in favour of protecting TCEs is the guardianship relationship, from which proportionate moral rights flow.155 Guardianship is to be contrasted with ownership, which is the concept buttressing most IP law systems, with the notable exception of moral rights. To wit, the Waitangi Tribunal did not recommend that TCEs be treated as owned, lest that would amount to building a legal wall around TCEs and end up choking culture.156 At any rate, cultural boundaries are porous and fluid, and it follows that blending, intermixing, hybridization or even “contamination” of cultures can be promoted.157

Obviously, cultures are seldom unique to a people. TCEs might be shared among different Indigenous groups that all identify and hold a guardianship relationship with them. In such cases, procedures should be in place to facilitate cooperation and settlement of disputes. What is more, no people are monolithic, a reality that is rendered in one illustrative phrase: “The Sámi people are one, but multiple.”158 Some communities might have distinct TCEs that have been part of their culture for a long time, with little or no outside influence. Others might have experienced contact with other cultures and incorporated various elements over the generations that have substantially modified previous iterations. For example, in the case of Mixe huipil at stake in the Isabel Marant case, some were quick to point out that the embroideries had, in the upshot of the Spanish conquest, incorporated European elements.159 Hence, when considering a relationship between a TCE and its holder, one should not exact uniqueness or exclusiveness, but embrace the fact that a group can identify with TCEs that are dynamic and kaleidoscopic, all the while remaining authentic.

Beneficiaries of protection should be TCE holding Indigenous communities as a whole, such that moral rights would be afforded to the entire community as group rights. Recognition of beneficiaries as well as determination of the authority to exercise the rights would have to be done from within the community, by way of application of customary law160 or be captured under the legal constructs of trusts, associations, or other legal entities holding the rights.161 Indigenous communities need to have the autonomy to exercise control over and make their own decisions regarding the management of their moral rights in their TCEs.162

Scope of Protection

At first glance, it is difficult to reconcile the notion of personhood, the cornerstone of moral rights, with the pluralistic conception of a community, by definition made up of several persons with their own individual personalities. In response, some scholars have wrought the concept of “peoplehood” to encapsulate the personality of a people in its entirety and provide a justification for granting a personality right to a group.163 As mentioned, TCEs often encompass cultural elements that are integral to Indigenous peoples’ sense of identity, that bear the distinct mark of their holders and, indeed, that reflect their peoplehood. Moral rights can therefore fulfill the duty, arising out of human rights law, to protect the identity of Indigenous peoples.164

Forasmuch as TCEs are collectively and communally held, so too must the moral rights of Indigenous peoples be communal.165 In fact, even conventional moral rights are not purely individualistic, and there has been a recognition of a “socially-informed view of the author” and “the social gestation of authorship... the social womb from which authors brought forth their works.”166 This strand of moral rights theory might be more congruent to accepting a group right for a community than the classic individual theory underpinning moral rights.167

Moral rights would only regulate the relationship between the community and the outside world; use in a traditional and customary context would not be affected. Just as moral rights vest automatically in the author (without any need for registration or any other form of assertion), so too would sui generis moral rights vest in the community.

Communal moral rights would include, at a minimum, the right of attribution, including false attribution (to ensure proper recognition of the community as the source and to prevent others from falsely claiming a guardianship over a TCE) and integrity (to protect TCEs against inappropriate, derogatory, or culturally insensitive use). It could be considered to also include the rights of disclosure (to make, where desired, TCEs known to the world and to retain the power to keep TCEs out of “public” reach, for example, in the case of sacred or secret TCEs) and withdrawal (to allow TCE holders to remove from circulation the TCEs that they no longer wish to make publicly available).

