## 1

#### Interpretation: Affirmatives must specify and cite an indigenous solvency advocate in the 1ac

#### Violation:

#### Standards:

#### In round violence

#### Methods of resistance

## 2

**Pleasure is the root of all good, and pain is the root of all bad, proves that all moral theories devolve to Util**

**Moen 15** Ole Martin Moen, Centre for the Study of Mind in Nature, Department of Philosophy, 9-12-2015, Springer, “An Argument for Hedonism”, [file:///C:/Users/axema/Documents/Debate/NSD%202020/Homework/AnArgumentForHedonism.pdf](file:///C:\Users\axema\Documents\Debate\NSD%202020\Homework\AnArgumentForHedonism.pdf) AX

Let us start by observing, empirically, that a widely shared judgment about intrinsic value and disvalue is that pleasure is intrinsically valuable and pain is intrinsically disvaluable. On virtually any proposed list of intrinsic values and disvalues (we will look at some of them below), pleasure is included among the intrinsic values and pain among the intrinsic disvalues. This inclusion makes intuitive sense, moreover, for there is something undeniably good about the way pleasure feels and something undeniably bad about the way pain feels, and neither the goodness of pleasure nor the badness of pain seems to be exhausted by the further effects that these experiences might have. ‘‘Pleasure’’ and ‘‘pain’’ are here understood inclusively, as encompassing anything hedonically positive and anything hedonically negative.2 The special value statuses of pleasure and pain are manifested in how we treat these experiences in our everyday reasoning about values. If you tell me that you are heading for the convenience store, I might ask: ‘‘What for?’’ This is a reasonable question, for when you go to the convenience store you usually do so, not merely for the sake of going to the convenience store, but for the sake of achieving something further that you deem to be valuable. You might answer, for example: ‘‘To buy soda.’’ This answer makes sense, for soda is a nice thing and you can get it at the convenience store. I might further inquire, however: ‘‘What is buying the soda good for?’’ This further question can also be a reasonable one, for it need not be obvious why you want the soda. You might answer: ‘‘Well, I want it for the pleasure of drinking it.’’ If I then proceed by asking ‘‘But what is the pleasure of drinking the soda good for?’’ the discussion is likely to reach an awkward end. The reason is that the pleasure is not good for anything further; it is simply that for which going to the convenience store and buying the soda is good.3 As Aristotle observes: ‘‘We never ask [a man] what his end is in being pleased, because we assume that pleasure is choice worthy in itself.’’4 Presumably, a similar story can be told in the case of pains, for if someone says ‘‘This is painful!’’ we never respond by asking: ‘‘And why is that a problem?’’ We take for granted that if something is painful, we have a sufficient explanation of why it is bad. If we are onto something in our everyday reasoning about values, it seems that pleasure and pain are both places where we reach the end of the line in matters of value.

**Continues**

I think several things should be said in response to Moore’s challenge to hedonists. First, I do not think the burden of proof lies on hedonists to explain why the additional values are not intrinsic values. If someone claims that X is intrinsically valuable, this is a substantive, positive claim, and it lies on him or her to explain why we should believe that X is in fact intrinsically valuable. Possibly, this could be done through thought experiments analogous to those employed in the previous section. Second, there is something peculiar about the list of additional intrinsic values that counts in hedonism’s favor: the listed values have a strong tendency to be well explained as things that help promote pleasure and avert pain. To go through Frankena’s list, life and consciousness are necessary presuppositions for pleasure; activity, health, and strength bring about pleasure; and happiness, beatitude, and contentment are regarded by Frankena himself as ‘‘pleasures and satisfactions.’’ The same is arguably true of beauty, harmony, and ‘‘proportion in objects contemplated,’’ and also of affection, friendship, harmony, and proportion in life, experiences of achievement, adventure and novelty, self-expression, good reputation, honor and esteem. Other things on Frankena’s list, such as understanding, wisdom, freedom, peace, and security, although they are perhaps not themselves pleasurable, are important means to achieve a happy life, and as such, they are things that hedonists would value highly. Morally good dispositions and virtues, cooperation, and just distribution of goods and evils, moreover, are things that, on a collective level, contribute a happy society, and thus the traits that would be promoted and cultivated if this were something sought after. To a very large extent, the intrinsic values suggested by pluralists tend to be hedonic instrumental values. Indeed, pluralists’ suggested intrinsic values all point toward pleasure, for while the other values are reasonably explainable as a means toward pleasure, pleasure itself is not reasonably explainable as a means toward the other values. Some have noticed this. Moore himself, for example, writes that though his pluralistic theory of intrinsic value is opposed to hedonism, its application would, in practice, look very much like hedonism’s: ‘‘Hedonists,’’ he writes ‘‘do, in general, recommend a course of conduct which is very similar to that which I should recommend.’’24 Ross writes that ‘‘[i]t is quite certain that by promoting virtue and knowledge we shall inevitably produce much more pleasant consciousness. These are, by general agreement, among the surest sources of happiness for their possessors.’’25 Roger Crisp observes that ‘‘those goods cited by non-hedonists are goods we often, indeed usually, enjoy.’’26 What Moore and Ross do not seem to notice is that their observations give rise to two reasons to reject pluralism and endorse hedonism. The first reason is that if the suggested non-hedonicintrinsic values are potentially explainable by appealtojust pleasure and pain (which, following my argument in the previous chapter, we should accept as intrinsically valuable and disvaluable), then—by appeal to Occam’s razor—we have at least a pro tanto reason to resist the introduction of any further intrinsic values and disvalues. It is ontologically more costly to posit a plurality ofintrinsic values and disvalues, so in case all values admit of explanation by reference to a single intrinsic value and a single intrinsic disvalue, we have reason to reject more complicated accounts. The fact that suggested non-hedonic intrinsic values tend to be hedonistic instrumental values does not, however, count in favor of hedonism solely in virtue of being most elegantly explained by hedonism; it also does so in virtue of creating an explanatory challenge for pluralists. The challenge can be phrased as the following question: If the non-hedonic values suggested by pluralists are truly intrinsic values in their own right, then why do they tend to point toward pleasure and away from pain?

