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TRIPS, Bilateralism And Patents: How They Are Failing Both the Developed And The Developing World and What To Do About It.

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TRIPS, bilateralism and patents: how they are failing both the developed and the developing world and what to do about It



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Abstract

The vast majority of the world's biological resources and traditional knowledge is located in the developing world, yet the vast majority of the world's intellectual property over biotechnology is owned by the developed world. Since the formation of the WTO the developing world has supported the developed world's demands for stronger intellectual property protection. However, as it now seeks the support of the developed world to exploit these resources, it finds that the developed world has only responded with overtures of bilateralism. Furthermore, the expected increases in foreign direct investment have not materialised, yet have continued to flow to China, a country that is the world's largest producer of counterfeit goods. In this paper, Luigi Palombi discusses TRIPS, post-TRIPS bilateralism and patents in the context of biological resources and traditional knowledge and seeks to provide a solution to the present intellectual property deadlock between the developed and developing worlds.

Keywords

TRIPS, traditional knowledge, patents, *sui generis* and bilateralism

1. Introduction: TRIPS

Collaboration between two of the world's most significant economies, the United States (US) and the European Union (EU), towards the end of the 20th century and into the 21st century has been no closer than with respect to intellectual property. Starting with the Uruguay Round of the GATT at Punta del Este, Uruguay, in September 1986, intellectual property was prioritised by them allegedly "to ensure that measures and procedures to enforce intellectual

property rights do not themselves become barriers to legitimate trade".¹ Despite protests from Brazil, India, Argentina, Thailand and other developing countries, intellectual property, a subject that hitherto had been only considered in the context of the counterfeiting of trademarked goods² was rather suddenly broadened to include all its forms in the context of the GATT.

While the directional push for this move first came from a diffuse collaboration of developed countries, including the US, Switzerland, Japan, the EU, Finland

and Norway, “the spark which ignited the work towards the TRIPS Agreement” (GERVAIS, 2003) actually came from the EU in March 1990 in the form of the *Draft Agreement on Trade-Related Aspects of Intellectual Property Rights*. In an approach that was seemingly oblivious to the controversy raging between the countries of the North and the South over the suitability of intellectual property in trade negotiations, the EU made its decisive move unexpectedly, catching all but the US off-guard. Within two months, the US followed suit with its own Draft Agreement³ in language that was so similar, that Daniel Gervais speculated that it was the product of “transatlantic consultations” (GERVAIS, 2003). In producing what was almost a mirror image of the EU’s draft, the US and the EU orchestrated events not only so as to enable them to take control of the agenda, the debate, and the drafting of what ultimately became known as the *Agreement on Trade Related Aspects of Intellectual Property* or TRIPS⁴ but persuaded both developed⁵ and a significant number of developing countries,⁶ many of which had only five years earlier vigorously resisted even the idea of incorporating intellectual property into multilateral trade negotiations, to sign TRIPS on April 15, 1994. On January 1, 1995, TRIPS as one of the key agreements of the World Trade Organisation (WTO), an international organisation that today has one hundred and fifty members, came into force.

Why the US and the EU were so persuasive in such a short space of time has puzzled many observers particularly, as Peter Drahos noted, that “in immediate trade terms the globalisation of intellectual property really only benefited the US and to a lesser extent the European Community” (DRAHOS, 2003). Even so since its inauguration, WTO membership has not only grown significantly,⁷ but today includes China, which according to the latest World Intellectual Property Organisation (WIPO) statistics has dislodged Switzerland to become the eighth largest international patent filing country with an increase of fifty-seven percent in Patent Cooperation Treaty (PCT) filings between 2005 and 2006 (WIPO, 2007). In fact, according to the WIPO, international patent applications from developing countries⁸ have, during the same period, increased by nearly twenty eight percent.

What these WIPO statistics suggest is that the WTO (i.e., GATT + TRIPS) has been effective in promoting the mutual recognition, protection and enforcement of intellectual property in both developed and developing countries, and importantly, in encouraging developing countries to establish their own capacity for the creation of indigenous intellectual property, particularly in the form of patents. This growth in international patent filings has prompted Dr. Francis Gurry, the Deputy Director General of WIPO to announce that “new centres of innovation, in particular in northeast Asia, are emerging and this is transforming both the geography of the patent system and future global economic growth”.

2. Post-TRIPS Bilateralism

In view of the growth in international patent filings by developing countries since the formation of the WTO and the multilateral trade dispute resolution forum which it provides, one would have thought that bilateralism, a strategy which the US successfully employed to pressure developing countries like Brazil and India to comply with US demands on intellectual property before TRIPS,⁹ would have been eradicated, but instead, not only has bilateralism continued to grow but it has steadily expanded.¹⁰ Since 2000, the US has concluded bilateral Free Trade Agreements (FTAs) with Jordan, Chile, Singapore, Australia, Bahrain, Morocco, El Salvador, Nicaragua, Honduras, Oman and Korea. The EU has also concluded or indicated interest in commencing negotiations for bilateral FTAs with ASEAN, Guatemala, El Salvador, Honduras, Nicaragua, Costa Rica, Panama, India, Korea, Argentina, Brazil, Paraguay, Uruguay and, Australia, Canada, Japan and New Zealand have each entered into their own FTAs with other countries.