In most national laws, moral rights are inalienable or non-transferable. In other words, they cannot be divested from the author — they cannot be assigned, licensed or given away. As mentioned, if an author transfers all their economic rights to a third party, the author retains their moral rights in the work.168 As such, sui generis moral rights in TCEs would be independent from any economic rights that might arise and be held and exercised separately, regardless of who might hold these economic rights (in cases, for example, where communities would commercialize their TCEs and grant licences) or who might have physical ownership of a TCE (such as a cultural institution). However, in some jurisdictions, such as Canada, the United States and the United Kingdom (but not Australia and France), moral rights can be waived, irreversibly, in whole or in part, explicitly, by contract, at the discretion of the author. In order to ensure flexible protection to TCEs, it could be envisaged that sui generis moral rights be made waivable.

When applying the right of integrity, the determination of what is offensive should not be narrowly prescribed but based on the facts at hand. Assessment should be done both subjectively, from the point of view of the community that claims violation, and objectively, by the court, within the framework of guidelines to be developed legislatively or through case law, as informed by Indigenous customary laws, practices and protocols. Reliance on particular facts may be difficult to reconcile with the need for certainty and predictability, but flexibility trumps these concerns, as no use should be considered offensive per se.

#### Thus, the only alternative is one of decolonization.

Tuck and Yang 12

(Eve Tuck, Unangax, State University of New York at New Paltz K. Wayne Yang University of California, San Diego, Decolonization is not a metaphor, Decolonization: Indigeneity, Education & Society Vol. 1, No. 1, 2012, pp. 1-40, JKS)

An ethic of incommensurability, which guides moves that unsettle innocence, stands in contrast to aims of reconciliation, which motivate settler moves to innocence. Reconciliation is about rescuing settler normalcy, about rescuing a settler future. Reconciliation is concerned with questions of what will decolonization look like? What will happen after abolition? What will be the consequences of decolonization for the settler? Incommensurability acknowledges that these questions need not, and perhaps cannot, be answered in order for decolonization to exist as a framework.

We want to say, first, that decolonization is not obliged to answer those questions - decolonization is not accountable to settlers, or settler futurity. Decolonization is accountable to Indigenous sovereignty and futurity. Still, we acknowledge the questions of those wary participants in Occupy Oakland and other settlers who want to know what decolonization will require of them. The answers are not fully in view and can’t be as long as decolonization remains punctuated by metaphor. The answers will not emerge from friendly understanding, and indeed require a dangerous understanding of uncommonality that un-coalesces coalition politics - moves that may feel very unfriendly. But we will find out the answers as we get there, “in the exact measure that we can discern the movements which give [decolonization] historical form and content” (Fanon, 1963, p. 36).

To fully enact an ethic of incommensurability means relinquishing settler futurity, abandoning the hope that settlers may one day be commensurable to Native peoples. It means removing the asterisks, periods, commas, apostrophes, the whereas’s, buts, and conditional clauses that punctuate decolonization and underwrite settler innocence. The Native futures, the lives to be lived once the settler nation is gone - these are the unwritten possibilities made possible by an ethic of incommensurability.

*when you take away the punctuation*

*he says of*

*lines lifted from the documents about military-occupied land*

*its acreage and location*

*you take away its finality*

*opening the possibility of other futures*

-Craig Santos Perez, Chamoru scholar and poet (as quoted by Voeltz, 2012)

Decolonization offers a different perspective to human and civil rights based approaches to justice, an unsettling one, rather than a complementary one. Decolonization is not an “and”. It is an elsewhere.

#### Representations and epistemology perpetuate settler practices – the way we understand and discuss the structures around us overdetermines our praxis

Seawright 14 Gardner Seawright is a doctoral candidate in the Education, Culture, and Society department at the University of Utah. “Settler Traditions of Place: Making Explicit the Epistemological Legacy of White Supremacy and Settler Colonialism for Place-Based Education.” EDUCATIONAL STUDIES, 50: 554–572, 2014, American Educational Studies Association. JJN