**Thus, the standard is maximizing expected well being. Prefer Additionally:**

**1)Preventing extinction is a pre-req to all other frameworks. Even if extinction is good, we still have reason to prevent it.**

**MacAskill 14**, William, Oxford Philosopher and youngest tenured philosopher in the world, Normative Uncertainty, 2014. AX Accessed 9/19/21 <http://commonsenseatheism.com/wp-content/uploads/2014/03/MacAskill-Normative-Uncertainty.pdf>

The human race might go extinct from a number of causes: asteroids, supervolcanoes, runaway climate change, pandemics, nuclear war, and the development and use of dangerous new technologies such as synthetic biology, all pose risks (even if very small) to the continued survival of the human race.184 And different moral views give opposing answers to question of whether this would be a good or a bad thing. It might seem obvious that human extinction would be a very bad thing, both because of the loss of potential future lives, and because of the loss of the scientific and artistic progress that we would make in the future. But the issue is at least unclear. The continuation of the human race would be a mixed bag: inevitably, it would involve both upsides and downsides. And if one regards it as much more important to avoid bad things happening than to promote good things happening then one could plausibly regard human extinction as a good thing.For example, one might regard the prevention of bads as being in general more important that the promotion of goods, as defended historically by G. E. Moore,185 and more recently by Thomas Hurka.186 One could weight the prevention of suffering as being much more important that the promotion of happiness. Or one could weight the prevention of objective bads, such as war and genocide, as being much more important than the promotion of objective goods, such as scientific and artistic progress. If the human race continues its future will inevitably involve suffering as well as happiness, and objective bads as well as objective goods. So, if one weights the bads sufficiently heavily against the goods, or if one is sufficiently pessimistic about humanity’s ability to achieve good outcomes, then one will regard human extinction as a good thing.187 However, even if we believe in a moral view according to which human extinction would be a good thing, we still have strong reason to prevent near-term human extinction. To see this, we must note three points. First, we should note that the extinction of the human race is an extremely high stakes moral issue. Humanity could be around for a very long time: if humans survive as long as the median mammal species, we will last another two million years. On this estimate, the number of humans in existence in the The future, given that we don’t go extinct any time soon, would be 2×10^14. So if it is good to bring new people into existence, then it’s very good to prevent human extinction. Second, human extinction is by its nature an irreversible scenario. If we continue to exist, then we always have the option of letting ourselves go extinct in the future (or, perhaps more realistically, of considerably reducing population size). But if we go extinct, then we can’t magically bring ourselves back into existence at a later date. Third, we should expect ourselves to progress, morally, over the next few centuries, as we have progressed in the past. So we should expect that in a few centuries’ time we will have better evidence about how to evaluate human extinction than we currently have. Given these three factors, it would be better to prevent the near-term extinction of the human race, even if we thought that the extinction of the human race would actually be a very good thing. To make this concrete, I’ll give the following simple but illustrative model. Suppose that we have 0.8 credence that it is a bad thing to produce new people, and 0.2 certain that it’s a good thing to produce new people; and the degree to which it is good to produce new people, if it is good, is the same as the degree to which it is bad to produce new people, if it is bad. That is, I’m supposing, for simplicity, that we know that one new life has one unit of value; we just don’t know whether that unit is positive or negative. And let’s use our estimate of 2×10^14 people who would exist in the future, if we avoid near-term human extinction. Given our stipulated credences, the expected benefit of letting the human race go extinct now would be (.8-.2)×(2×10^14) = 1.2×(10^14). Suppose that, if we let the human race continue and did research for 300 years, we would [to] know for certain whether or not additional people are of positive or negative value. If so, then with the credences above we should think it 80% likely that we will find out that it is a bad thing to produce new people, and 20% likely that we will find out that it’s a good thing to produce new people. So there’s an 80% chance of a loss of 3×(10^10) (because of the delay of letting the human race go extinct), the expected value of which is 2.4×(10^10). But there’s also a 20% chance of a gain of 2×(10^14), the expected value of which is 4×(10^13). That is, in expected value terms, the cost of waiting for a few hundred years is vanishingly small compared with the benefit of keeping one’s options open while one gains new information.

