### 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, PhD, Director of the Women's and Gender Studies Program and Professor of English at the University of North Carolina, Greensboro. “Settler common sense.” Settler Colonial Studies, 2013 Vol. 3, Nos. 3–4, 322–340, http://dx.doi.org/10.1080/2201473X.2013.810702. JJN

In Walden (1854), Henry David Thoreau offers a vision of personhood divorced from the state, characterizing his experience of “Nature” during his time at Walden Pond as providing him with a sense of his own autonomous embodiment and a related set of ethical resources that enable him to reject the demands of contemporary political economy.1 The invocation of “Nature” appears to bracket the question of jurisdiction, opening into a different conceptual and phenomenological register that displaces the problem of locating oneself in relation to the boundaries of the state. However, the very feeling that one has moved beyond geopolitics, that one has entered a kind of space that suspends questions of sovereignty or renders them moot, depends on the presence of an encompassing sovereignty that licenses one’s access to that space. If the idea of “Nature” holds at bay the question of jurisdiction so as to envision a kind of place for cultivating a selfhood that can oppose state logics/politics, it also effaces the ways that experience/vision of personhood itself may arise out of the legal subjectivities put in play by the jurisdictional claiming/clearing of that space as against geopolitical claims by other polities, specifically Native peoples. Thoreau offers an example of how settlement – the exertion of control by non-Natives over Native peoples and lands – gives rise to modes of feeling, generating kinds of affect through which the terms of law and policy become imbued with a sensation of everyday certainty. This affective experience productively can be characterized as an instantiation of what more broadly may be characterized as settler common sense. The phrase suggests the ways the legal and political structures that enable non-Native access to Indigenous territories come to be lived as given, as simply the unmarked, generic conditions of possibility for occupancy, association, history, and personhood. Addressing whiteness in Australia, Fiona Nicoll argues that “rather than analysing and evaluating Indigenous sovereignty claims…, we have a political and intellectual responsibility to analyse and evaluate the innumerable ways in which White sovereignty circumscribes and mitigates the exercise of Indigenous sovereignty”, and she suggests that “we move towards a less coercive stance of reconciliation with when we fall from perspective into an embodied recognition that we already exist within Indigenous sovereignty”. 2 Addressing the question of how settlement as a system of coercive incorporation and expropriation comes to be lived as quotidian forms of non-Native being and potential, though, may require tactically shifting the analytical focus such that Indigenous sovereignties are not at the center of critical attention, even as they remain crucial in animating the study of settler colonialism and form its ethical horizon. “An embodied recognition” of the enduring presence of settler sovereignty, as well as of quotidian non-Native implication in the dispossession, effacement, and management of indigeneity, needs to attend to everyday experiences of non-relation, of a perceptual engagement with place, various institutions, and other people that takes shape around the policies and legalities of settlement but that do not specifically refer to them as such or their effects on Indigenous peoples. In order to conceptualize the mundane dynamics of settler colonialism, the quotidian feelings and tendencies through which it is continually reconstituted and experienced as the horizon of everyday potentiality, we may need to shift from an explicit attention to articulations of Native sovereignty and toward an exploration of the processes through which settler geographies are lived as ordinary, non-reflexive conditions of possibility. In Marxism and Literature, Raymond Williams argues for the necessity of approaching “relations of domination and subordination” as “practical consciousness” that saturat[es] … the whole substance of lived identities and relationships, to such a depth that the pressures and limits of what can ultimately be seen as a specific economic, political, and cultural system seem to most of us the pressures and limits of simple experience and common sense.3 Understanding settlement as, in Williams’s terms, such a “structure of feeling” entails asking how emotions, sensations, psychic life take part in the (ongoing) process of realizing the exertion of non-Native authority over Indigenous peoples, governance, and territoriality in ways that saturate quotidian life but are not necessarily present to settlers as a set of political propositions or as a specifically imperial project of dispossession. In the current scholarly efforts to characterize settler colonialism, the contours of settlement often appear analytically as clear and coherent from the start, as a virtual totality, and in this way, the ongoing processes by which settler dominance actively is reconstituted as a set of actions, occupations, deferrals, and potentials slide from view. We need to ask how the regularities of settler colonialism are materialized in and through quotidian non-Native sensations, inclinations, and trajectories. Moreover, administrative initiatives and legalities become part of everyday normalizations of state aims and mappings but in ways that also allow for an exceeding of state interests that potentially can be turned back against the state, giving rise to oppositional projects still given shape and momentum by the framings that emerge out of the ongoing work of settler occupation – such as in Walden. The essay will close with a brief reading of Thoreau’s text that illustrates how its ethical framing emerges out of, and indexes, everyday forms of settler feeling shaped by state policy but not directly continuous with it. 1. The figure of the vanishing Indian still remains prominent within US popular and scholarly discourses, both explicitly and implicitly. Within this narrative, Native peoples may have had prior claims to the land, but they, perhaps tragically, were removed from the area, or died out, or ceased to be “really” Indian, or simply disappeared at some point between the appearance of the “last” one and the current moment, whenever that may be.4 As against this tendency, scholars who seek to track the workings of settler colonialism face an entrenched inattention to the ways non-Native conceptions and articulations of personhood, place, property, and political belonging coalesce around and through the dispossession of Native peoples and normalization of (the) settler (-state’s) presence on Native lands. Insistence on the systemic quality of such settler seizures, displacements, identifications responds to this relative absence of acknowledgment by emphasizing its centrality and regularity, arguing that the claiming of a naturalized right to Indigenous place lies at the heart of non-Native modes of governance, association, and identity. However, such figurations of the pervasive and enduring quality of settler colonialism may shorthand its workings, producing accounts in which it appears as a fully integrated whole operating in smooth, consistent, and intentional ways across the socio-spatial terrain it encompasses. Doing so, particularly in considering the exchange between the domains of formal policy and of everyday life, may displace how settlement’s histories, brutalities, effacements, and interests become quotidian and common-sensical. Looking at three different models, I want to sketch varied efforts to systemize settler colonialism, highlighting some questions that emerge when they are read in light of issues of process and affect. 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.” 5 Offering perhaps the most prominent definition of settler colonialism, Wolfe’s formulation emphasizes the fact that it cannot be localized within a specific period of removal or extermination and that it persists as a determinative feature of national territoriality and identity. He argues 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”, adding, “Settler colonialism destroys to replace.” 6 Rather than being superseded after an initial moment/period of conquest, however, colonization persists since “the logic of elimination marks a return whereby the native repressed continues to structure settler-colonial society” (390), and “the process of replacement maintains the refractory imprint of the native counter-claim” (389). Yet, when and how do projects of elimination and replacement become geographies of everyday non-Native occupancy that do not understand themselves as predicated on colonial occupation or on a history of settler-Indigenous relation (even though they are), and what are the contours and effects of such experiences of inhabitance and belonging? In characterizing settlement as a “structure”, “logic”, and a “will”, Wolfe seeks to integrate the multivalent aspects of ongoing processes of non-Native expropriation and superintendence, but doing so potentially sidesteps the question of how official governmental initiatives and framings become normalized as the setting for everyday non-Native being and action in ways that cannot be captured solely by reference to “the murderous activities of the frontier rabble” (392–3).

