#### Counterplan text: The member nations of the World Trade Organization) should implement and fund a Health Impact Fund as per the Hollis and Pogge 08 card

#### The Health Impact Fund would guarantee patent rights and increase profits, while also equalizing the cost of medicines

Hollis & Pogge ’08 - Aidan Hollis [Associate Professor of Economics, the University of Calgary] and Thomas Pogge [Leitner Professor of Philosophy and International Affairs, Yale University], “The Health Impact Fund Making New Medicines Accessible for All,” *Incentives for Global Health* (2008) AT

We propose the Health Impact Fund as the most sensible solution that comprehensively addresses the problems. Financed by governments, the HIF would offer patentees the option to forgo monopoly pricing in exchange for a reward based on the global health impact of their new medicine. By registering a patented medicine with the HIF, a company would agree to sell it globally at cost. In exchange, the company would receive, for a fixed time, payments based on the product’s assessed global health impact. The arrangement would be optional and it wouldn’t diminish patent rights.¶ The HIF has the potential to be an institution that benefits everyone: patients, rich and poor alike, along with their caregivers; pharmaceutical companies and their shareholders; and taxpayers.¶ HOW THE HEALTH IMPACT FUND WORKS FOR PATIENTS¶ The HIF increases the incentives to invest in developing medicines that have high health impact. It directs research toward the medicines that can do the most good. It can also reward the development of new products, and the discovery of new uses for existing products, which the patent system alone can’t stimulate because of inadequate protection from imitation. All patients, rich and poor, would benefit from refocusing the innovation and marketing priorities of pharmaceutical companies toward health impact.¶ Any new medicines and new uses of existing medicines registered for health impact rewards would be available everywhere at marginal cost from the start. Many patients – especially in poor countries, but increasingly in wealthy ones too – are unable to afford the best treatment because it is too expensive. Even if fully insured, patients oft en lack access to medicines because their insurer deems them too expensive to reimburse. The HIF simply and directly solves this problem for registered drugs by setting their prices at marginal cost.¶ HOW THE HEALTH IMPACT FUND WORKS FOR PHARMACEUTICAL COMPANIES¶ Most proposals for increasing access to medicines would reduce the profits of pharmaceutical companies and hence their ability to fund research. The HIF, however, leaves the existing options of pharmaceutical firms untouched. It merely gives them the opportunity to make additional profits by developing new high-impact medicines that would be unprofitable or less profitable under monopoly pricing. Selling such registered medicines at cost, firms won’t be forced to defend a policy of charging high prices to poor people and they won’t be pressured to make charitable donations. With HIF-registered medicines they can instead “do well by doing good”: bring real benefit to patients in a profitable way. Research scientists of these firms will be encouraged to focus on addressing the most important diseases, not merely those that can support high prices.¶ HOW THE HEALTH IMPACT FUND WORKS FOR TAXPAYERS¶ The HIF will be supported mainly by governments, which are supported by the taxes they collect. Taxpayers want value for their money, and the HIF provides exactly that. Because the HIF is a more efficient way of incentivizing the pharmaceutical R&D we all want, total expenditures on medicines need not increase. However, if they do, the reason is that new medicines that would not have existed without the HIF are being developed. The HIF mechanism is designed to ensure that taxpayers always obtain value for money in the sense that any product regis-tered with the HIF will have a lower cost for a given amount of health impact than products outside the HIF. Taxpayers may also benefit from a reduction in risks of pandemics and other health problems that easily cross national borders.

In the squo, pharmaceutical companies have no incentive to ensure drugs are distributed and used properly. HIF incentivizes them to ensure rational use and positive health outcomes.

Hollis & Pogge ’08 - Aidan Hollis [Associate Professor of Economics, the University of Calgary] and Thomas Pogge [Leitner Professor of Philosophy and International Affairs, Yale University], “The Health Impact Fund Making New Medicines Accessible for All,” *Incentives for Global Health* (2008