**2) Weighability: only consequentialism explains degrees of wrongness—if I break a promise to hang out with my friends, that is not as bad as breaking a promise to take a dying person to the hospital. Only the consequences of breaking the promise explain why the second one is so much worse than the first.**

**3] Util is a lexical pre-requisite to any other framework: Threats to bodily security and life preclude the ability for moral actors to effectively utilize and act upon other theories since they are in a constant state of crisis that inhibit the ideal moral conditions which other theories presuppose – so, util comes first and my offense outweighs theirs under their own framework**

**4] Actor specificity: [a] Governments aren’t philosophers—officials don’t know how to apply more complex moral principles but they know how to do studies. Empirically proven—congressional reports are always about end-states and helping the majority[b] Governments must aggregate since every policy benefits some and harms others, which also means side constraints freeze action.**

**Prefer this interp:**

**A] Resolvability – it is impossible way to weigh between deontological violations but you only need basic math for util. That outweighs – every round needs a winner.**

**B] ground – a) most articles are written through the lens of util because they’re crafted for policymakers and the public who take consequences to be important, not philosophy majors. Even if another framework is substantively true, there isn’t good discussion of it in the topic lit so we can’t have good debates. Impacts to real world education. B)** **every impact functions under util whereas other ethics flow to one side exclusively. Kills fairness since we both need arguments to win and harms education since we have little args**

**Permissibility negates – Neg is to deny the truth of obligation, the aff must prove an obligation**

**Presumption negates – because its more likely a statement is false then it is true – Eg. there are only a few correct answers but infinite wrong answers**

## 3

#### Reducing IP leads to an increase in the production of low quality generics in the Global South which causes antimicrobial resistance

Hegde 17 Raghuraj S Hegde “Why Branded Drugs Cost Way More than Their Generic Counterparts-India News , Firstpost.” Firstpost, 29 Apr. 2017, Accessed 9/16/21 <https://www.firstpost.com/india/why-branded-drugs-cost-way-more-than-their-generic-counterparts-3412922.html>. AX