Situating Settler Traditions Settler traditions of place are an epistemic genealogy—the ethics, logics, and ideologies foundational to a knowledge system that have been passed down across generations, a knowledge framework that establishes what is known (the socially constructed commonsense of a culture), how things come to be known (the process of attaining new knowledge), how the world is to be interpreted according to what is known (the social construction of reality), and how the self is known in relation to perceived reality (the politics of self). Tradition is used as a conceptual tool allowing for domination to be empha- sized as an on-going historical process, while also allowing for epistemology as tradition to simultaneously be evolutionary and a cherished cultural artifact. As a cultural product, settler traditions of place are transmitted across generations through discipline, teaching, modeling and other forms of direct and subtle so- cial communication resulting in normalized habits, beliefs, values, and practices. In speaking about “western cultural traditions,” Val Plumood (2002) argues that there are “epistemic and moral limitations” embedded in these traditions—these normalized habits—that perpetuate hierarchized notions of the world that privi- lege white-hetero-landowning males (99). As Martusewicz et al. (2011) explain, these subtle discourses manifest as taken-for-granted cultural assumptions that are rooted in racism, sexism, classism that intertwine with and reflect the cultivation of violent relationships with the more-than-human world and natural systems that we depend on for life (119). The tradition in question here is the social air that penetrates the Western world, interacting with human beings whether they want it to or not. Using tradition as a metaphor for epistemology allows me to emphasize the way epistemology can im- pact every aspect of life while remaining removed from a deterministic position. Embedded in discourse, tradition appears as ever-present; despite this, individual social actors have the agency to break tradition. Consequently, in the same way that an individual breaks from familial, cultural, or religious tradition and faces the ramifications for transgressing, epistemic transgression can also incur social fallout and cause friction. When an individual epistemically transgresses, they employ an epistemic praxis (the operationalization of an alternative or critical epistemology) that goes against the grain and is counter to the tradition that defines the social environment. For conversations concerning the cultivation of criticality (like the one herein) this break in tradition is absolutely desirable and can inspire what Jose ́ Medina (2013) calls epistemic friction. Epistemic friction is contained in those uncomfortable moments in which our taken-for-granted assumptions about the world begin to crack. These moments can be transformative and cat- alyze critical consciousness to imagine and hopefully actualize an alternative epistemology.

### CASE

#### IP reductions expand generic drug market

IGBA ’15 [IGBA, September 2015, "Fostering International Trade in Generic and Biosimilar Medicines," International Generic and Biosimilar Medicines Association, <https://www.igbamedicines.org/doc/09.24.15%20IGBATradePrinciples_ForWeb_FINAL.pdf> // belle

The International Generic and Biosimilar Medicines Association (IGBA) is an international network of generic and biosimilar medicines associations that works to promote generic and biosimilar pharmaceutical products and secure patient access to high-quality, safe, and effective medicines. The IGBA strongly supports the negotiation of trade agreements aimed at fostering trade in generic and biosimilar medicines. The competitiveness of the generic and biosimilar industries is threatened by regulatory divergences with respect to country requirements for the approval and marketing of generic and biosimilar medicines, and excessive standards for intellectual property rights (IPR) protection. Specific instances of IPR abuse/misuse, as well as pricing and reimbursement policies are also areas of concern. The removal of such barriers will reduce costs for the development of generic and biosimilar medicines, and ensure that such products can be traded freely and enter markets without delay.

#### Generics stratifies nations – only sends higher quality drugs to harsher inspectors who are mostly Western countries. Independently, generics leave strong pathogens in tact and spike risk of global epidemic of drug-resistance pathogens.