As highlighted throughout this book, one main barrier to access to available drugs is price. When manufacturers’ prices are lower, then the prices consumers are charged through both public and private distribution systems will also be lower. Affordable manufacturers’ prices are therefore crucial to improved access. But manufacturers’ prices are not the sole determinant of the cost to the consumer. Import duties, port clearage charges, inspection fees, pharmacy board fees, central and regional government taxes, storage and transportation costs, and wholesale and retail markups add substantially to the manufacturers’ price.1 These supplementary costs are not always passed on to the consumer in their entirety, since the state or the nonprofi t sector may provide subsidies to consumers. But in this case the financial burdens placed on the state or the nonprofi t sector are increased by high prices. Even where supplementary costs are only partially passed on to consumers, they can significantly aff ect the aff ordability of essential medicines. Price, while crucial, is not the only determinant of access. In many low-income countries, weak health infrastructure signifi cantly limits the extent to which essential drugs are accessible. For example, Ministries of Health are often reluctant to distribute drugs to hospitals and health clinics if they believe these facilities lack the trained and motivated medical staff or the physical assets needed to ensure that the drugs are properly stored, prescribed and dispensed.2 Alternatively, a Ministry of Health’s administrative systems may be such that it is not able to manage the efficient distribution of the drugs that are available to it, resulting in shortages, particularly in less accessible parts of the country. Weaknesses in transportation systems and drug management practices can also result in spoilage, thereby compromising the quality of available drugs.3 On the demand side, weak infrastructure oft en imposes significant costs and time burdens on poor people in need of health treatment. For example, patients may have long distances to travel, and in many countries, “informal payments” or bribes are required to obtain access to subsidized medicines (Lewis, 2007). The second main element of the last mile problem is the failure to use correctly the drugs to which patients do have access. The WHO estimates that worldwide 50 percent of all medicines are prescribed, dispensed, or sold incorrectly, and that about half of all patients do not take medicines as directed (WHO 2004b, 75). This incorrect use exacts a huge toll in increased morbidity and mortality, in addition to the toll exacted by lack of access. Estimates suggest that between 60 and 90 percent of household health expenditure in developing countries is on medicines (DFID 2006, 1). Poor prescribing and dispensing practices, and weak adherence by patients to treatment requirements, means that much of this spending brings little in the way of health benefits. It can actually be harmful, increasing the likelihood that certain diseases will develop resistance to the drugs that are used to treat them.5 These problems occur not only in developing, but also developed countries. Common types of incorrect medicine use include (WHO 2004b, 76): • use of too many types of medicines per patient (polypharmacy); • prescription of antimicrobials in inadequate dosage or for inadequate periods or the prescription of antibiotics for non-bacterial infections (the WHO estimates that around two-thirds of all antibiotics worldwide are sold without prescription); • use of injections where oral formulations would be better, increasing the transmission of hepatitis, HIV/AIDS and other blood-borne diseases; • failure to prescribe in accordance with clinical guidelines (survey data show that between 1990 and 2004 only around 40 percent of primary care level patients in Africa, Asia, and Latin America were treated in accordance with clinical guidelines for a number of common conditions, with no improvement over this period; WHO 2006c, 2); and • inappropriate self-medication, oft en of prescription-only drugs. A key cause of incorrect use is the lack of suitably qualifi ed medical personnel available to developing country health systems. Recent fi gures show that the number of health workers per 1,000 people was only 2.3 in Africa and 4.3 in South & East Asia, compared to 18.9 and 24.8 in Europe and the Americas respectively.6 Moreover, many developing-country health workers are poorly trained and paid and are not given adequate administrative support. This in turn contributes to low morale and a high incidence of absenteeism. This problem is especially acute in rural and remote areas. Health facilities that are understaffed or staffed by inadequately trained or motivated workers are very poorly placed to meet the requirements of rational drug use (Das, Hammer, and Leonard 2008). The WHO estimates that 57 countries suffer critical shortfalls of doctors, nurses, and midwives that prevent these countries from meeting even the most basic standards of health care (WHO 2006d, 5, 11–12). This human-resource crisis is complicated by the fact that in many low-income countries staff salaries take up an inordinately large share of the health budget, leaving insufficient funds for non-staff requirements such as vaccines, essential drugs, diagnostic tools and infrastructure maintenance. Public sector health payrolls are oft en poorly administered, and phenomena such as so-called ghost workers (people who are on payrolls but do not provide the relevant services) result in significant inefficiencies. Resource-constrained countries are confronted with the need to reduce the share of the wage bill in their health budgets while increasing the number and quality of health professionals, particularly in poorer areas. In many cases, greater efficiency in the use of existing resources, while necessary, will not be sufficient to remedy these problems entirely. There is no escaping the need for significantly larger amounts of resources to be made available to developing country health sectors.7 While public sector and not-for-profit private providers are key parts of the health sector in most low-income countries, the for-profit private sector— particularly in the form of private drug outlets—is often the first point of call for large parts of the populations of these countries when they fall sick. In Cambodia, for example, it is estimated that more than 70 percent of the population first approach private drug sellers when they fall sick, and that 75 percent of legal antimalarials are sold through the private sector. In Senegal, four private wholesalers linked to pharmacies and chemists represent nearly 65 percent of all sales of antimalarials (Institute of Medicine 2004, 40–41).8 Worldwide, an increasing share of health care is being delivered through the private sector (WHO 2006c, 4). Especially in low-income countries, governments often regulate private-sector drug outlets poorly. Even where suitable regulations and licensing procedures exist, the supervisory and enforcement support needed to ensure compliance is often lacking. Coupled with poor training of staff in private drug outlets, these regulatory, supervisory and enforcement shortcomings result in poor diagnosis and dispensing practices, and subsequently in the sale of unnecessary or contra-indicated drugs or incomplete courses of medication. This wastes resources, compromises successful treatment, and can lead to adverse patient reactions and the development of drug-resistant disease forms. The incentives that private sellers have to maximize sales regardless of clinical requirements add to the likelihood of incorrect use. These incentives are present not only in the private sector, but apply where the prescribing and dispensing functions are combined, as is sometimes the case in some public health facilities in low-income countries. Th is point notwithstanding, survey data available to the WHO show that, in developing and transition countries, the use of medicines is signifi - cantly worse in the private than in the public sector (WHO 2006c, 4).9 Even where drugs are correctly prescribed, they are often sold in inappropriate packaging, with inadequate instructions for patient use, or both. Th is creates serious problems when patients are illiterate or ill-informed about