In the 1960s, the USA changed it’s laws which then required drug manufacturers to demonstrate that a particular drug works as they claim it would before they could sell on the market. This was the birth of the modern avatar of United States Food and Drug Administration (USFDA) (though the body was originally established in 1906). The evidence of effectiveness demanded by the USFDA gave rise to extensive clinical trials which in turn encouraged scientific rigor through evidence based medicine (EBM). In addition to basic science research to discover new drugs, clinical trials required thousands of patients to be administered the drug to be tested and proof of efficacy of a medicine established scientifically. The results were to be submitted to the regulatory body for approval. Today costs of developing a new drug and conducting clinical trials runs into millions and sometimes billions of dollars- The Cost Of Creating A New Drug Now $5 Billion. So when a successful drug comes through this long winded and expensive process, companies try to recover the R&D costs by selling those drugs at huge profit margins before the drug patent expires (typically about 10–20 years depending on the country and less than that in some countries). This is why branded drugs are expensive when a new drug comes in the market. So the high price of branded drugs comes down to market economics and the society’s need for the invention of new and effective drugs. It is watered down to this simplified axiom- No profits→ no R&D; No R&D→ no new drugs discovered. The new regulations spread to the rest of the world. Most industrialized countries accepted it and evidence based medicine became the global standard. To ensure ethical and safe clinical trials, Helsinki Declaration was drafted in 1964 which brought in new rules to follow with regard to clinical trials. The clinical trials also created a difficult entry threshold for new companies to bring new products to the market since most of the new companies couldn’t afford either good quality basic science research or the ever increasing costs of clinical trials. In 1984, USA changed it’s drug regulatory laws again to regulate those manufacturers who manufacture the proprietary drug after it’s patent had lapsed. The new laws were aimed at simplifying the process, preventing reduplication of established results and for reducing cost threshold for new entrants. These new regulations didn’t require the new manufacturers to repeat the expensive clinical trials of the original molecule but instead mandated that the new companies conduct and submit Bio-equivalence (BE) and Bio-availability (BA) studies to USFDA for approval of the drugs. The USFDA was also proactively involved in the enforcement of the good manufacturing practices in the factories even before BE/BA reports were filed. This ensured that quality was maintained throughout the whole process. These rules were again readily accepted by drug regulatory authorities throughout the world. This was the birth of the generic medicines market. Bio-equivalence studies are tests to show that a generic version of the drug works just as well as the original formerly patented drug. Bio-availability studies conducted to ensure that the available active ingredient of the drug in the body is the same that provided by the original molecule. These studies typically require only a few hundred healthy volunteers. The costs of such studies are obviously much lower than full fledged clinical trials. This is why generics are so cheap. The manufacturers don’t have to spend as much as the big pharma giants to bring these new drugs to the market. It was a win-win for both the pharma companies as well as the consumers- who now had to pay less for their medicines. It seemed like an ideal solution to rising costs of healthcare but a disaster was luzrking in the background waiting to show it’s ugly head. The ugly side of the generic medicine manufacturing and regulation (India perspective) The introduction of generics and its proper regulation (BE/BA reports) ensured that European and American markets received good quality generics at lower costs supplied to their population. However poor laws and regulation in developing countries ensured that corners were cut resulting in low quality generics and contaminated drugs finding their way to patients especially in countries with large populations (India &China) and even poor countries of Africa (where even recording of drug-related deaths were absent). In India, the generic manufacturing boomed in the 80s and 90s due to lax laws and socialistic tendencies of successive governments which were only bothered about reduction in drug prices but not quality of the drugs manufactured. India now is placed 4th in the global generics market but leads the race in the global burden of counterfeit medicines as 75% of all counterfeit medicines traces it’s roots to India followed not very closely by Egypt (7%) and China (6%). The greed for cashing in on the foreign developed markets has resulted in reputed Indian pharma giants like Ranbaxy, GVK Biohealthcare, Dr. Reddy’s Laboratories being proven guilty of submitting fabricated BA/BE studies to push generics into the international markets. They pleaded guilty in the courts and had to give millions of dollars in settlements. Only this year ( April 2017) did the Indian government enact amendments to the Drug and Cosmetics Act (1940) which made it mandatory for manufacturers to submit BE/BA reports for approval of generic medicines into the market. How seriously these rules would be enforced remains to be seen. The earlier regime only required BE/BA reports for generics of those patented drugs approved by the Drug Controller General of India (DCGI) within the first four years of introduction of the innovator drug. Beyond that no generics manufacturer required to submit any BE/BA reports to sell their drugs in the markets. Only the finished drugs are sometimes submitted for testing at the Central Drugs Standard Control Organization (CDSCO) and there is no regulation ensuring of good manufacturing practices presently. Currently only 0.01% of the drugs in the Indian market are even tested. Some of the generics are not even tested on basic effectiveness so they don’t even have to put in an active ingredient which gives retailers sometimes 1000% profit margins. Due to such lax rules and regulations- substandard, contaminated and sometimes toxic drugs end up even in government generic medicine supplies. When such generics produced with dubious manufacturing processes fail to pass muster in developed countries due to their strong regulatory authorities, they end up in remote domestic markets in India and several poor African countries. These substandard or fake drugs do not cause direct drug related deaths but by increase in deaths by not curing the disease as well as increase in multi-drug resistant strains in the community. For example in Tuberculosis, if drugs with low effective doses or no active ingredient is given, it doesn't cure the disease and increases incidence of drug resistant tuberculosis in the community. The deaths caused by this is attributed to multi-drug resistant tuberculosis strains while the real culprit is the substandard medicines supplied earlier. Similarly many strains of antibiotic resistant strains of bacteria develop in such countries increasing disease burden in the community as well as making such infections difficult to treat. The Delhi Superbug is the result of such inadequacies as well as rampant unhindered use of antibiotics in the country. There are three types of drugs in the market at present. — Branded drugs which have brand names and is marketed/advertised to doctors and hospitals by reputed established companies. — Branded generic drugs which are also manufactured by reputed companies but are dependent on retailers/chemists to drive sales. — Unbranded generics which are manufactured from lesser known companies and many of them indulging in bad manufacturing processes and even sometimes not putting in the active ingredient of a particular drug. Recently the Medical Council of India (MCI) issued a directive that all registered practitioners of modern medicine should write only chemical names in their prescriptions. On it’s own it is not a bad move and it was intended to fix the physician- pharma nexus that is deeply entrenched in India. However with such a poor regulatory regime in India it probably does more harm than good. The authority to dispense medicines has shifted from the doctor to often unqualified employees/owners of chemist shops and alternative medicine practitioners (because they are not bound to the MCI directive and can do what they want). This in my opinion is quite a dangerous trend. I recently wrote an article about my views on this new directive. Whether a particular drug is branded or generic, it’s efficacy and safety profile should be the same. Often with the intention to reduce costs of medicines, less ethical means are taken to that end. If drug regulation is poor, unethical businessmen will stop at nothing to increase their profit margins. Our focus should not only be in reducing costs of drugs but more on ensuring that quality and reliable safe drugs reach the end consumers-the patients. The Indian government could do well to understand this aspect-so poignantly described this letter to US President Franklin D Roosevelt in 1937 by a woman describing the death of her child after a toxic drug consumption: "The first time I ever had occasion to call in a doctor for [Joan] and she was given Elixir of Sulfanilamide. All that is left to us is the caring for her little grave. Even the memory of her is mixed with sorrow for we can see her little body tossing to and fro and hear that little voice screaming with pain and it seems as though it would drive me insane. ... It is my plea that you will take steps to prevent such sales of drugs that will take little lives and leave such suffering behind and such a bleak outlook on the future as I have tonight."