The obvious question is: why? The answer: in part, strengthening intellectual property laws and regulatory mechanisms favour the pharmaceutical and biotechnology industries (CORREA, 2006). As Carlos Correa explains,

“These new free trade agreements, negotiated outside the World Trade Organisation, require even higher levels of intellectual property protection for medicines than those mandated by the TRIPS Agreement, and in some cases go beyond what is required in the developing countries that are promoting them.” (CORREA, 2006)

While this ratcheting-up of intellectual property protection may go some way towards explaining the continuing pursuit of bilateralism by developed countries in a post-TRIPS world, especially by those that have significant pharmaceutical and biotechnological industries such as the US and the EU, for the developing countries it does not, especially when as Correa points out, the stronger intellectual property protection mechanisms required by these bilateral agreements “reduce access to medicines” (CORREA, 2006) and are subject to “the adverse opinion of their public health authorities” (CORREA, 2006).

It is a paradox that despite these disadvantages, the developing world is playing along with the developed world’s bilateral agenda, and the WIPO patent statistics seem to bear this out. Clearly, this paradox has an explanation because the developing world is not irrational nor unconcerned by the impact that stronger intellectual property protections impose on the health of their peoples. If one seeks an answer it would appear that it lies in their expectation, encouraged by developed countries, that in the long term their acquiescence to their demands on intellectual property will accelerate the transformation of their economies from developing to developed by attracting foreign direct investment (FDI) and that this transformation

will not only bring higher standards of living, but also will encourage industrial development. In essence, they accept the position that the immediate pain imposed on their people in terms of the reduction to access to medicines will be transitory as eventually FDI will increase their capacity to provide medicines through their own pharmaceutical and biotechnology industries.¹¹

However, while this sounds feasible not everyone accepts that the increased FDI will be the economic panacea that the developing world expects (HALLWARD-DRIMEIER, 2003). In fact, some argue that even though FDI may very well increase, the quality of this investment, in concert with the constraints imposed upon them through bilateral agreements, may be actually retarding¹² rather than contributing to, their economic development.

As Robert Wade points out,

“The rules being written into multilateral and bilateral agreements actively prevent developing countries from pursuing the kinds of industrial and technology policies adopted by the newly developed countries of East Asia, and by the older developed countries when they were developing.”¹³

The dysfunction described by Wade is apparent when comparing the inflow of FDI with the outflow of royalties¹⁴ (FINK *et al*, 2005) and other costs, in the form of higher prices for commodities such as medicines,¹⁵ caused by the application of intellectual property mechanisms that are consistent with TRIPS and the post-TRIPS bilateral FTAs. While some argue that the increase in the costs of medicines in developing countries will provide positive benefits by encouraging research into treatments for common diseases that are endemic in developing countries, such as malaria or tuberculosis, others point out that this will be of little consolation to the poor who will be unable to afford the price of these new treatments and medicines. What this debate implies is that the strengthening of intellectual property laws by developing countries does not necessarily result in improvements to access to affordable treatments or medicines for their peoples and that as Ganslandt, Maskus and Wong on behalf of the World Bank explain “these problems point squarely to the need for further public involvement in encouraging new drugs and in procuring and distributing medicines” (FINK *et al*, 2005). By this they mean a publicly funded scheme subsidised by developed countries that provides pharmaceutical companies with “a long-term guarantee for new innovations” (FINK *et al*, 2005) to encourage them in the development, production and supply of medicines to designated developing countries at affordable prices “but with tight controls to prevent the low-cost drugs from escaping those areas” (FINK *et al*, 2005). Whether this proposal is viable is not something that this paper is able to assess, but the fact that it has been mooted indicates that the authors believe that even if FDI does increase in developing countries commensurate with their implementation of stronger

intellectual property laws, there is no guarantee that this will lead pharmaceutical and biotechnology companies to undertake research and development that will produce the treatments and medicines necessary to alleviate illness and disease in the developing world. In their words, “the prevailing system of [intellectual property rights] fail to provide sufficient incentives to develop new treatments and distribute them at low cost” (FINK *et al*, 2005).

Beyond this, however, what TRIPS and post-TRIPS bilateralism have imposed upon developing countries, as Wade points out, are international regimes that effectively deprive them of their ability to tailor and implement policies concerning the recognition and enforcement of intellectual property. Critically, these imposts have failed to meet the unique set of economic circumstances which they must address, not only to achieve the economic transformation of a developed country, but to achieve it in a way that also meets the social, ethical and moral needs of their peoples. What is particularly inequitable about both TRIPS and post-TRIPS bilateralism is the lack of reciprocal obligations placed upon the developed world, the owners of the vast majority of the world’s intellectual property, to provide the developing world with specific, tangible and enforceable benefits that they can rely upon on their way to economic equality with the developed world. Specifically, the benefits referred to in this context are those that go beyond the kinds of benefits that would flow from the general reductions of tariffs, customs duties, import quotas for agricultural goods and agricultural subsidisation which was the objective of the GATT. So it would seem, that in return for GATT + TRIPS, the developed world not only established an international floor for the mutual recognition and enforcement of intellectual property, but did so without being required to extend tangible trading and economic benefits to the developing world beyond what was already contemplated by the GATT. Unfortunately, post-TRIPS bilateralism has only aggravated this disparity. The assumption which the developed world has always made in the pursuit of TRIPS and post-TRIPS bilateralism is that the stronger the intellectual property protections provided by the developing world the more likely that FDI would flow commensurately in their direction.