the implications of not taking medication as directed. Th is is particularly problematic with respect to medicines whose partial completion is oft en suffi cient to relieve symptoms. The result is a serious problem with patient adherence to the requirements of their drug treatment. Drug prices are also a factor in lack of patient adherence to treatment regimens. Poor patients may purchase insufficient amounts of the medicine, in an attempt to economize. A 2006 WHO report suggests that, unless effective action is taken, the problem of incorrect drug use is likely to get worse. This is so for two reasons. First, an increasing share of health care worldwide is being provided through the private sector. In developing countries and countries in transition to a market economy, provision through the private sector is likely to result in a higher incidence of incorrect drug use than provision through the public sector, which is important given the prominence of private drug sellers as a first point of call. Second, many large-scale initiatives to treat diseases of major public health importance, such as malaria, HIV/ AIDS, and tuberculosis, concentrate primarily on access and give insufficient attention to the problem of irrational use (WHO 2006c, 4). Irrational use also occurs in developed countries. As Avorn (2004) notes, there is a paucity of reliable clinical trials comparing the risks and benefits of different medicines, and at the same time, pharmaceutical companies’ marketing muscle sometimes leads to poor prescribing choices by clinicians. Under present arrangements, pharmaceutical companies have little incentive to do anything about the last mile problem, particularly in poor countries where this problem is most acute. Typically drug manufacturers sell their products to public health authorities or private wholesalers well removed from consumers of the product, and do so at a price designed to maximize profits.10 Nonprice factors associated with the accessibility of their product and issues relating to its correct prescription and use are matters that manufacturers have little incentive to address, for two interrelated reasons. First, these problems are complex and difficult to address in many developing countries. And, second, the financial gains pharmaceutical companies might reap from helping to resolve such problems—higher sales volumes flowing from wider accessibility and better outcomes—are, under current remuneration arrangements, uncertain and likely to be small. (In fact, correct and effective use of a medicine may reduce demand for it). It might be argued that pharmaceutical companies should not be given a role in tackling the last mile problem because they are ill-equipped to deal with it, especially with respect to issues such as systemic problems in the health systems of low-income countries. Th at pharmaceutical companies are poorly equipped to deal with such issues is true but unsurprising, given the lack of incentives that they currently have to address them. The important question is whether such companies could help solve the last mile problem if they were provided with a very different set of incentives. Rewarding pharmaceutical companies on the basis of their product’s health impact changes their relationship to the last mile problem in a fundamental way. Far from having no interest in this problem, Health Impact Fund registrants would have a strong incentive to address it, since their profi ts are based on their product’s health impact. How will companies respond to the last mile problem with respect to the drugs they have registered with the HIF? Consider first lack of access due to unaffordability. As detailed elsewhere in this book, HIF registrants will be required to sell their product worldwide within a price window ranging between the average and marginal cost of production and distribution as determined by the HIF. Furthermore, registrants will have strong incentives to try to reduce wholesale and retail mark-ups on their products, and to use their lobbying power with politicians to ensure that taxes and other government charges are kept to a minimum. It is therefore reasonable to expect that the retail prices of HIF-rewarded medicines will be within the reach of a very large proportion of those who need them. The incentives of suppliers of HIF-registered medicines are quite different from those of suppliers of patented medicines outside the HIF. HIF registered drugs sell at very low prices and are more likely to have many highly price-sensitive customers. A small addition to the retail price can deter a large number of patients at a significant cost to the registrant in terms of reduced payments from the HIF. Thus, retail mark-ups and taxes, which both increase the price to the patient, may substantially reduce the registrant’s profits. As a result, HIF registrants will be strongly motivated to lobby for reduced taxes and also to monitor and try to restrict retail mark-ups. Th ese incentives are much weaker for suppliers of patented medicines not registered with the HIF. Such medicines sell at much higher prices, where variations in mark-ups and taxes typically have smaller eff ects on the number of patients buying the product. And their suppliers will therefore not be as interested in controlling mark-ups and taxes. What about lack of access caused by nonprice factors? Take the case where a country’s health ministry is unwilling to purchase a particular drug, or willing to purchase it only in relatively small amounts, because it considers that the necessary medical and logistical support to administer the drug effectively does not exist in parts of the health system, or because the ministry’s drug distribution system is not up to the task of distributing the drug effectively. How would the HIF registrant respond? At present, developing country governments, supported by aid donors, are directing large amounts of time and money to strengthening public health systems, including procurement and distribution systems. Much of this work is being done through so-called Sector Wide Approaches (SWAps) and similar sector-focused programs, in which donors work with governments to develop a comprehensive health-sector budget, providing a framework within which government and donor funds are prioritized, disbursed, and ac counted for. If systemic shortcomings in the health sector were adversely affecting the widespread accessibility of its HIF-registered drug, a pharmaceutical company might well be prepared to provide financial and other support to a SWAp designed to address these problems, though the company would understandably be focused on issues relating to the distribution of its own product. It should be emphasized that the kind of support here envisaged would in no way represent the outsourcing of responsibility for a country’s health system to pharmaceutical companies. Clearly, governments should take primary responsibility for public health systems. But just as bilateral and multilateral aid donors can participate in SWAps without absolving home governments of their responsibilities, private companies could play a constructive supporting role as well. It might be objected that pharmaceutical companies with substantial resources at their disposal and with big financial rewards at stake might skew the implementation of a SWAp in their own favor, potentially undermining the process of priority setting which the SWAp is designed to facilitate. Such dangers would doubtless exist, but the composition of a SWAp, which normally includes a number of major donors as well as the home government, would act as a strong countervailing force. Th e involvement in a SWAp of a commercial company with a specifi c and relatively narrow area of interest might also bring significant advantages. SWAps and similar initiatives are sometimes criticized on the grounds that, insofar as they involve cooperation between a several agencies directed at the achievement of broadly-specified goals, they lack the individualized accountability needed for success. It is a short step, the argument goes, from everyone being responsible for everything to no one being responsible for anything at all (Birdsall 2007, 2; Easterly 2006, 14–15). A pharmaceutical company continually questioning how the work being undertaken through the SWAp is overcoming obstacles to the competent use of its