#### Antimicrobial resistsnace is rising now, the increase of antimicrobial resistance from generics pushes us over the brink

Neily 14 Jim O Neily(Jim O Neily is an Honorary Professor of Economics at the University of Manchester.He was appointed Commercial Secretary to the Treasury in the Second Cameron Ministry, a position he held until his resignation on 23 September 2016, He is the current chairman of the Council of Chatham House, the Royal Institute of International Affairs.) “The Review on Antimicrobial Resistance”, 2014, Accessed 9/16/21 <https://amr-review.org/home.html> AX

“The Review on Antimicrobial Resistance (AMR), was commissioned in July 2014 by the UK Prime Minister, who asked economist Jim O’Neill to analyse the global problem of rising drug resistance and propose concrete actions to tackle it internationally. The Review on AMR was jointly supported by the UK Government and Wellcome Trust, although operated with full independence from both. Established as a two-year, time-limited process, the Review engaged widely with international stakeholders to understand and propose solutions to the problem of drug-resistant infections from an economic and social perspective, and produced its final report and recommendations in the summer of 2016. "If we fail to act, we are looking at an almost unthinkable scenario where antibiotics no longer work and we are cast back into the dark ages of medicine" – David Cameron, former UK Prime Minister The real implications of spreading drug resistance will be felt the world over, with developing countries and large emerging nations bearing the brunt of this problem. Routine surgeries and minor infections will become life- threatening once again and the hard won victories against infectious diseases of the last fifty years will be jeopardised. Hospital stays and expenses, for both public health care providers and for out of –pocket payers will increase significantly. Drug resistant infections are already on the rise with numbers suggesting that up to 50,000 lives are lost each year to antibiotic-resistant infections in Europe and the US alone. Globally, at least 700,000 die each year of drug resistance in illnesses such as bacterial infections, malaria, HIV/AIDS or tuberculosis. “We have reached a critical point and must act now on a global scale to slow down antimicrobial resistance” – Professor Dame Sally Davies, UK Chief Medical Officer

#### Antimicrobial resistance leads to extinction

Talkington 20 “The U.S. Is Not Prepared to Combat “Existential Threat” of Antibiotic-Resistant Superbugs.” [https://pew.org/2OZgjNp. Accessed 16 Sept. 2021](https://pew.org/2OZgjNp.%20Accessed%2016%20Sept.%202021). <https://www.pewtrusts.org/en/research-and-analysis/articles/2020/07/27/the-us-is-not-prepared-to-combat-existential-threat-of-antibiotic-resistant-superbugs> AX

At the July launch of the AMR Action Fund, Admiral Brett P. Giroir, U.S. assistant secretary for health, said the following: "Antimicrobial resistance, I do believe, is the existential threat of this century." Giroir’s warning is dire—but it’s not new. For years, leading public health and national security experts around the world have sounded the alarm about the growing threat posed by antibiotic-resistant bacteria. Commissions led by world-renowned economists, declarations from the United Nations General Assembly, urgent threat reports from the Centers for Disease Control and Prevention, and more have all come to the same conclusion: Antimicrobial resistance is a known and certain danger—and the global level of preparedness does not match the magnitude of the threat. In June, The Pew Charitable Trusts sent a letter to the leaders of the Senate Committee on Health, Education, Labor, and Pensions, providing recommendations for how the U.S. can better prepare for future pandemics. The letter highlighted the urgent need for government incentives to help fix the broken antibiotic market. Pew recently reiterated this call to action in partnership with the World Health Organization. There is widespread and longstanding consensus that such incentives are needed to revitalize and sustain the woefully inadequate antibiotic pipeline. Without them, antibiotic developers will continue to go bankrupt, and innovation will continue to stagnate. Now is the time for action. Policymakers must ensure that the U.S. is not caught flat-footed when the inevitable superbug outbreak hits. Some threats we cannot begin to anticipate, but when it comes to antibiotic-resistant bacteria, there’s no excuse for being unprepared.