#### 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.

#### 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.

#### The aff’s understanding of public knowledge requires an alternative – the negative is a sui generis moral rights framework that emphasizing guardianship over ownership.

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.

### 1NC – CP

#### CP: The member nations of the World Trade Organization except for the Republic of India should reduce intellectual property protections for medicines. The Republic of India should reduce intellectual property protections for medicines excluding traditional medicine.

#### Traditional medicine protections key for sustaining communities – India is a key leader

WIPO 11 (WIPOMAGAZINE, [WIPO is the global forum for intellectual property (IP) services, policy, information and cooperation, self-funding agency of the United Nations, with 193 member states.], June 2011, “Protecting India’s Traditional Knowledge“, No Publication, accessed: 8-8-2021, https://www.wipo.int/wipo\_magazine/en/2011/03/article\_0002.html) ajs

In just under two years, in Europe alone, India has succeeded in bringing about the cancellation or withdrawal of 36 applications to patent traditionally known medicinal formulations. The key to this success has been its Traditional Knowledge Digital Library (TKDL), a database containing 34 million pages of formatted information on some 2,260,000 medicinal formulations in multiple languages. Designed as a tool to assist patent examiners of major intellectual property (IP) offices in carrying out prior art1 searches, the TKDL is a unique repository of India’s traditional medical wisdom. It bridges the linguistic gap between traditional knowledge expressed in languages such as Sanskrit, Arabic, Persian, Urdu and Tamil, and those used by patent examiners of major IP offices. India’s TKDL is proving a powerful weapon in the country’s fight against erroneous patents, sometimes referred to as “biopiracy”. In this article, Dr. V.K. Gupta2, the author and architect of India’s TKDL, explains the critical role that this unique tool plays in protecting India’s traditional knowledge.