drug—obstacles that are likely to be endemic and therefore relevant to essential medicines generally—could play a constructive role in keeping SWAp members focused on the need to undertake rigorous priority-setting for health-sector expenditure and to support this with practical, solution-oriented programs. Insofar as the HIF, by tying reward to health impact, aligns the financial interests of HIF-rewarded companies and the health interests of relevant population groups, such companies could strengthen the accountability of the health system to patients by forcefully representing their interests within SWAps and similar programs. While SWAps are designed to incorporate all major players in the health sector, they typically are more representative of the public than the private sector. Th ey rarely include private for-profi t drug retailers, for example, even though these outlets often play a major role in the distribution and sale of vital drugs in low-income countries. Manufacturers of HIF-rewarded drugs would therefore have strong incentives to ensure that private distribution systems were as effi cient as possible in getting their drugs to private outlets. In addition, the incentives that companies would have to ensure good handling, diagnostic, dispensing, and labeling practices in relation to their drugs would in turn lead them to support improved public regulatory and supervisory systems, because the alternative of developing and running alternative systems themselves, or contracting them out to private sector agencies, would not be cost-eff ective. In other words, HIF registrants would be motivated to support the development of an eff ective public regulatory system. Th e following section discusses in greater detail the incentives that drug manufacturers would have to address rational use issues. Rewarding pharmaceutical companies on the basis of the health impact of their products clearly gives these companies a pressing interest in how their drugs are actually used. In order to promote a drug’s health impact, a company will want all those who need the drug to have timely access to it in the right amounts, will want the quality of the drug to be good, and will want the drug to be used properly by patients. HIF registrants would have strong incentives to work toward achieving these conditions. Th ere are a variety of measures that are being or could be taken through the public sector to encourage rational use of essential drugs. Th ese include:11 • the establishment of a national body to develop an essential medicines use policy; • the development of a national essential medicines list; • the preparation of clinical guidelines for treatment of specific diseases; • the preparation of standard operating procedures to govern pharmaceutical management tasks relating to specific drug treatments; • the establishment of drug and therapeutics committees in hospitals and health clinics; • continuing in-service medical education; • strengthening regulation, supervision, audit and feedback mechanisms, including pharmacovigilance systems; • improving public education about medicines and their use; and • providing sufficient funds to facilitate the availability of medicines and suitably qualifi ed and motivated staff . While several countries have implemented or are implementing some of these policies, data from the period between 1999 and 2003 shows that a signifi - cant number of countries fail to make use of many of the options available to them. Of member states reporting to the WHO: less than 60% had monitored the use of medicines in the previous two years; about 50% had undertaken a public-education program on use of medicines in the previous two years; about 40% supported independent, continuing medical education for prescribers and had established a medicines information centre; 30% to 40% had drug and therapeutic committees in most hospitals and regions; in about 60% clinical guidelines had been updated in the previous fi ve years; just over 70% had a national essential medicines list but only 30% used this list for insurance reimbursement; and only 60% to 70% trained their prescribers in the essential medicines concept, pharmacotherapy, rational prescribing and the application of clinical guidelines. (WHO 2006c, 4) While these measures are of broad scope, and have impacts beyond the distribution and use of any particular drug, a HIF registrant might support one or more of them directly or use its influence to advocate for their introduction or expansion by relevant governments. We have already suggested that a strengthened regulatory and supervisory system is something that would interest an HIF registrant, and a pharmaceutical company may well be able to mobilize the resources needed to make a significant difference to the reach and performance of these systems. Registrants might also be willing and able to provide financial resources—which in other circumstances might be directed to marketing—to improve the pay and conditions of health workers in those areas of the system that suff er from acute human resource shortages, to improve pre-service or in-service training of frontline health care workers, or both, to the extent that such expenses supported the increase in the use of their products leading to higher payments from the HIF.12 Registrants might fi nd it attractive to provide funding for consumer education campaigns. It is worth considering that pharmaceutical manufacturers provide services to encourage rational use in developed countries, because the high prices they charge make it worthwhile for them to do so. Th ey have large numbers of sales representatives whose job it is to provide clinicians with relevant information on their products. They support pharmacies in providing supplementary information to patients, and they engage in very expensive patient education campaigns. To be sure, much of the current marketing to doctors and patients is designed not so much to inform as to persuade (this is especially true when competing fi rms off er similar products in a given therapeutic class). However, some current marketing is informative and valuable. Because the HIF is designed to provide large rewards only to first-in-class medicines, with small rewards for follow-on products, the extent of competitive marketing is likely to be small, but fi rms will still have incentives to engage in informative promotional activities. Promotional activities by pharmaceutical fi rms to doctors and patients have been widely criticized. Firms whose only reward is a high price, regardless of the therapeutic outcome, have an incentive to encourage as much use as possible of their product, and this had led to promotional spending that has not been useful and may even have been harmful to patients. Whether a drug is actually indicated for a patient does not affect the profit earned by a monopolist. It should be recognized that the incentives for HIF registrants will be somewhat different from those of nonregistrants in two significant ways. First, the HIF only offers high rewards per unit for products that have a high impact per unit. Thus, the motivation to increase sales will be strongest for those products which are really therapeutically important, not those with the highest price. The incentive to sell products that are less therapeutically eff ective than older alternatives will be very low, since the HIF payments for such products will also be very low. Second, the HIF will assess health impact, including how the product is used in practice. If sampling of prescribing practice—whether through private drug retailers or government clinics—shows that the drug is being sold inappropriately, the HIF will take that into account in determining the health impact of the medicine, and the assessed health impact will fall, rather than rise, because of such sales. To be sure, the HIF will not be able to measure health impact perfectly, and there will evidently be challenges as fi rms attempt to expand sales volumes inappropriately. But overall it is important to recognize that some of the less attractive outcomes of pharmaceutical promotion will be avoided for HIF-registered drugs because the reward is based on health impact, not simply on price times volume. Th ese benefits of better-aligned incentives with respect to pharmaceutical promotion apply equally to developing and developed countries.