The problem with this assumption, as Mary Hallward-Driemeier has explained, is that there is scant evidence to support it (HALLWARD-DRIEMEIER, 2003). To the contrary, the Chinese experience shows that FDI flows are not dependant upon TRIPS nor post-TRIPS bilateral FTAs. Even before it became a member of the WTO in December 2001, China received significant inflows of FDI and by 2000 was the leading developing country and the second (to the US) among the APEU countries in its stock of FDI of around USD 300 billion (GRAHAM *et al*, 2001). These inflows occurred despite the fact that China had a poor reputation for the enforcement of intellectual property

rights prior to its accession to the WTO, but even since its accession, according to the United States Trade Representative (USTR), “addressing weak IPR protection and enforcement in China continues to be one of the Administration’s top priorities” (USTR, 2005) and in its 2005 ‘Special 301 Report’ explained that the US was “critical [of China] in light of the rampant counterfeit and piracy problems that plague China’s domestic market and the fact that China has become a leading exporter of counterfeit and pirated goods to the world” (USTR, 2005). As a result China was the subject of a separate assessment by the USTR which, in its report, stated:

“Overall piracy rates in China have not declined significantly since WTO accession, and in some sectors have increased from already extremely high levels. OCR submissions report estimated U.S. losses due to piracy of copyrighted materials alone ranging between \$2.5 billion and \$3.8 billion annually”. (USTR, 2005)

Despite the USTR dire warnings and condemnations, according to China’s Ministry of Commerce, in the first six months of 2004 FDI increased by twelve percent to USD 34 billion and in June 2004, General Motors confirmed that it would invest USD 3 billion in order to double its production capacity by 2007 and Volkswagen AG announced that it would invest nearly USD 1 billion on two new engine plants and one car factory (CHINA DELAY, 2004).

So if the assumption of increased FDI flows, which the developing world has been encouraged to expect as the return for imposing on themselves and their peoples more stringent intellectual property requirements, is either false or overrated, how then are the developing countries going to transform themselves into developed countries?

One option is to ignore the proposed fallacy of this assumption and fully embrace the intellectual property agenda put in place with TRIPS and accelerated with post-TRIPS bilateralism. It would seem that the latest WTO patent filing statistics confirm that this is indeed what the developing world has done. Certainly, a twenty-seven percent increase in international patent filings between 2005 and 2006 from the top seven developing countries (in patent filings) seems to support WIPO’s claim that the post-TRIPS intellectual property regimes are indeed “transforming both the geography of the patent system and future global economic growth.” So if a measure of development and increased economic growth is the number of international patent applications filed then there is some room for optimism and the statistics from China and Korea are positive in this regard. The problem however, is that if China and Korea are taken out of the equation, quite a different picture emerges. Rather than a growth of twenty seven percent, there is a regression of six percent.

World economic growth in terms of developing countries is therefore skewed towards North East Asia,

which in terms of China can be attributed to a significant degree by the exceptionally high levels of FDI that it has received whilst being the world’s largest producer of counterfeit goods, and in the case of Korea, can be attributed to increasing levels of FDI after 1997, its geographical and economic proximity to China, and the export of its semiconductors to the US (MIN, 2006). The fact that for the past ten years both the Chinese economy has grown at exceptional levels and the US demand for semiconductors has been strong, provide more credible explanations for the economic growth enjoyed by Korea and its recovery from the Asian economic crisis of 1997 than the post-TRIPS intellectual property regimes.

What then for the rest of the developing world, the other 104 countries of the 136 countries that have signed the PCT? This is a significant issue and one that cannot be masked by the hyperbole about the contribution that strong intellectual property laws make to their economic development as is so often effused by the agencies of the developed world, such as WIPO, the European Patent Office (EPO), the United States Patent and Trademark Office (USPTO) and the Japanese Patent Office (JPO). This is especially true if one accepts that the options for economic development for the developing world have been restricted, not enhanced, by TRIPS¹⁶ and post-TRIPS bilateralism.¹⁷

3. The Patent Debate Over Biological Resources and Traditional Knowledge: Developed v Developing Countries

Interestingly, despite attempts by Brazil, India, Pakistan, Peru, Thailand and Tanzania to use the multilateral forum of the WTO to achieve international recognition of the role which their vast natural biological resources and traditional knowledge play in the research and development of new treatments and medicines, they have been spectacularly unsuccessful. Taking their lead from the example set by both the US and the EU back in 1990, these developing countries have been trying throughout the Doha Round of the WTO to effect an amendment to TRIPS that would provide that “where the subject matter of a patent application concerns, is derived from or developed with biological resources and/or associated traditional knowledge, Members shall require applicants to disclose the country providing the resources and/or associated traditional knowledge”¹⁸ The difference between the two situations is that unlike the US and the EU which had the support of the developed world in 1990, Brazil, India, Pakistan, Peru, Thailand and Tanzania, do not in 2006. In a classic case of one law for the developed and one for the developing countries, the developed countries have hindered debate in the WTO and tried to break the resolve of developing countries by using bilateralism as a lever.¹⁹