Eban ’19 [KATHERINE EBAN, 5-17-2019, "How Some Generic Drugs Could Do More Harm Than Good," Time, <https://time.com/5590602/generic-drugs-quality-risk/> // belle ]

For the 16 years that Dr. Brian Westerberg, a Canadian surgeon, worked volunteer missions at the Mulago National Referral Hospital in Kampala, Uganda, scarcity was the norm. The patients usually exceeded the 1,500 allotted beds. Running water was once cut off when the debt-ridden hospital was unable to pay its bills. On some of his early trips, Westerberg even brought over drugs from Canada in order to treat patients. But as low-cost generics made in India and China became widely available through Uganda’s government and international aid agencies in the early 2000s, it seemed at first like the supply issue had been solved. Then on February 7, 2013, Westerberg examined a feverish 13-year-old boy who had fluid oozing from an ear infection. He suspected bacterial meningitis, though he couldn’t confirm his diagnosis because the CT scanner had broken down. The boy was given intravenous ceftriaxone, a broad-spectrum antibiotic that Westerberg believed would cure him. But after four days of treatment, the ear had only gotten worse. As Westerberg prepared to operate, the boy had a seizure. With the CT scanner working again, Westerberg ordered an urgent scan, which revealed small abscesses in the boy’s skull, likely caused by the infection. When a hospital neurosurgeon looked at the images and confidently declared that surgery was unnecessary and the swelling and abscesses would abate with effective antibiotic treatment, Westerberg was confused. They had already treated the boy with intravenous ceftriaxone, which hadn’t worked. His confusion deepened when his colleague suggested that they switch the boy to a more expensive version of the drug. Why swap one ceftriaxone for another? Most people assume that a drug is a drug — that Lipitor, for example, or a generic version, is the same anywhere in the world, so long as it’s made by a reputable drug company that has been inspected and approved by regulators. That, at least, is the logic that has driven the global generic-drug revolution: that drug companies in countries like India and China can make low-cost, high-quality drugs for markets around the world. These companies have been hailed as public-health heroes and global equalizers, by making the same cures available to the wealthy and impoverished. But many of the generic drug companies that Americans and Africans alike depend on, which I spent a decade investigating, hold a dark secret: they routinely adjust their manufacturing standards depending on the country buying their drugs, a practice that could endanger not just those who take the lower-quality medicine but the population at large. These companies send their highest-quality drugs to markets with the most vigilant regulators, such as the U.S. and the European Union. They send their worst drugs — made with lower-quality ingredients and less scrupulous testing — to countries with the weakest review. The U.S. drug supply is not immune to quality crises — over the last ten months, dozens of versions of the generic blood pressure drugs valsartan, losartan and irbesartan have been subject to sweeping recalls. The active ingredients in some, manufactured in China, contained a probable carcinogen once used in the production of liquid rocket fuel. But the patients who suffer most are those in so-called “R.O.W. markets” — the generic-drug industry’s shorthand for “Rest of World.” In swaths of Africa, Southeast Asia and other areas with developing markets, some generic drug companies have made a cold calculation: they can sell their cheapest drugs where they will be least likely to get caught. In Africa, for instance, pharmaceuticals used to come from more developed countries, through donations and small purchases. So when Indian drug reps offering cheap generics started arriving, the initial feeling was positive. But Africa soon became an avenue “to send anything at all,” said Kwabena Ofori-Kwakye, associate professor in the pharmaceutics department at the Kwame Nkrumah University of Science and Technology in Kumasi, Ghana. The poor quality has affected every type of medication, and the adverse impact on health has been “astronomical,” he told me. Multiple doctors I spoke to throughout the continent said they have adjusted their medical treatment in response, sometimes tripling recommended doses to produce a therapeutic effect. Dr. Gordon Donnir, former head of the psychiatry department at the Komfo Anokye teaching hospital in Kumasi, treats middle-class Ghanaians in his private practice and says that almost all the drugs his patients take are substandard, leading him to increase his patients’ doses significantly. While his European colleagues typically prescribe 2.5 milligrams of haloperidol (a generic form of Haldol) several times a day to treat psychosis, he’ll prescribe 10 milligrams, also several times a day, because he knows the 2.5 milligrams “won’t do anything.” Donnir once gave ten