## Indigenous Medicines PIC

In the world of the AC, pharma companies are going hunting for new medicines to remain competitive since they can no longer rely on their infinitely renewable patents – their first place to look is historically indigenous medicine

#### Indigenous people need strong intellectual property rights to traditional medicines – their unique medicinal knowledge is open to appropriation and theft from larger Western pharmaceutical companies without it – Sinela and Ramcharan ‘05

SINJELA, MPAZI, and ROBIN RAMCHARAN. “Protecting Traditional Knowledge and Traditional Medicines of Indigenous Peoples through Intellectual Property Rights: Issues, Challenges and Strategies.” International Journal on Minority and Group Rights, vol. 12, no. 1, 2005, pp. 1–24. LK

At one stage a desire began to emerge in indigenous circles for a forum in the United Nations that dealt not only with human rights issues but with the broad range of environmental, developmental and cultural issues affecting indigenous populations. This led to calls for the establishment, as a subsidiary body of the ECOSOC, of a permanent forum on indigenous issues. This forum was finally established in 2000 and met for the first time at UN headquarters in New York in the summer of 2002.9 The Permanent Forum has thus far held three sessions. As of the time of writing there is a debate going on whether the buo Commission's Working Group on Indigenous Populations should be continued in the light of the establishment of the Permanent Forum. Some governments have apparently favored the discontinuance of the Working Group while indigenous peoples favor its continuation. At the Summer Session of the ECOSOC in 2004 the Secretary General of the United Nations submitted a report summarizing the views of States and indigenous organizations on this issue, and, as of the time of writing, the issue still remains open. The study by Mr. Martinez Cobo, the Working Group on Indigenous issues, the working group on a draft declaration and the Permanent Forum have thus been the main building blocks within the United Nations in the past four decades to advance the human rights of indigenous peoples. In the course of their work, they have, inter alia, highlighted the need for the protection of the intellectual property rights of indigenous peoples. Following on from the work of Mr. Martinez Cobo, cultural heritage and intellectual property have been issues of interest to the Working Group. In 1992, the Working Group and the World Intellectual Property Organization (WIPO) held a Technical Conference on Indigenous peoples at which participants recommended that the United Nations develop more effective measures to protect the intellectual and cultural property rights of indigenous peoples.10 A 1993 report by Erica Daes, Chairperson of the Working Group, on the protection of cultural and intellectual property, noted that the term "'indigenous' embraces the notion of a distinct and separate culture and way of life, based on long-held traditions and knowledge which are connected, fundamentally, to a specific territory. Indigenous peoples cannot survive, or exercise their fundamental human rights as distinct nations, societies and peoples, without the ability to conserve, revive, develop and teach the wisdom they have inherited from their ancestors."" The Chairperson was "compelled to the conclusion" that the distinction between cultural and intellectual property, from the indigenous viewpoint, was an artificial one. Indeed, "Industrialized societies tend to distinguish between art and science, or between creative inspiration and logical analysis. Indigenous peoples regard all products of the human mind and heart as interrelated, and as flowing from the same source: the relationship between the people and their land, their kinship with other living creatures that share the land, and with the spirit world. Since the ultimate source of knowledge and creativity is the land itself, all of the art and science of a specific people are manifestations of the same underlying relationship, and can be considered as manifestations of the people as a whole."12 It is not a coincidence that Article 8(j) of the 1992 Convention on Biological Diversity (CBD) adopted at the Rio Earth Summit, creates legal obligations for States party to respect, preserve and maintain knowledge, innovations and practices of indigenous people related to the conservation and sustainable use of bio diversity. The protection of cultural and intellectual property "is connected fundamentally with the realization of the territorial rights and self determination of indigenous peoples".13 The Chairpersons' report noted that the Working Group had received news from "indigenous representatives from every continent about the priority and urgency they attach to the protection of their spiritual and cultural life, arts and scientific and medical knowledge".14Consequently, the Draft Declaration prepared by the Sub-Commission, while recognizing in its preamble the "inherent rights and characteristics of indigenous peoples, especially their rights to their lands, territories and resources," provided for the right to fully participate, inter alia, in the cultural life of the State (Article 4), the right to revitalize and practice their cultural traditions (Article 11), the right to revitalize, use, develop and transmit to future generations their language, oral traditions, writing systems and literatures (Article 13) and, more importantly for present purposes, "the right to their traditional medicines and health practices, including the right to the protection of vital medicinal plants, animals and minerals" (Article 22). In this vein, the draft Article 27 provides that "[indigenous peoples have the right to special measures to protect, as intellectual property, their sciences, technologies and cultural manifestations, including genetic resources, seeds, medicines, knowledge of the properties of fauna and flora, oral traditions, literatures, designs and visual performing arts". Moreover, Article 28 provides that States should seek the free and informed consent of indigenous peoples "prior to commencement of any projects on their lands and territories, particularly in connection with natural resource development or exploitation of mineral or other sub-surface resources".15 In December 1995, to give impetus to the Decade for Indigenous People, the UN General Assembly adopted a Program of activities aimed at strengthening international cooperation for the solution of problems faced by indigenous people in such areas as human rights, the environment, development, health, culture