The US, EU, Japan and most of the developed world have not, however, expressed outright opposition to

the idea, but to the process towards achieving consensus. Their position has been firm; first there needs to be principles and objectives established that will lead to legally precise definitions of ownership in terms of biological resources and traditional knowledge (NEW, 2006). Of course, there is more to the argument than that. The essential cause for the schism between the North and South over the issue of biological resources and traditional knowledge is whether the patent system is the appropriate vehicle to drive the discussion forward. The developing countries are relying on the patent system upon which to base their claim to intellectual property protection to these resources. The developed countries, on the other hand, believe that “new patent disclosure requirements are not an appropriate solution to meet the concerns raised” (WTO, 2006) and that with regard to the possible misappropriation of these resources that “a more appropriate solution ... would be to strengthen national regimes outside the patent systems” (WTO, 2006). According to the developed world, while leaving the patent system untouched, the developing world should use fragmented ad hoc legislative and regulatory controls to strengthen access to and exploitation of their vast biological resources. The idea is that through these controls the developing world will be better able to negotiate the terms upon which the developed world’s pharmaceutical and biotechnology industries can exploit the rainforests as they seek to identify pharmacologically useful, but naturally occurring, biological materials.

The underlying concern for developed countries is the impact which amending the patent system would have on their pharmaceutical and biotechnology companies, many of which have secured patents on compounds derived from naturally occurring biological materials. Nowhere is this concern more evident than in the US, which readily issues patents over isolated biological materials that are otherwise identical to naturally occurring biological materials. The issues of what is the ‘invention’ and what led to the ‘invention’ do not, in conventional US patent law jurisprudence, extend to those that pointed the way, and for the US, there is no good commercial reason to go down that path. In fact, the idea of sharing a portion of the billions of dollars in revenue generated from medicines developed from natural biological resources with the country of origin of that material, or with the traditional owners of the knowledge that led to the ‘discovery’ of the pharmacological substances, is an anathema.

The US strongly maintains that the work that leads to ‘invention’ for the purposes of securing a patent cannot include the mere fact that the biological materials from which the relevant compound was isolated or derived from, originated in a developing country or that it was made possible by the traditional knowledge of the local indigenous peoples (WTO, 2006). Consistent with US patent law jurisprudence, there is a significant distinction between the *in situ* natural compound and the ‘invention’ of a medicine or

treatment derived from that compound and the US has explained that this distinction “overlooks the real and often costly efforts undertaken to develop a biological resource into a commercially successful product, and the risks involved in undertaking such research and development” (WTO, 2006).

4. Resolving The Patenting Deadlock

The developed and developing countries are deadlocked.²⁰ Unless this is resolved the WTO, as a forum, will have failed the developing world which on the one hand, has accepted the demands of developed countries for stronger intellectual property protections and on the other hand, is seeking the cooperation of the developed countries in order to use the very same intellectual property protections to legitimately exploit their valuable and vast biological and traditional knowledge resources. The problem is that while both sides are right, they are both wrong! In terms of arriving at an alternative proposal that will be mutually acceptable, the assumptions which both make about the patent system and its suitability in providing the protections for the intellectual property of pharmacologically useful, but naturally occurring biological materials, need to be tested. Indeed, while the developed world is right to point out that significant research is needed to transform a naturally occurring biological material into an efficacious treatment or medicine, often the starting point of that research is not something that is ‘invented’, but rather, is merely an isolate derived from a naturally occurring biological material. The developed world uses this distinction as a sword against the developing world.

The starting point for this exercise goes back to 1988 when questions were being raised about the patentability of isolated biological materials as products. At that time, the USPTO, EPO and JPO issued a joint communiqué which stated in absolute terms that isolated biological materials are not excluded from patentability because they are not products of nature but are ‘inventions’.²¹ Eventually, in 2000 the EU passed the Biotechnology Directive to make this clear in terms of European patent law²² and, of course, earlier in 1980 the US Supreme Court case of *Diamond v Chakrabarty*²³ was credited with giving the biotechnology industry *carte blanche* to patent anything made under the sun made by man and that included living, but genetically modified, organisms.

The underlying proposition that isolated biological materials are patentable subject matter has however not been adequately answered and there is some very real concern over whether they are indeed ‘inventions’.²⁴ In this regard, it must be noted that in *Kirin-Amgen, Inc v Hoechst Marion Roussel Ltd* the English House of Lords held that patent claims to the human hormone, erythropoietin, even in an isolated form and produced by a technical means, were not valid because the hormone, even in an isolated and purified form, was not new. More recently, the US Supreme Court has

questioned just how far patent law can legitimately encroach into the realms of what should be in the public domain. In *Laboratory Corporation v Metabolite Laboratories*,²⁵ Justice Breyer explained that the principle of law that excludes natural phenomena from patentability “finds its roots in both English and American law” and that “the reason for the exclusion is that sometimes *too much* patent protection can impede rather than ‘promote the Progress of Science’ ... [his emphasis] because patents “can discourage research by impeding the free exchange of information, for example by forcing researchers to avoid the use of potentially patented ideas, by leading them to conduct costly and time consuming searches of existing or pending patents, by requiring complex licensing arrangements, and by raising the costs of using the patented information, sometimes prohibitively so.”

The nub of the problem in terms of patent law is the simple fact that much of the commercial value of the intellectual property resides in the production of isolated biological materials that merely replicate the function or performance of those found in nature. It is the *in vivo* identity that is valuable but it is this which cuts across the prohibition against the patenting of “laws of nature, physical phenomena, and abstract ideas”²⁶ which is implicit in patent law. This point however, has not been accepted by the pharmaceutical and biotechnology industries, particularly in the US, EU and Japan. Rather, for the sake of commercial expediency and in order to keep their patents protected, they have carefully avoided raising this point before the courts. Consequently, for them the Holy Grail lies in securing patent protection over the isolated products derived from natural biological materials. Of course the developing world wants a slice of the action.