## 4

#### CP text: The member nations of the world trade organization should

#### ---exclude patent applications for medicines based on Indigenous knowledge from patentability except for claims filed by Indigenous people.

#### --- Transfer existing settler patents to indigenous people

#### ---establish an international legal instrument to protect indigenous intellectual property from the IGC

#### That is in line with indigenous demands.

IGC – International governmental committee on IP and Genetic resources, Traditional knowledge + Folklore, Sessions of the IGC begin with presentations by over 30 representatives from indigenous and local communities. Full link here: https://www.wipo.int/tk/en/igc/panels.html

**WIPO no date** WIPO, "Traditional Knowledge and Intellectual Property – Background Brief," No Publication, <https://www.wipo.int/pressroom/en/briefs/tk_ip.html?fbclid=IwAR2iLd8fJ4lNl_fhhwQBHvCdoFEfB44H5GHIWBBb0xGPVBt1fRJT-uzUXDU> Accessed 9/17/21 AX

The current international system for protecting intellectual property was fashioned during the age of industrialization in the West and developed subsequently in line with the perceived needs of technologically advanced societies. However, in recent years, indigenous peoples, local communities, and governments, mainly in developing countries, have demanded equivalent protection for traditional knowledge systems. In 2000, WIPO members established an Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC), and in 2009 they agreed to develop an international legal instrument (or instruments) that would give traditional knowledge, genetic resources and traditional cultural expressions (folklore) effective protection. Such an instrument could range from a recommendation to WIPO members to a formal treaty that would bind countries choosing to ratify it. Traditional knowledge is not so-called because of its antiquity. It is a living body of knowledge that is developed, sustained and passed on from generation to generation within a community, often forming part of its cultural or spiritual identity. As such, it is not easily protected by the current intellectual property system, which typically grants protection for a limited period to inventions and original works by named individuals or companies. Its living nature also means that “traditional” knowledge is not easy to define. Recognizing traditional forms of creativity and innovation as protectable intellectual property would be an historic shift in international law, enabling indigenous and local communities as well as governments to have a say over the use of their traditional knowledge by others. This would make it possible, for example, to protect traditional remedies and indigenous art and music against misappropriation, and enable communities to control and benefit collectively from their commercial exploitation. Although the negotiations underway in WIPO have been initiated and propelled mainly by developing countries, the discussions are not neatly divided along “North-South” lines. Communities and governments do not necessarily share the same views, and some developed country governments, especially those with indigenous populations, are also active. Two types of intellectual property protection are being sought: Defensive protection aims to stop people outside the community from acquiring intellectual property rights over traditional knowledge. India, for example, has compiled a searchable database of traditional medicine that can be used as evidence of prior art by patent examiners when assessing patent applications. This followed a well-known case in which the US Patent and Trademark Office granted a patent (later revoked) for the use of turmeric to treat wounds, a property well known to traditional communities in India and documented in ancient Sanskrit texts. Defensive strategies might also be used to protect sacred cultural manifestations, such as sacred symbols or words from being registered as trademarks. Positive protection is the granting of rights that empower communities to promote their traditional knowledge, control its uses and benefit from its commercial exploitation. Some uses of traditional knowledge can be protected through the existing intellectual property system, and a number of countries have also developed specific legislation. However, any specific protection afforded under national law may not hold for other countries, one reason why many indigenous and local communities as well as governments are pressing for an international legal instrument. WIPO’s work on traditional knowledge addresses three distinct yet related areas: traditional knowledge in the strict sense (technical know-how, practices, skills, and innovations related to, say, biodiversity, agriculture or health); traditional cultural expressions/expressions of folklore (cultural manifestations such as music, art, designs, symbols and performances); and genetic resources (genetic material of actual or potential value found in plants, animals and micro-organisms). Although for many communities traditional knowledge, genetic resources and traditional cultural expressions form part of a single integrated heritage, from an intellectual property standpoint they raise different issues and may require different sets of solutions. In all three areas, in addition to work on an international legal instrument, WIPO is responding to requests from communities and governments for practical assistance and technical advice to enable communities to make more effective use of existing intellectual property systems and participate more effectively in the IGC’s negotiations. WIPO’s work includes assistance to develop and strengthen national and regional systems for the protection of traditional knowledge (policies, laws, information systems and practical tools) and the Creative Heritage Project which provides hands-on training for managing intellectual property rights and interests when documenting cultural heritage. Traditional knowledge When community members innovate within the traditional knowledge framework, they may use the patent system to protect their innovations. However, traditional knowledge as such - knowledge that has ancient roots and is often informal and oral - is not protected by conventional intellectual property systems. This has prompted some countries to develop their own sui generis (specific, special) systems for protecting traditional knowledge. There are also many initiatives underway to document traditional knowledge. In most cases the motive is to preserve or disseminate it, or to use it, for example, in environmental management, rather than for the purpose of legal protection. There are nevertheless concerns that if documentation makes traditional knowledge more widely available to the general public, especially if it can be accessed on the Internet, this could lead to misappropriation and use in ways that were not anticipated or intended by traditional knowledge holders. At the same