and education. Among the specific actions to be taken were: (i) "the promotion and protection of the rights of indigenous people and their empowerment to make choices which enable them to retain their cultural identity while participating in political, economic and social life, with full respect for their cultural values, languages, traditions and forms of social organization" and (ii) a request for specialized agencies of the UN system and other international and national agencies, as well as communities and private enterprises, "to devote special attention to development activities of benefit to indigenous peoples".16 WIPO has responded accordingly and the report by the Coordinator of the UN Decade for Indigenous Peoples has noted that WIPO's response "has been dramatic" as there is an entire division as part of the regular budget which is now responsible for traditional knowledge and related issues.17 The Permanent Forum has maintained a keen interest in traditional knowledge, soliciting information from all relevant parts of the UN system, notably WIPO.18 The last three sessions of WIPO have focused on its activities in the areas of intellectual property and genetic resources, traditional knowledge and traditional cultural expressions, and are described in greater detail below. Before proceeding to a consideration of the protection of the intellectual property rights of indigenous peoples, we shall in the next section, examine a major heritage of indigenous peoples - traditional medicine. TM, an important part of TK, refers to medicines used by local, tribal and indigenous communities. Such medicine is often herbal and sometimes combined with spiritual elements, such as those practiced by the shaman in tribal communities.19 TM has been refined over centuries of practice by communities who have inherited knowledge from their ancestors. For example, Felix, a member of the Arawak indigenous community of Guyana who works in the Shanklands resort on the banks of Essequibo River, conveyed his impressive knowledge of his community's medicinal uses of various plants and trees in the tropical rainforest. Using the native names of trees, he related the use of the 'yarula' tree for preventing and curing malaria, the use of the 'kakaballi' tree for treating diarrhea and the use of the 'capadulla' tree as a local viagra.20 While relying on textbooks for the Latin names, Felix's knowledge came from his father, the shaman in his community and from inherited knowledge among his people. Thus, often such knowledge is held communally and does not 'belong' to any single person or entity. Equally often, such knowledge cross-cuts communities as well as territorial boundaries. These aspects have implications for intellectual property protection, which we will consider below. The type of TM differs from community to community depending on the type of healing system that is historically prevalent. Until recently non-western healing systems and medicines were disregarded by western health systems, which insist on the development of medicines and healing techniques based on scientific proof and testing. Centuries-old healing systems of the world, such as Chinese traditional medicine and Indian Ayurveda, were given scant attention as the 'scientific' approach was allegedly missing. In Chinese medicine, for example, "disease is viewed as a disharmony of the various elements of the body and the personality of the patient. Chinese therapeutic thought concerns the entire organism's balance, rather than being devoted to clearly localizing and defining the nature of the illness" as in western medicine.21 The argument that non-western medicine is not based on scientific evidence may well ignore the centuries of trial and error, which has actually gone into making a particular medicine or remedy appropriate to a given community. Western science has grudgingly accepted alternative healing systems. However, they have readily sought after TK/IK, which could lead to the production of new drugs, "especially since the cost of putting new drugs on the market is becoming very high".22 Erica Daes noted in her 1993 report, cited above, that studies found that "using traditional knowledge increased the efficiency of screening plants for medical properties by more than 400 percent".23 Already by 1993, estimates of the total world sales of products derived from traditional medicines ran as high as USD 43 billion.24 However, only a tiny fraction of the profits are returned to the indigenous peoples and local communities. For example, it was estimated in the early 1990s, "that less than 0.001 per cent of profits from drugs developed from natural products and traditional knowledge accrue to the traditional people who provided technical leads for research".25 Attempts by Western governments and drug producing companies to harness such TK and TM for their own benefit have led to phenomena such as 'bio piracy' (theft of genetic resources by 'bioprospectors'). Concern has arisen for the preservation of biological diversity and genetic resources. The United States National Cancer Institute had already, by 1960, began a global program to collect and study naturally occurring substances and had tested some 35,000 plant species and a larger number of micro-organisms by 1981. This process intensified with the advent of research to combat AIDS. Pharmaceutical companies, necessarily driven by profit, have become increasingly aware of the potential economic rewards of TK/TM. Among the major US pharmaceutical companies engaged in screening plant species were Merck and Co., Smithkline Beecham, Monsanto, Sterling and Bristol Meyers. But this creates a conflict with the holders of TK/TM. The problem was stated thus by former Filipino President, Fidel Ramos at a ceremony for the signing of a Traditional and Alternative Health Care Law (R.A. 8423) in Manila on 9 December 1998: "We have looked forward to other nations for new technologies and cures, even for ordinary ailments. Indeed, many other nations have been exploiting the potentials of our own resources, claiming them as their own discoveries without giving due credit to us, and in addition to making tremendous profits at our own expense".26 The problem was recognized by Mrs. Daes in her report in 1993, namely that 'collectors' or bio-prospectors, "do not ordinarily have any formal contractual arrangements ... with the indigenous peoples upon whose knowledge of ecology they may rely. Indigenous people have also objected to alleged appropriation of their bodily substances which is taking place in the context of the Human Genome Diversity Project.28