The problem, as Stephen Crespi has explained, is that “the word ‘invented’ sounds strained when applied to something already existing” (CRESPI, 1995). Of course he is right, because it is impossible to invent something that already exists, even if its existence is unknown. To suggest, as he does, that “the word ‘discovered’ ... glosses over the painstaking work that has to be done by the scientist before he can see the pure substance in the test tube” (CRESPI, 1995), and that therefore ‘isolation’ is a legitimate device to transform a product of nature (i.e., a ‘discovery’) into a product of man (i.e., something capable of being an ‘invention’) ignores the fact that the threshold for ‘invention’ under the patent system is not “painstaking work”, but ‘invention’ itself. If it were not the case, then literally anything “made by man” could be considered to be an ‘invention’, and that, as the US Supreme Court in *Diamond v Chakrabarty* made absolutely clear, is not enough. While acknowledging the broad Congressional intent to allow patenting across a range of technologies, in its adoption of the words “anything under the sun made by man”, the US Supreme Court did not mean that trifling, routine or even painstaking work would give man the right to claim a living organism as his own. Rather, it required

that that the work leading to its creation not only be substantial²⁷ but that the organism itself display characteristics not found in nature.²⁸

As is often the case, most product patents over isolated biological materials claim ownership to biological materials that are so substantially identical to naturally occurring biological materials that they are genetically, biologically and efficaciously the same and, like it or not, the ‘painstaking work’ involved in their identification and isolation does not make them eligible for patent protection. Unfortunately, this does not address the fact that the ability to mass produce isolated biological materials is commercially, medically and scientifically advantageous and that the isolation of biological materials has greatly contributed to the betterment of human health throughout the world and that this work is painstaking, expensive, risky and time consuming.

In these circumstances is it not only fair, but appropriate, that the work that has facilitated the isolation of biological materials, including their identification, be rewarded? This is the point which Stephen Crespi, the pharmaceutical and biotechnology industries and the developed world have made time and time again. Their failing, however, has been to stubbornly rely upon the ‘international’ patent system, rather than to advocate for a *sui generis* intellectual property right. What they have failed to accept is that the patent system has its limits – that the road map is outdated. Unfortunately, in hitching itself to the developed world’s wagon train, the developing world is making the same journey using the same outdated road map, while all the time having to endure the developed world’s attempts at kicking the coupling off on the developing world’s wagon. The irony is that while they fight and argue they are on the same road which is about to fall off the map.

If both the developed and developing world believe that it is appropriate to encourage research into new treatments and medicines, and that in all probability, these are going to be sourced from the vast and diverse biological resources of the rainforests of the developing world, is not the solution to be found in the creation of a *sui generis* intellectual property system that is tailored made to meet this objective? This paper argues that it is and proposes the creation of the Genetic Sequence Right (GSR) as a *sui generis* system of intellectual property.

5. The Genetic Sequence Right: A *sui generis* intellectual property right

Under this proposal the GSR would be administered using the existing administrative system utilised by the present ‘international’ patent system so as to minimise establishment costs and to facilitate its adoption. A GSR would be granted to the first person to file and disclose a genetic sequence defining biological material of any origin and explaining its function and utility. A GSR would be the subject of a

written application filed in the patent office of the country of application, similar to a PCT application for a patent. The GSR would become part of an international electronic database which would be freely accessible by any person.

Importantly, if the GSR were to be identified through the provision of traditional, tribal or indigenous knowledge or information a portion of the GSR fee due to the GSR holder would be paid to the persons who are the owners of that knowledge or information. Their entitlement would be commensurate with the contribution made in the identification of the GSR and would be determined by the central administrative authority, which would also oversee the distribution of the GSR fee revenue to the relevant countries and indigenous peoples. This would clearly provide economic benefit not only to developing countries but also their indigenous peoples.

Upon registration the GSR holder would have the right to a *GSR use fee* (GSR fee). The GSR fee would vary depending on the nature of the use. For publicly funded institutions such as universities, experimental use would not attract a GSR fee, but for commercial entities, the GSR fee would apply commensurately with the nature of the use. For example there could be a scale for commercial entities starting at experimental use and moving through to full commercialisation. It is envisaged that there would be a multitude of variations in between. The amount of the GSR fee would be set by a published scale determined by a centralised world body responsible for the global administration of the GSR, for example, WIPO. This body would collect and distribute the GSR fee revenue and could earn revenue by the collection of application and annual administrations fees, as well as by retaining a small percentage of the GSR fee revenue collected. Specific allowance could also be made for GSR holders to seek GSR fees above the published scale if the GSR holder could establish that due to factors relating to the nature of the GSR or unforeseeable events (e.g., war), the total amount of GSR fees would be insufficient to recoup a fair return on the investment in the research and development leading to the GSR.

GSR users would be required to register their use with the local administrative authority and that use would be registered on the GSR electronic database. This would provide a public record of use.

The life of the GSR would be ten years from the date of registration. Infringement of GSRs could be dealt with through the relevant national courts. The holder would accordingly have the right to seek injunctions, declarations, or damages. Criminal provisions would also make it an offence for breaches of the GSR holder's rights.