time, documentation can help protect traditional knowledge, for example, by providing a confidential or secret record of traditional knowledge reserved for the relevant community only. Some formal documentation and registries of traditional knowledge support sui generis protection systems, while traditional knowledge databases - such as India’s database on traditional medicine - play a role in defensive protection within the existing IP system. These examples demonstrate the importance of ensuring that documentation of traditional knowledge is linked to an intellectual property strategy and does not take place in a policy or legal vacuum. In the WIPO talks, many argue that use of traditional knowledge ought to be subject to free, prior and informed consent, especially for sacred and secret materials. However, others fear that granting exclusive control over traditional cultures could stifle innovation, diminish the public domain and be difficult to implement in practice. Genetic resources Genetic resources themselves are not intellectual property (they are not creations of the human mind) and thus cannot be directly protected as intellectual property. However, inventions based on or developed using genetic resources (associated with traditional knowledge or not) may be patentable or protected by plant breeders’ rights. In considering intellectual property aspects of use of genetic resources, WIPO’s work complements the international legal and policy framework defined by the Convention on Biological Diversity (CBD), and its Nagoya Protocol, and the International Treaty on Genetic Resources for Food and Agriculture of the United Nations Food and Agriculture Organization. Issues under discussion at WIPO include: Defensive protection of genetic resources: This strand of the work aims at preventing patents being granted over genetic resources (and associated traditional knowledge) which do not fulfil the existing requirements of novelty and inventiveness. In this context, to help patent examiners find relevant prior art, proposals have been made that genetic resources and traditional knowledge databases could help patent examiners avoid erroneous patents and WIPO has improved its own search tools and patent classification systems. The other, more controversial, strand concerns the possible disqualification of patent applications that do not comply with CBD obligations on prior informed consent, mutually agreed terms, fair and equitable benefit-sharing, and disclosure of origin. “Biopiracy” is a term sometimes used loosely to describe biodiversity-related patents that do not meet patentability criteria or that do not comply with the CBD’s obligations – but this term has no precise or agreed meaning. Disclosure requirements: A number of countries have enacted domestic legislation putting into effect the CBD obligations that access to a country’s genetic resources should depend on securing that country’s prior informed consent and agreeing to fair and equitable benefit sharing. WIPO members are considering whether, and to what extent, the intellectual property system should be used to support and implement these obligations. Many, but not all, WIPO members want to make it mandatory for patent applications to show the source or origin of genetic resources, as well as evidence of prior informed consent and a benefit sharing agreement. Parallel discussions are also taking place in the World Trade Organization’s Council on Trade Related Aspects of Intellectual Property (TRIPS). WIPO also deals with the intellectual property aspects of mutually agreed terms for fair and equitable benefit-sharing. It has developed, and regularly updates, an online database of relevant contractual practices, and has prepared draft guidelines on intellectual property clauses in access and benefit-sharing agreements. Traditional cultural expressions Traditional cultural expressions (folklore) are seen as integral to the cultural and social identities of indigenous and local communities, embodying know-how and skills, and transmitting core values and beliefs. Protecting folklore contributes to economic development, encourages cultural diversity and helps preserve cultural heritage. Traditional cultural expressions can sometimes be protected by existing systems, such as copyright and related rights, geographical indications, appellations of origin, trademarks and certification marks. For example, contemporary adaptations of folklore are copyrightable, while performances of traditional songs and music may come under the WIPO Performances and Phonograms Treaty. Trademarks can be used to identify authentic indigenous arts, as the Maori Arts Board in New Zealand, Te Waka Toi, has done. Some countries also have special legislation for the protection of folklore. Panama has established a registration system for traditional cultural expressions, while the Pacific Regional Framework for the Protection of Traditional Knowledge and Expressions of Culture gives “traditional owners” the right to authorize or prevent use of protected folklore and receive a share of the benefits from any commercial exploitation. Developing an international legal instrument Because the existing international intellectual property system does not fully protect traditional knowledge and traditional cultural expressions, many communities and governments have called for an international legal instrument providing sui generis protection. An international legal instrument would define what is meant by traditional knowledge and traditional cultural expressions, who the rights holders would be, how competing claims by communities would be resolved, and what rights and exceptions ought to apply. Working out the details is complex and there are divergent views on the best ways forward, including whether intellectual property-type rights are appropriate for protecting traditional forms of innovation and creativity. To take just one example, communities may wish to control all uses of their traditional cultural expressions, including works inspired by them, even if they are not direct copies. Copyright law, on the other hand, permits building on the work of others, provided there is sufficient originality. The text of the legal instrument will have to define where the line is to be drawn between legitimate borrowing and unauthorized appropriation. On genetic resources, countries agree that intellectual property protection and the conservation of biodiversity should be mutually supportive, but differ on how this should be achieved and whether any changes to current intellectual property rules are necessary. Representatives of indigenous and local communities are assisted by the WIPO Voluntary Fund to attend the WIPO talks, and their active participation will continue to be crucial for a successful outcome. WIPO members have agreed to expedite their work so as to decide in late 2012 whether to convene a diplomatic conference for final adoption of one or more international instruments.