#### CP Text: The member nations of the World Trade Organization ought to reduce intellectual property protections for medicines except for those medicines created, discovered, preserved, or primarily used by Indigenous peoples. IP rights for those medicines should be expanded in a flexible and culturally appropriate context according to principles of IP law including but not limited to repression of unfair competition, recognition of rights, equity and benefit-sharing, prior informed consent, full and effective participation of knowledge holders, and an appropriate framework for access as per the Sinjela and Ramcharan card. IP rights should never prevent Indigenous people from taking advantage of their own knowledge.

SINJELA, MPAZI, and ROBIN RAMCHARAN 05 “Protecting Traditional Knowledge and Traditional Medicines of Indigenous Peoples through Intellectual Property Rights: Issues, Challenges and Strategies.” International Journal on Minority and Group Rights, vol. 12, no. 1, 2005, pp. 1–24. // mb-va

The question is whether the existing laws, national and international, govern ing intellectual property allow for the effective protection of traditional knowl edge and folklore in particular. If the laws are not appropriate then is there a need for a sui generis system. On the latter point, a sui generis system must be in function of the needs and demands of the TK holders. As Kongolo and Shyllon note, "the fact is that knowledge that is claimed to have been 'invented' and hence 'patented' and converted into intellectual property is often an existing innovation in traditional or indigenous knowledge systems". With respect to the use of traditional medicinal plants, they posit four main issues for consideration: (1) whether the contribution of traditional knowledge to a final product is the sort of contribution that would allow one or more traditional persons to be considered joint inventor; (2) whether publication of information concerning indigenous plant use would bar the availability of a patent, (3) how to address the problems of compensation in the exploitation of herbal knowledge, and (4) whether devel oping countries should recognize through national legislation the rights of tradi tional flows from industrialized countries.61 Any system of protection must recognize the customary laws under which the knowledge evolved. In this connection, WIPO has noted, in the context of the work of the IGC, that, "the use of private property rights for TK protection should thus be carefully balanced with other policy measures to reflect the char acteristics of the protected TK, the stakeholder interests involved, the customary uses, and custodianship patterns. Most countries which have implemented TK protection have therefore supplemented a limited use of private property rights with a combination of other measures."62 Examples of sui generis initiatives include the combination of the grant of exclusive rights with access regulation in Brazil; combination of defensive protection of native insignia with repression of unfair competition in native Indian products in the United States; and combina tion of exclusive property rights, access regulation and unfair competition law to create tailored TK protection measures in Costa Rica and Portugal. "By learning from such national experiences, the combined or comprehensive approach would thus join different legal doctrines and policy tools which have been identified by Member States and have been proven effective in their jurisdictions in order to achieve an appropriate form of protection."63 Thus a 'bundle of rights and methods' may be best suited for the protection of TK. This combined approach "would result in the availability of TK protec tion through a bundle of rights at the national level, which would include the use of existing IP rights, sui generis measures, and non-IP tools, such as access reg ulation and contractual agreements". 61 T. Kongolo and F. Shyllon, 'Panorama of the Most Controversial IP Issues in Developing Countries', 6 European Intellectual Property Review, p. 260. 62 WIPO, Traditional Knowledge: Policy and Legal Options, WIPO/GRTKF/IC/6/4, 12 December 2003, para. 11. The international dimension of protection is addressed in-depth in doc ument WIPO/GRTKF/IC/6/6. Defensive protection of TK is covered only briefly, since documents WIPO/GRTKF/IC/5/6 and WIPO/GRTK.F/IC/6/8 cover this more extensively. 63 6. Key Legal Issues for the Protection of TK/TM What, then, are the core principles and legal doctrines that must underwrite the protection of TK. For this purpose we rely on WIPO studies undertaken for the IGC.64 The principles and doctrines enumerated below have emerged from exten sive discussions within the IGC on national experiences of TK protection. 6.1. Core Principles First, a comprehensive and combined approach is a starting point. It is recog nized that a comprehensive and TK specific approach must be taken using exist ing IP mechanisms, the repression of unfair competition, the grant of exclusive sui generis rights and/or the application of prior informed consent requirements linked to access regimes. It has been noted that a "bundle of rights" and meth ods might be applied for protection. Such a combined approach is not foreign to conventional IP law. For example, ornamental or visually distinctive aspects of products can be protected by a combination of copyright, individual or unfair competition law. Second, the repression of unfair competition, including appropriation and mis take of distinctive traditional characteristics. This may entail the suppression of any false, misleading or culturally offensive references to TK in the commercial arena, and any false or misleading indications or linkage with or endorsement of TK holders. Third, the principle of recognition of rights of TK holders, pertains to con ventional IP rights arising from innovation and intellectual creativity contained in TK elements, as well as to sui generis exclusive rights that may be available for TK. Aggrieved TK holders should be able to seek remedies for misuse of TK and possibly to gain remuneration and benefit-sharing. Fourth, the principle of prior informed consent (PIC) entails confirming that TK, held by a traditional community should not be accessed, recorded, used or commercialized without the prior informed consent of TK holders. Fifth, the principle of equity and benefit-sharing, entails protecting TK in a manner conducive to social and economic welfare, balancing rights and obliga tions, and the equitable sharing of benefits. "A broad principle of equity is cen tral to IP law, and is also implied in non-IP international legal instruments".65 Sixth, the principle of regulatory diversity, including sectoral distinctions, entails that a comprehensive use of TK protection "may need to reflect distinct policy objectives in specific sectors, and may need to be integrated with several regulatory systems at the national level".66 Distinct measures have been taken in some countries to regulate traditional medicine, traditional agricultural practices, TK associated with genetic resources and tradition-based industries.67 64 Ibid., para. 22. 65 Ibid. 66 Ibid., para. 23. 67 Seventh, a principle of adapting the form of protection to the nature of TK. Whatever law is adopted, that law may be shaped or guided by the particular characteristics of the TK. TK may be disclosed or undisclosed, attributable or unattributable, collectively or individually held, codified or uncodified, and may be defined and bounded by diverse forms of customary laws and protocols."68 Eighth, a principle of effective and appropriate remedies entails "making avail able effective and expeditious remedies such as injunctions and penalties, or mechanisms for payment of use fees or other compensation where there is out right prohibition on third party use".69 Ninth, a principle of safeguarding customary uses entails the encouragement of the use of TK and associated genetic resources, which "should not be restrained by the formal legal protection of TK, nor by other IP rights".70 Tenth, the principle of consistency with access and benefit-sharing frameworks for associated genetic resources entails adopting measures which regulate access to genetic resources and benefit-sharing. Legal protection of TK associated with genetic resources should be coordinated with policy frameworks for associated genetic resources, including conservation, sustainable use and benefit-sharing.71 Related principles governing procedural and consultative process might be con sidered including the principle of