The significance of traditional knowledge

Traditional knowledge (TK) is integral to the identity of most local communities. It is a key constituent of a community’s social and physical environment and, as such, its preservation is of paramount importance. Attempts to exploit TK for industrial or commercial benefit can lead to its misappropriation and can prejudice the interests of its rightful custodians. In the face of such risks, there is a need to develop ways and means to protect and nurture TK for sustainable development in line with the interests of TK holders. The preservation, protection and promotion of the TK-based innovations and practices of local communities are particularly important for developing countries. Their rich endowment of TK and biodiversity plays a critical role in their health care, food security, culture, religion, identity, environment, trade and development. Yet, this valuable asset is under threat in many parts of the world.

There are concerns that this knowledge is being used and patented by third parties without the prior informed consent of TK holders and that few, if any, of the derived benefits are shared with the communities in which this knowledge originated and exists. Such concerns have pushed TK to the forefront of the international agenda, triggering lively debate about ways to preserve, protect, further develop and sustainably use TK. Documenting and digitizing TK-related information in the form of a TKDL is proving to be an effective means of preserving TK and of preventing its misappropriation by third parties. India is a pioneer in this field.

#### It’s key to health

Sen and Chakraborty 17 (Saikat Sen[] and Raja Chakraborty [], 06-28-2017, “Revival, modernization and integration of Indian traditional herbal medicine in clinical practice: Importance, challenges and future“, PubMed Central (PMC), accessed: 8-8-2021, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5388083/) ajs

Plants are always the key source of drug or treatment strategy in different traditional medicinal systems. In recent years, many people are choosing to plant based medicines or products to improve their health conditions or as curative substance either alone or in combination with others. According to the WHO, herbs or herbal products are used by the large number of populations for basic healthcare needs. Herbal medicine includes herbs, herbal materials (like plant parts) or preparations, processed and finished herbal products, active ingredients.20, 21 In recent years, a huge resurgence of the use of herbal product due to the side effects of modern drugs, failure of modern therapies for against chronic diseases, and microbial resistance. It is estimated that nearly 75% of the plant based therapeutic entities used worldwide were included from traditional/folk medicine. In India, approximately 70% of modern drug are discovered from natural resources and number of other synthetic analogues have been prepared from prototype compounds isolated from plants.20, 22, 23 It was reported that more than 60% of cancer drug available in market or in testing are based on natural products. Currently, about 80% of antimicrobial, immunosuppressive, cardiovascular, and anticancer drugs are derived from plant sources. More than 70% entities among 177 anticancer drugs approved are based on natural products or mimetic. About 25% prescription drug found globally are derived from plant sources, and nearly 121 such drugs entity are in use. Thirteen drugs of natural origin are approved in United States between 2005 and 2007, and clinical trials are going on more than 100 natural product-based drugs. It was also estimated that 11% of the total 252 drugs found in essential medicine list of WHO are exclusively of plant origin.24, 25 In Indian traditional medicine a large number of plants are used. It was estimated that Ayurveda uses 1200–1800 plants, Siddha medicine includes 500–900 plants, Unani utilize 400–700 medicinal plants and Amchi medicine uses nearly 300 plants while folk healers of India use more than 7500 medicinal plants in different medicine. Three classical Ayurvedic literature Charaka Samhita, Sushruta Samhita and Astanga Hridaya mentioned about 526,573 and 902 number of plants.17, 26, 27

### 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.”

#### Drug resistance causes extinction

Sample 13 – Ian Sample, Science Correspondent for The Guardian, citing a report by British Chief medical officer Dame Sally Davies, Master of Science degree from the University of London (“Antibiotic-resistant diseases pose 'apocalyptic' threat, top expert says,” *The Guardian*, January 23rd, https://www.theguardian.com/society/2013/jan/23/antibiotic-resistant-diseases-apocalyptic-threat)

Britain's most senior medical adviser has warned MPs that the rise in drug-resistant diseases could trigger a national emergency comparable to a catastrophic terrorist attack, pandemic flu or major coastal flooding.

Dame Sally Davies, the chief medical officer, said the threat from infections that are resistant to frontline antibiotics was so serious that the issue should be added to the government's national risk register of civil emergencies.