times the typical dose of generic Diazepam, an anti-anxiety drug, to a 15-year-old boy, an amount that should have knocked him out. The patient was “still smiling,” Donnir said. Many hospitals also keep a stash of what they call “fancy” drugs — either brand-name drugs or higher-quality generics — to treat patients who should have recovered after a round of treatment but didn’t. Confronted with the ailing boy at the Mulago hospital, Westerberg’s colleagues swapped in the more expensive version of ceftriaxone and added more drugs to the treatment plan. But it was too late. In the second week of his treatment, the boy was declared brain dead. Westerberg’s Ugandan colleagues were not surprised. Their patients frequently died when treated with drugs that should have saved them. And there were not enough “fancy” drugs to go around, making every day an exercise in pharmaceutical triage. It was also hard to keep track of which generics were safe and which were not to be trusted, said one doctor in Western Uganda: “It’s anesthesia today, ceftriaxone tomorrow, amoxicillin the next day.” Westerberg, shaken by his newfound knowledge, flew back to Canada and teamed up with a Canadian respiratory therapist, Jason Nickerson, who’d had similar experiences with bad medicine in Ghana. They decided to test the chemical properties of the generic ceftriaxone that had been implicated in the Ugandan boy’s death. Another of Westerberg’s colleagues brought him a vial from the Mulago hospital pharmacy. The drug had been made by a manufacturer in northern China, which also exported to the U.S. and other developed markets. But when they tested the ceftriaxone at Nickerson’s lab, it contained less than half the active drug ingredient stated on the label. At such low concentration, the drug was basically useless, Nickerson said. He and Westerberg published a case report in the CDC’s Morbidity and Mortality Weekly Report. Although they couldn’t say with certainty that the boy had died due to substandard ceftriaxone, their report offered compelling evidence that he had. Some companies claim that, while their drugs are all high-quality, there may be some variance in how they are produced because regulations differ from market to market. But Patrick H. Lukulay, former vice president of global health impact programs for USP (formerly U.S. Pharmacopeia), one of the world’s top pharmaceutical standard-setting organizations, calls that argument “totally garbage.” For any given drug, he says, “There’s only one standard, and that standard was set by the originator,” meaning the brand-name company that developed the product. It’s not just those in developing markets who should be alarmed. Often, substandard drugs do not contain enough active ingredient to effectively cure sick patients. But they do contain enough to kill off the weakest microbes while leaving the strongest intact. These surviving microbes go on to reproduce, creating a new generation of pathogens capable of resisting even fully potent, properly made medicine. In 2011, during an outbreak of drug-resistant malaria on the Thailand-Cambodia border, USP’s chief of party in Indonesia Christopher Raymond strongly suspected substandard drugs as a culprit. Treating patients with drugs that contain a little bit of active ingredient, as he put it, is like “putting out fire with gasoline.” USP is so concerned about this issue that in 2017 it launched a center called the Quality Institute, which funds research into the link between drug quality and resistance. In late 2018, Boston University biomedical engineering professor Muhammad Zaman studied a commonly used antibiotic called rifampicin that, if not manufactured properly, yields a chemical substance called rifampicin quinone when it degrades. When Zaman subjected bacteria to this substance, it developed mutations that helped it resist rifampicin and other similar drugs. Zaman concluded from his work that substandard drugs are an “independent pillar” in the global menace of drug resistance. The low cost of generic drugs makes them essential to global public health. But if those bargain drugs are of low quality, they do more harm than good. For years, politicians, regulators and aid workers have focused on ensuring access to these drugs. Going forward, they must place equal value on quality, through an exacting program of unannounced inspections, routine testing of drugs already on the market and strict legal enforcement against companies manufacturing subpar medicine. One model is the airline industry, which through international laws and treaties, has established clear global standards for aviation safety. Without something similar for safe and effective drugs, the twin forces of subpar medicine and growing drug resistance will be so destructive that developed countries won’t be able to ignore them. As Elizabeth Pisani, an epidemiologist who has studied drug quality in Indonesia, put it, “The fact is, pathogens know no borders.”

#### Generic companies are just incompetent – 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.