full and effective participation of TK holders and the principle of coordination with other relevant fora and processes.72 These principles clearly are geared towards affording maximum flexibility to TK holders, legislators and policy makers. The development of a bundle or menu of legal and policy options, "flexibility can be achieved by drawing selectively on general legal doctrines in order to tailor the form of protection to specific needs, TK subject matter and the legal systems of a given jurisdiction".73 6.2. Legal Doctrines and Policy Tools Various doctrines have been used as policy tools for TK protection in national law. Their selective use "could build a sufficiently versatile doctrinal basis for TK protection". The major doctrines are as follows. The first is the grant of exclusive property rights for TK. Such rights may be communally or collectively held. This is for TK that is distinct and has a clear owner. Existing IP rights have been used to protect TK or TK related subject matter. For example, practitioners of traditional medicine have protected their innovations by using patent rights under patent systems. An example is China, which granted 4479 patents for Traditional Chinese Medicine (TCM) in 2002.74 Where existing exclusive IP rights are deemed to be insufficient to take into 68 Ibid., para. 24. 65 Ibid., para. 25. 70 Ibid., para. 26. 71 Ibid., para. 27. 72 76id., paras. 28-30. 73 76/d., para. 31. 74 The Economist, supra note 43. 21 account the specificities of TK, sui generis rights have been called for. Difficul ties have arisen in this regard: meeting requirements of novelty or originality, and inventive step or non-obviousness; requirements in many IP laws for protected subject-matter to be fixed in material form; and the frequently informal nature of TK and the customary laws and protocols that define ownership; concern that protection systems should correspond to a positive duty to preserve and maintain TK, and not merely provide means to prevent unauthorized use; perceived tension between individualistic notions of IP rights and the sense of collective owner ship of TK; and limitations on the term of protection in IP systems (20 years in the case of patents).75 The second, is the application of the principle of prior informed consent (PIC). This enables a regulatory framework so as to control the use of TK by third par ties and ensure a flow of benefits to the knowledge holders, in ways consistent with the collective nature of TK. The third, is the compensatory liability approach, which would entitle TK holders to compensatory contributions from TK users who borrowed traditional know-how for industrial applications of their own during a specified period of time. This would ensure that TK holders gain a share of the economic and moral rewards resulting from exploitation of such knowledge and at the same time con tribute to ensuring access to such knowledge. The fourth, is repression of unfair competition. The law of unfair competition includes a wide range of remedies, including repression of misleading and decep tive trade practices, unjust enrichment, passing off, and taking of unfair com mercial advantage. The fifth, is recognition of customary laws and protocols, "which functions as a cross-cutting interface with local legal systems in all the above-mentioned tools".76 An African Model Law77 and the sui generis laws of Peru78 and the Philippines79 incorporate customary laws by reference to such laws. 7. Strategies and interim measures These then are the main legal principles and doctrines, which must be consid ered. At the national level, several steps are vital in the search for a functioning and effective TK protection system. 75 Ibid., para. 21. 76 Ibid., para. 45. 77 African Model Law for Protection of the Rights of Local Communities, Farmers and Breeders and the regulation of access to Biological Resources, 2000. 78 See 'Efforts at Protecting Traditional Knowledge: The Experience of Peru', document prepared for WIPO Roundtable on Intellectual Property and Traditional Knowledge, Geneva, 1-2 November 1999. See also WIPO, Intellectual Property Needs and Expectations of Traditional Knowledge Holders. WIPO Report on Fact-finding Missions on Intellectual Property and Traditional Knowledge (1998-1999) Report of Fact Finding missions of the WIPO, Publication No. 768. ™ Philippines Executive Order, No. 247, 1995, Section 2(a). Policy objectives have to be clearly defined for any sui generis system. In the case of TK and TM, for example, the following objectives could be considered: - to create an appropriate system for access to TK - to ensure fair and equitable benefit-sharing for TK - to promote respect, preservation, wider application and development of TK - to provide mechanisms for the enforcement of rights of TK holders; and - to improve the quality of TK-based products and remove low quality tra ditional medicine. (ii) The scope of the subject matter has to be defined and eligible for TK pro tection. The use of appropriate terms and criteria for eligibility has to be clearly spelled out. (iii) Formal requirements for acquisition of rights need to be established. For example, TK protection may be automatic (as in copyright protection which is automatic upon creation of the work) or a formal step may be required, such as registering the TK before protection becomes effective (as in the case of a trademark). (iv) Substantive criteria for eligibility must be established. For example, in Panama's sui generis law, only elements of TK that remain 'traditional', that is intrin sically linked to the community that has originated them, would be pro tected under the sui generis system.80 (v) The nature of rights in TK conferred depends on the legal doctrine or com bination of doctrines used for protection (vi) The scope of rights will determine the degree of control, which the right holder will be able to exercise. Potential rights may include prevention of unauthorized access to protected TK, unauthorized commercial use of such TK, third party claims over protected TK and so on. (vii) Determination of the custodians or beneficiaries. Does an individual or the community own the TK? Is TK understood in the national context to refer to a collective product? This may then dictate the granting of collective rights and not to individuals. On the other hand, distinctive right holders may not be necessary, as collective marks and certification marks may be protected on behalf of a group of beneficiaries. (viii) Expiration and loss of rights. The duration of rights, normally a key issue, may be problematic, as sui generis systems sometimes do not contain expiration and loss of rights provisions. Article 23 of the African Model Law states that community intellectual rights "shall at all times remain inalienable".8' (ix) Sanctions and enforcement. Appropriate mechanisms will need to be devised. Ley de Propiedad Intellectual Indigena, Ley No. 20 (26 June 2000). African Model Law, supra note 77. Defensive protection. This involves, for example, the publication of TK on a digital database, so as to record that a particular community has been using that knowledge. This may avoid the misguided grant of patents men tioned above. (xi) Linkages with benefit sharing schemes. As some TK is closely related to biological and genetic resources, such as when these resources are linked with traditional ways of life, regulation of access to biological resources may serve as a basis for protection of TK. In this regard, related conven tions such as the CBD will have to be closely studied

## Case

#### We solve better for poverty-related diseases – rather than hoping that pharma companies will innovate instead of just giving up when we get rid of patents, the neg maintains current patent-based motives for innovation while creating new ones, helping

#### Take their impacts of “contagious cancer” with many grains of salt –

1. The Tasmanian devil disease sounds like it’s just the development of external tumors, which can be solved with surgery on the off chance that this disease is ever communicated to humans – it’s QUITE a leap to assume that a disease whose defining characteristic is developing independently inside the body would suddenly become contagious – it’s an extremely high-magnitude impact for an extremely low-magnitude probability, most of the article is just assumptions
2. If these impacts are true, we solve better – any contagious disease poses more of a risk to poorer people who have no choice but to interact with the world around them – COVID proves
3. How does pharma fix superbugs???