**Re-structuring the IP framework to protect indigenous knowledge corrects historical injustices against indigenous groups, and provides key safeguards for biodiversity**

DeGeer 03 Marcia Ellen DeGeer, 2003, “Biopiracy: The Appropriation of Indigenous Peoples’ Cultural Knowledge”, [https://ipmall.law.unh.edu/sites/default/files/hosted\_resources/PLANT\_PATENT\_ARTICLES/biopiracy\_and\_indigenous\_knowledges.pdf Accessed 9/17/2021](https://ipmall.law.unh.edu/sites/default/files/hosted_resources/PLANT_PATENT_ARTICLES/biopiracy_and_indigenous_knowledges.pdf%20Accessed%209/17/2021) AX

Under the test for patent applicability are the grounds to negate corporate patents of Indigenous Peoples’ plants. Under the usefulness prong of patent law, a patent will not be issued if it is illegal or immoral.136 The Patent Trade Office has recently used the Moral Utility doctrine to exclude inventions that combined human and animal cells.137 “The courts have interpreted the utility requirement to exclude inventions deemed to be ‘injurious to the well-being, good policy, or good morals of society.’”138 Placing pressure on our governments and the international community through public awareness could persuade the courts and the TRIPS agreement to consider the validity of the Indigenous Peoples’ claims to their plants and cultural knowledge. Public awareness could expose bioprospecting for what it is, illegal and immoral appropriation. Another possible solution for protection is to redefine and broaden the intellectual property regime to include Indigenous Peoples. The newness requirement could be altered to apply retroactively. Clearer statutes could be written so that Congress’ original intentions, to exclude plants from being patented, could be factored into the non- obviousness requirement. The heightened usefulness requirement under TRIPS could acknowledge that profitability is not the only way a plant can be useful. Nation states could encourage and educate the Indigenous Peoples within their borders to assign trade secrets to their plants and cultural knowledge. Important to this potential solution is that the Indigenous Peoples are a participant in the process of redefining intellectual property laws. They need to decide how to best protect their plants and cultural knowledge. Indigenous Peoples need access to international forums so that they can help shape intellectual property laws. Indigenous Peoples have a right to self-determination but without active participation their survival is threatened. One way for Indigenous Peoples to gain the education and protections they need is through the assistance of lawyers’ pro bono work and the advocacy law schools’ legal clinics. The open market on Indigenous Peoples’ plants and cultural knowledge is exasperated by the imbalances of money and power held by governments and corporations over the Indigenous Peoples. Additionally, the dispartity of access to decision-making forums increases the Indigenous Peoples’ inability to make any, let alone informed, decisions about their plants and cultural knowledge. In order for Indigenous Peoples to self-determine their future, patent laws need to reflect their rights as inventors and not give patent rights based on a western definition of “invention” by manipulating genes. Indigenous Peoples need access to information about how to protect themselves using, for example, trade secrets and also the TRIPS agreement needs to encompass the Convention on Biological Diversity’s mandate to preserve cultural and biological diversity. Justice dictates that western countries treat Indigenous Peoples with respect; they need the support of national and international laws and equal footing at the negotiation tables. Western countries need to take the time to see and support the Indigenous Peoples’ perspective in order to preserve their existence, the world’s natural resources, and promote human rights.

## Case