The GSR would thereby provide a system by which the developing countries, that are the source of biological materials, as well as investors in genetic research could be remunerated without the GSR holders having the power to control the uses to which that GSR may be put. The GSR would thereby facilitate the publication

of genetic sequence information and encourage the use of genetic sequence information, the production of corresponding biological materials and their use in the development of new treatments and medicines. However, by removing the element of absolute control, the GSR would prevent GSR holders from controlling further down-stream research or other uses.²⁹ This is an important feature of the GSR for developing countries and their access to affordable medicines, because while they would be receiving GSR revenues from the exploitation of their biological resources by the developed world, they would be free to use those very same biological materials to conduct research and development so as to develop and produce their own treatments and medicines. They therefore would not need to rely on pharmaceutical and biotechnology industries of the developed world for treatments and medicines, but could develop their own. This is a significant advantage over the present patent system which deprives them of that ability by vesting absolute control over the isolated biological material to patent owners, which more than likely will be from the developed world.

The GSR holder would not need to satisfy any 'invention' or 'inventive step' criteria. Novelty of the genetic sequence could be established by a search of the GSR database or other genetic sequence databases. Novelty of the GSR could also be established by function and utility, so that even if the genetic sequence is already known or the subject of an existing GSR, establishing a novel function and utility not previously known could give rise to a new GSR. However, broad GSR description regarding function and utility would not be permitted unless substantiated throughout the breadth of the description. The GSR would therefore incorporate a description of the function and utility of the GSR.

The GSR would also address the many concerns that surrounding experimental use. One issue that is problematic with experimental use exemptions for patent infringement in the context of biotechnology, is that many patents have been granted over 'research tools' that are useful in the search for new drugs. In the context of each of these applications, the patented biological materials have been used by research institutions, such as universities, and the issue that has arisen is whether such use is or should be exempted from patent infringement.

Under the GSR, use by a teaching or research institution would be zero rated for GSR fee purposes. However, a commercial entity's use of a GSR, either directly or indirectly through a university, would attract a GSR fee commensurate with such use. The obligation to pay the GSR fee would remain with the commercial entity. Therefore, if any commercial entity entered an agreement with a university to conduct research on its behalf or as part of a joint enterprise or collaboration, the obligation to pay the GSR fee would continue. This would remove the debate about when, and if, universities that are conducting commercially funded research should be the subject of an experimental use exemption.³⁰

The GSR proposal recognises that the use of genetic sequences or biological materials (that are identical to naturally occurring sequences and materials) for whatever purpose should not be controlled nor come under the ownership and control of any one organisation or person. Its purpose is to encourage third party use. It recognises that irrespective of whether a genetic sequence is an 'invention' or not, the elucidation of a genetic sequence and the identification of its function is important work that should be encouraged. It therefore enables universities to fund their research projects by becoming GSR holders without incurring any obligation to pay GSR fees. It provides a system to record GSR's and assess the uses to which they are put. The fact that universities are in the business of education or, that today, see themselves as part of a broader commercial world becomes irrelevant.

Unlike the patent system which creates property in the patented invention and gives the patent owner the right to deal with that property as he or she sees fit, the GSR does not. Rather the GSR holder is recognised as being the first to enable the publication of new biological materials and their function and accordingly the *quid pro quo* for its disclosure is the entitlement to receive a GSR fee revenue. Accordingly, the more use of that GSR the greater the potential GSR fee revenue; whereas with the patent system, the price of the patented invention can be subject to manipulation through the patentee's ability to control third party use. It is this ability to control and restrict use that provides the rationale for the experimental use exemption in an attempt to balance the needs of the patentee with the needs of society. However, with the GSR there is no further balancing or fine tuning required because the whole system is designed to encourage both commercial and non-commercial use equally.

6. Conclusion

The GATT, a product of the Bretton Woods Agreements of 1944, was the culmination of the work of Cordell Hull.¹ Hull believed that "unhindered trade dovetailed peace" (HULL, 1981) and much of the free trade rhetoric that has effused from the USTR since he wrote these words in 1948 has concurred with it. However, for the developing world, which since World War II has sought independence, development and a legitimate share of the developed world's wealth for itself and its peoples, they must surely sound hollow. Hull blamed bilateralism, and the "high tariffs, trade barriers and unfair economic competition" (HULL, 1981) which it produced, for much of the world's economic problems.

This paper has argued that the WTO, the child of GATT + TRIPS, has done little to bridge the gap between the developed and developing world, but rather has provided a one sided distortion to the objectives of the GATT by incorporating intellectual property into the world free trade equation. Having done so, and

with the support of the developing world, the developed world has abandoned the multilateral forum in favour of bilateralism. In doing so, it has been motivated by its need to protect, even more than already provided by TRIPS, intellectual property.

The developing world now seeks to create its own form of intellectual property based upon the value of its own biological resources and the cumulative traditional knowledge of its peoples. It is only fair that the developed world not only aid them in this ambition, but essential that they make it happen so that "the living standards of all countries might rise" (HULL, 1981).

The GSR proposal is merely an attempt to resolve one of the issues that have deadlocked the developed and developing worlds during the Doha Round of the WTO and it is hoped that it may lead to some fruitful discussion.