She described what she called an "apocalyptic scenario" where people going for simple operations in 20 years' time die of routine infections "because we have run out of antibiotics".

The register was established in 2008 to advise the public and businesses on national emergencies that Britain could face in the next five years. The highest priority risks on the latest register include a deadly flu outbreak, catastrophic terrorist attacks, and major flooding on the scale of 1953, the last occasion on which a national emergency was declared in the UK.

Speaking to MPs on the Commons science and technology committee, Davies said she would ask the Cabinet Office to add antibiotic resistance to the national risk register in the light of an annual report on infectious disease she will publish in March.

Davies declined to elaborate on the report, but said its publication would coincide with a government strategy to promote more responsible use of antibiotics among doctors and the clinical professions. "We need to get our act together in this country," she told the committee.

She told the Guardian: ""There are few public health issues of potentially greater importance for society than antibiotic resistance. It means we are at increasing risk of developing infections that cannot be treated – but resistance can be managed.

"That is why we will be publishing a new cross-government strategy and action plan to tackle this issue in early spring."

The issue of drug resistance is as old as antibiotics themselves, and arises when drugs knock out susceptible infections, leaving hardier, resilient strains behind. The survivors then multiply, and over time can become unstoppable with frontline medicines. Some of the best known are so-called hospital superbugs such as MRSA that are at the root of outbreaks among patients.

"In the past, most people haven't worried because we've always had new antibiotics to turn to," said Alan Johnson, consultant clinical scientist at the Health Protection Agency. "What has changed is that the development pipeline is running dry. We don't have new antibiotics that we can rely on in the immediate future or in the longer term."

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

Hillman and Tippett 21 [Jennifer A; Senior fellow for trade and international political economy; Alex; Research associate for international economics, at the Council on Foreign Relations; “Europe and the Prospects for WTO Reform,” CFR; 3/10/21; <https://www.cfr.org/blog/europe-and-prospects-wto-reform>] Justin

The WTO has been in the clutches of a slow-moving crisis for years. At its heart are a series of disputes about the role of the WTO’s Appellate Body, the final arbiter in the WTO’s Dispute Settlement System. Today, the Appellate Body sits empty, severely undermining the capacity of the WTO to resolve trade disputes.

Since the start of the Trump administration, the United States has refused to appoint any new members to the body, effectively allowing countries to avoid compliance with WTO rulings. The primary driver of this drastic action has been American frustration at perceived judicial overreach. U.S. policymakers, starting with the George W. Bush administration, have repeatedly voiced their displeasure with Appellate Body decisions, contending that certain decisions have reached beyond the text of existing WTO agreements.

#### Beyond getting rid of patents, 1AC can’t solve – conservative nations would never agree.

Murphy 7/13 [Tim Murphy, 7-13-2021, "Advocates Are Unhappy with the Global AIDS Agenda's Drug Patent Language," No Publication, <https://www.thebody.com/article/drug-patent-language-unaids> //belle

Other Sore Points With the Declaration A second stress point during negotiations was about language urging countries to do more to decriminalize and destigmatize the behavior of so-called “key populations”—traditionally marginalized or persecuted groups such as men who have sex with men, sex workers, transgender people, and people who use drugs—who are generally at higher risk for HIV. A new report written by Kavanagh and his Georgetown colleagues shows that countries that decriminalize such groups have higher success rates for fighting HIV. The U.S. was among countries pushing for strong language in the UNAIDS political declaration calling for countries to do so, as well as to empower women and girls around education and reproductive health. But such countries got strong pushback from conservative nations, including China, Russia, Iran, and the Africa Group (a coalition of 54 African Union member states within the UN) to drastically dial back that language—and assert “the sovereign rights of member states.” What the declaration was left with, says Sawyer, was “aspirational language about addressing these issues, but no specific statements saying countries that criminalize these things need to take those laws away.” According to Sawyer, “Russia had the biggest impact on the declaration, all of which was negative, limiting rights, protections, and access to essential services. They pushed back against decriminalizing key populations, drug use and harm reduction, sex work, trans issues, LGBTQ issues, sexual reproductive health and rights, and comprehensive sex ed.”

#### No instrastructure, can’t scale up production, AND Governments continue to dismiss HIV/AIDs concerns – South Africa proves.