Notes

1 Text from the GATT Ministerial Conference list of subjects for negotiations dated September 20, 1986.

2 The subject of the counterfeiting of trademarked goods was first raised during the Tokyo Round of the GATT held between 1973 and 1979. This led to the circulation of a draft *Agreement on Measures to Discourage the Importation of Counterfeit Goods* between 1979 and 1984. This draft in turn led to the formation of *The Group of Experts on Trade in Counterfeit Goods* which met between September and October 1985. In fact, even at the commencement of the Uruguay Round in September 1986 the focus remained on counterfeit goods as the name of the negotiating group led by Sweden's Ambassador, Lars Anell, suggests. It was called the *Negotiating Group on Trade-Related Aspects of Intellectual Property Rights, Including Trade in Counterfeit Goods*.

3 The US Draft of the *Agreement on Trade-Related Aspects of Intellectual Property Rights* was proposed in May 1990.

4 Gervais explains that "this 'common' structure was eventually adopted and, subject to a few changes, would serve as the basis for the emerging Agreement." Ibid.

5 Australia, Austria, Belgium, Canada, Czech Republic, Denmark, FYROM, France, Germany, Greece, Hong Kong, Hungary, Iceland, Ireland, Italy, Japan, Korea, Luxembourg, Malaysia, Malta, Netherlands, New Zealand, Norway, Portugal, Romania, Singapore, Slovak Republic, Spain, Sweden, United Kingdom and the United States. The European Community is a separate member.

6 Argentina, Bahrain, Bangladesh, Barbados, Belize, Brazil, Brunei Darussalam, Chile, Costa Rica, Côte d'Ivoire, Dominica, Gabon, Ghana, Grenada, Guyana, Honduras, India, Indonesia, Kenya, Kuwait, Macao, Mauritius, Mexico, Morocco, Myanmar, Nigeria, Pakistan, Paraguay, Peru, Philippines, Saint Lucia, Saint Vincent & the Grenadines, Senegal, South Africa, Sri

Lanka, Suriname, Swaziland, Tanzania, Thailand, Uganda, Uruguay, Venezuela and Zambia.

7 From 77 members at January 1, 1995 to 150 members on January 11, 2007.

8 Ibid. These countries include Korea (5,935 PCT applications); China (3,910); India (627); Singapore (402), South Africa (349); Brazil (265) and Mexico (150).

9 “Each bilateral brought that country much closer to [the] TRIPS agreement, so accepting TRIPS was no big deal”. A US trade negotiator quoted by P. Drahos, *op cit* fn 11, p 105.

10 “During 2006, more than 100 developing countries were engaged in over 67 bilateral or regional trade negotiations, and signed over 60 bilateral investment treaties. More than 250 regional and bilateral trade agreements now govern more than 30 per cent of world trade, whilst an average of two bilateral investment treaties have been agreed every week over the last ten years.” Oxfam Briefing Paper, *Signing Away The Future*, March 2007, p 5.

11 “It has been the case so far that most R&D activities that Indian firms engage in are minor modifications of pharmaceutical products developed in foreign (mainly western) countries, and that very little R&D effort has been devoted towards the development of any new drugs. However, this situation is likely to change soon with the emergence of major Indian R&D companies such as Ranbaxy and Dr Reddy’s Laboratories.” Shamnad Basheer, *Limiting The Patentability of Pharmaceuticals Inventions and Micro-Organisms: A TRIPS Compatibility Review*, November 2005.

12 “TRIPS raises the price of patentable knowledge to consumers and so raises the flow of rents from South to North. According to World Bank estimates, US companies would pocket an additional net \$19 billion a year in royalties from full application of TRIPS. They own many patents in many countries required to tighten intellectual property protection, while TRIPS does not require tightening of US patent law.” Robert H Wade, *What Strategies Are Viable For Developing Countries Today? The WTO and the Shrinking of ‘Development Space’*, *Review of International Political Economy*, 10:4 November 2003: pp 621 – 644 at p 624.

13 Ibid, p 622. For an excellent and detailed history of how the United States established its chemical and pharmaceutical industries in 1919 by confiscating 5,000 patents from Germany see Kathryn Steen, *Patents, Patriotism, and “Skilled in the Art”*, *The History of Science Society*, 2001, 92:91-121.

14 Carsten Fink and Keith Maskus (Ed), *Intellectual Property And Development*, World Bank and Oxford University Press, 2005 particularly Keith Maskus, Chapter 3 pp 41–73 at p 44 Table 3.1 and p 46 Table 3.2.

15 “In economic terms, under the current system, the

incentives to achieve efficient dynamic and static provision of medicines are grossly inadequate in the face of massive poverty. Two programs have been advanced in recent years to address the problem; these programs are considerably at odds with each other. On the one hand, the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) within the World Trade Organization (WTO) requires member countries to grant and enforce patents for new pharmaceutical products (Maskus 2000a; Gorlin 1999). More precisely, developers of new drugs have enjoyed exclusive marketing rights (EMRs) to all WTO members since January, 1995. Although product patents are not required until 2005 in the least developed countries, EMRs provide similar protection. *Various economic studies suggest that this new regime could raise prices of new drugs markedly in developing countries* (Fink 2000; Lanjouw 1998; Subramanian 1995; Watal 1999), though substantial uncertainty remains on this point. Thus, some possibility exists that patents will raise incentives for R&D in these neglected diseases (Lanjouw 1998). *However, this policy shift does nothing directly to increase the incomes of patients, who would, if anything, become less able to afford new medicines.*” Ibid, Mattias Ganslandt, Keith Maskus and Eina Wong, Chapter 9 pp 207-223 at p 208.

16 For example, art 30 TRIPS restricts the ability of WTO members from implementing policies that restrict the “exclusive rights conferred by a patent”. It is well documented that in patent legislations that operated in many countries of Europe until about 1980 that product patents were not permissible for pharmaceuticals and chemicals (Italy is one example). Moreover, between 1907 and 1977 the UK patents legislation specifically provided remedies against a patent that was not worked within the UK. Similar provisions existed in the patent laws of most European countries, including France and Germany. These restrictions on intellectual property were in accord with specific economic policies that were designed to favour economic development in the host country.

17 “The worst of the agreements strip developing countries of the capacity to effectively govern their economies and to protect their poorest people. Going beyond the provisions negotiated at a multilateral level, they impose far-reaching, hard-to-reverse rules that systematically dismantle national policies designed to promote development.” Oxfam Briefing Paper, *Signing Away The Future*, March 2007, p. 2.

18 Communication from Brazil, India, Pakistan, Peru, Thailand and Tanzania to the General Council, Trade Negotiations Committee, WTO, WT/GC/W/564, 31 May 2006 p. 2. Proposed Article 29bis entitled “Disclosure of Origin of Biological Resources and/or Associated Traditional Knowledge”.

19 In a side letter signed in April 2006 to the US-Peru FTA it was agreed that “The Parties recognize the importance of traditional knowledge and biodiversity, as well as the potential contribution of traditional

knowledge and biodiversity to cultural, economic, and social development.”

20 On April 4, 2007 the EU's Trade Commissioner Peter Mandelson on the eve of ministerial discussions to be held in New Dehli said that “these talks are timely and important [and that] if we fail, Doha's prospects for this year will be lost.” Xinhua News Agency, *EU eyes Indian meeting to save Doha trade talks*, April 4, 2007.

21 “Purified natural products are not regarded under any of the three laws as products of nature or discoveries because they do not in fact exist in nature in an isolated form. Rather, they are regarded for patent purposes as biologically active substances or chemical compounds and eligible for patenting on the same basis as other chemical compounds.” The source of the text is footnote 9, Nuffield Council of Bioethics Discussion Paper, 2002, *The Ethics of Patenting DNA*, 26, para 3.14.

22 Article 3.2. “Biological material which is isolated from its natural environment or produced by means of a technical process may constitute a patentable invention even if it previously occurred in nature.”

23 *Diamond, the Commissioner of Patents v Chakrabarty* (1980) 447 U.S. 303 (US Supreme Court).

24 For a detailed explanation of the jurisprudential argument see Luigi Palombi, *The Patenting of Biological Materials In The Context of TRIPS* PhD Thesis, University of New South Wales, Sydney, Australia, September 2004. <http://cgkd.anu.edu.au/menus/PDFs/PhDThesisFinal.pdf>.

25 *Laboratory Corporation v Metabolite Laboratories* (2006) 126 S. Ct. 2921 at 2922-3.

26 Op cit 55 at p. 309.

27 In this instance, the work was the genetic manipulation of the natural bacterium, not merely its isolation.

28 “... the patentee has produced a *new* bacterium with *markedly different characteristics from any found in nature* and one having the potential for *significant utility*.” *Diamond, The Commissioner of Patents v Chakrabarty* (1980) 447 U.S. 303 (US Supreme Court) per Justice Berger, p. 305.

29 As has been amply demonstrated by the experience of health care systems throughout the world in the early 1990's with HCV diagnostics, Chiron's refusal to license competing but complementary HCV diagnostics had serious consequences. This level of control, while being appropriate for traditional types of inventions such as mechanical or engineering or electrical or even pharmaceutical in some cases, is not appropriate when the scope of the claims captures the very ingredient upon which human health was dependent. While one cannot undermine the significant benefit to humanity of the scientific work which lead to the cloning and sequencing of HCV, it needs to also be appreciated that much of the funding for that work came from public sources. It also needs to be appreciated that while significant, the information provided by the discovery of HCV was so

fundamentally connected with human health that it was obscene to treat it like any other commodity.

30 See *Madey v Duke University* (2002) Case 01-1567 (CAFC) decision delivered October 3, 2002.

31 Cordell Hull was US Secretary of State between 1933 and 1944.

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Luigi Palombi read law and economics at the University of Adelaide between 1976 and 1981. He practiced law in Australia between 1982 and 1997, specialising in intellectual property law, particularly patent law and biotechnology. He was a partner of the patent attorney and law firm, Davies Collison Caves, and the law firms Michell Sillar, Palombi Hazan and Banki Palombi Haddock & Fiora. He lead the Australian litigation team for Murex in its patent litigation against Chiron with respect to its hepatitis C virus patents, breaking the stranglehold which Chiron had on the HCV genome in August 1996. In 1997 he ceased practicing law in Australia and became an international consultant and adviser to many companies particularly with regard to biotechnology and gene patents. In 2004 he completed his PhD thesis and was awarded his doctorate from the University of New South Wales in 2005. In 2005 he consulted to Minter Ellison, Australia’s largest law firm, in biotechnology patents. Since 2006 he has headed the Genetic Sequence Right Project at the Australian National University. He has lead and advised litigation teams in patent litigation conducted in Courts in many jurisdictions and before the European Patent Office and now advises various bodies and organizations around the world with regard to biotechnology and gene patents.