Imasogie & Lai 5/14 [Osagie Imasogie & Alicia Lai; Osagie Imasogie has over 35 years of experience in the field of law, finance, business management, healthcare, and the pharmaceutical industry. Imasogie is a serial entrepreneur, investor, and trustee of the University of Pennsylvania and a member of the executive committee of the university, in addition to being the chairman of the board of the University of Pennsylvania Carey Law School, where he is an adjunct professor of intellectual property law. Alicia Lai is a recent graduate of the University of Pennsylvania Law School, where she was a Cutler fellow and articles editor of the Law Review. She has published on intellectual property law, tech regulation, and innovation policy. ( 5-14-2021, "The Fallacy of IP Waivers," Treasury & Risk, https://www.treasuryandrisk.com/2021/05/14/the-fallacy-of-ip-waivers-411-25064/?slreturn=20210730195700

But voluntarily public consignment is not always applicable. As former U.S. Patent and Trademark Office Director Andrei Iancu noted, “I think folks need to understand that suspending IP rights actually will make the [Covid-19] situation worse, not better.” The U.S. approach to the HIV/AIDS epidemic provides a salient example of IP waivers gone awry. First, whether patent rights are enforced or waived is only one piece of the global health puzzle. Many developing countries lack the public health infrastructure and manufacturing capacity to effectively support Covid-19 vaccination manufacturing and distribution. In 2006, Roche announced its AIDS Technology Transfer Initiative to provide permission and technical assistance to manufacturers in sub-Saharan Africa to produce generic HIV medication based on its own patented processes. Yet for years, despite the waiver of IP enforcement, no implementation occurred. Local interest flourished, but local manufacturing was insufficient. In fact, U.S. companies without proper infrastructure also find it difficult to scale up production. Earlier this year, a Johnson & Johnson contractor plant contaminated 15 million doses of the Covid-19 vaccine with issues ranging from unsanitary conditions to poorly trained staff. Without adequate infrastructure, skilled workers, technical expertise, and open trade secrets, IP waivers—as Moderna, for instance, has announced—are mere lip service. They do little to equalize vaccine access around the globe. Other pharmaceutical players argue that it would also undermine vaccine safety and quality control. Even when vaccines are manufactured in the West and delivered to developing countries—as Pfizer and Moderna vaccines are—safe and effective storage of the vaccines requires a cold room chain. In many developing countries, this crucial public health infrastructure is not readily available. Second, the compulsory licensing exception has historically been discriminatorily applied. Article 31 of TRIPS permits the manufacturing and importing of patented products in narrow cases. Specifically, the drug must be “essential” in a “national emergency” or “other extreme urgency.” However, historically, what this definition encompasses depends on the say-so of developed countries. In 1997, the U.S. government determined the HIV/AIDS epidemic in South Africa—afflicting 27.2 percent of the population of 42.7 million, i.e. nearly 12 million people, with over 3 million deaths from HIV/AIDs in the following 15 years—did not constitute a sufficient “medical emergency.” South Africa had passed a law allowing two “controversial” practices: one allowing importers to buy HIV/AIDS drugs from cheaper sources regardless of patent owner consent, another allowing compulsory licensing for South African firms to produce cheaper versions of HIV/AIDS drugs patented by foreign companies. The U.S. joined GlaxoSmithKline and 38 other pharmaceutical companies to sue Nelson Mandela over the law, arguing that the TRIPS medical emergency exception did not apply. In contrast, the U.S. government determined that the 2001 anthrax attacks—which left five dead and 17 sick in the United States—did rise to the level of “medical emergency.” The United States threatened to institute compulsory licensing of the antiviral drug Cipro. As a result, the manufacturer Bayer acquiesced to significantly cutting the price so the government could stockpile the drug for Americans. So, while compulsory licensing could benefit developing countries, arbitrary enforcement of these exceptions may only entrench existing power dynamics. Patent reform debate has long been ongoing. Developing countries are seeing devastating surges in Covid-19 cases. But unfortunately, despite potential benefits, mere IP waivers—without other structural reforms and safeguards—are unlikely to be a realistic solution to drastic inequalities in international access to pharmaceutical drugs. As Americans who remain exposed to the Covid-19 virus as long as it is endemic anywhere in the world, it is in all of our interests for the U.S. government to provide leadership in managing the pandemic and implementing realistic solutions to assist the developing world to access Covid-19 vaccines.

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

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

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

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

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

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

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

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

#### Minor tweaks of drugs are key to ensure adequate treatment- otherwise patients skip doses or medicines fail in hot climates

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

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

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