Pre-publication Extract.

DEFUSING DISCLOSURE IN PATENT APPLICATIONS:

A positive strategy to strengthen legal certainty in the International Regime and support WIPO's IGC on ABS, TK and Folklore.[1]

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Introduction

Have you ever wondered why so little progress has been made on the issue of disclosure of biodiversity and regulatory information in patent applications? It is a key issue in current negotiations within no less than three International bodies, the Convention on Biological Diversity (CBD), The World Intellectual Property Organisation (WIPO) and the World Trade Organisation (WTO). Yet the absence of substantive progress begs the question: Why? For nearly a decade there has been keen discussion, committees established, mandates given, meetings held, proposals put. But no outcome results. Why?

This paper seeks to answer that question and in doing so, to suggest a positive way forward enabling common objectives to be met and practical difficulties to be understood and resolved.

Authority to act

On the face of it, the answer cannot be a lack of authority or commitment by the Governments of the World. The 2002 World Summit on Sustainable Development (WSSD) Plan of Implementation is quite explicit: [2] Countries agreed at paragraph 44 to:

- 44(n) - promote the implementation of the Bonn Guidelines through national action
- 44(o) – negotiate an International regime on ABS
- 44(p) – successfully conclude the WIPO IGC process and Working Group on Article 8J of the CBD
- 44(q) – share technology benefits from the use of genetic resources
- 44(r) – promote discussion on the relationship between CBD and trade convention as set out in the Doha Ministerial Declaration.

These commitments were further embedded in the international system with the UN General Assembly's endorsement of the Plan the following year.[3] Eight years later,

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[2] "44 (n) Promote the wide implementation of and continued work on the Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of Benefits arising out of their Utilization of the Convention, as an input to assist Parties to the Convention when developing and drafting legislative, administrative or policy measures on access and benefit-sharing, and contract and other arrangements under mutually agreed terms for access and benefit-sharing;

(o) Negotiate within the framework of the Convention on Biological Diversity, bearing in mind the Bonn Guidelines, an international regime to promote and safeguard the fair and equitable sharing of benefits arising out of the utilization of genetic resources;

(p) Encourage successful conclusion of existing processes under the World Intellectual Property Organization Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore, and in the ad hoc open-ended working group on article 8 (j) and related provisions of the Convention;

(q) Promote practicable measures for access to the results and benefits arising from biotechnologies based upon genetic resources, in accordance with articles 15 and 19 of the Convention, including through enhanced scientific and technical cooperation on biotechnology and biosafety, including the exchange of experts, training human resources and developing research-oriented institutional capacities;

(r) With a view to enhancing synergy and mutual supportiveness, taking into account the decisions under the relevant agreements, promote the discussions, without prejudging their outcome, with regard to the relationships between the Convention and agreements related to international trade and intellectual property rights, as outlined in the Doha Ministerial Declaration;

[3] Adopted by UN General Assembly Resolution 57/253, in February 2003, endorsing both the *Johannesburg Declaration on Sustainable Development* and the *Plan of Implementation.*

not a lot has changed. The IR is only now drawing to a conclusion, The WIPO IGC, with its new mandate, has another 2 years to run and the Doha Round is stalled.

Clearly the problem lies not in the authority to resolve the issue of disclosure in patent applications or in the international machinery established for the matter to be addressed. This leads us to conclude that the impediment to progress is more fundamental. Identifying that impediment(s) and understanding it, would then allow thought to be given to its removal or at least to reducing its impact.

Conventional arguments against changing the status quo

In the meantime, critics of the proposals to amend the international patent system have identified a number of contributing factors to this lack of progress. These arguments are seen by their proponents as validating the need for caution, and by others, as serving as a smoke screen for a lack of action in protecting the status quo.

Firstly it has been rightly pointed out that the CBD is a multilateral *environment* convention. It is argued in consequence that it has neither the expertise nor authority to deliberate on Intellectual Property (IP) matters, particularly the operation of the patent system. There is some truth in this assertion, in so far as the professional background of many delegates to the meetings of the Convention tends more to the biological sciences than to IP law. The argument is however based on a false premise.

In fact, the third objective of the Convention - benefit-sharing from natural resource use[4] - is an economic one. The CBD is a trade and environment treaty. More, not less, delegates with a trade background are needed to assist in its deliberations. The advancement of national sovereignty over natural resources and obtaining a share in benefits deriving from its use is a legitimate trade and economic matter. Unsurprisingly, therefore the Convention has a legitimate interest in the operation of the IP system as the preeminent means of crystallising value in inventions based on genetic resources and any related traditional knowledge. This being the case, the question becomes what is the appropriate way for the CBD to pursue that interest?

The second counter-argument questions the legitimacy of using the patent system to achieve non-IP related ends. The argument runs that, using the patent system to identify possible misappropriation of natural resources and to demonstrate compliance with national access and benefit-sharing (ABS) laws is a wrongful use of the system with serious and not thought-through consequences. This begs the question: what is the purpose of the Patent system? At its simplest, the patent system exists for the public benefit of supporting innovation through the disclosure of the nature of new inventions in return for a time-limited right of monopoly use by the inventor. It is argued that this system increases the rewards for innovation and accordingly encourages investment and risk-taking in research and development. While this philosophy may underlie the system, over the years its application has also served other purposes, including ironically, protection of national industry, prevention of technical transfer, and economic warfare.

As recently as the immediate post-war period, the British government shaped patent law to minimise the costs of medicines to its National Health Service.[5] Without expressing any value judgements about national actions to meet varying public policy

[4] Article 1 'The objectives of this Convention … are…the fair and equitable sharing of the benefits arising out of the utilisation of genetic resources…"

[5] Page 99, *Gene Cartels: Biotech Patents in the Age of Free Trade,* Luigi Palombi Pub: Edward Elgar, 2009. This book contains an informative guide to the history of the development of the patent system.

needs, the history of the patent system suggests that it has served multiple uses. The second objection to this is that most proposals are for information to be disclosed in the application and do not affect the criteria on which a patent is granted. Like the patent system itself, disclosure of information about the origins and circumstances of genetic resources used in the development of an invention seeks to achieve its public policy ends through transparency. That public policy end is the demonstration of compliance with applicable national ABS laws and the prevention of misappropriation of genetic resources covered by the CBD through deterrence.

A triangular relationship

If these two arguments are capable of rebuttal what are the factors that have led to a lack of progress? We contend that, in essence, the parallel pursuit of the resolution of the issue of disclosure in CBD, WIPO and WTO TRIPS Council has placed the three in tension, that this tension creates a dysfunctional dynamic and results in a policy development blockage that is exploited for other ends. This dynamic can be described in the following circular terms: A lack of progress in the WIPO IGC is used to justify action in the CBD. A lack of progress in the WIPO IGC is also used to justify action in TRIPS. A lack of progress in TRIPS is used to justify action in the CBD and so on. In each of these fora other issues are in play and disclosure, as an issue, becomes a bargaining chip in a greater game. For example, progress might be made contingent on resolving market access issues or advancing a line on geographical indicators or simply a means of seeking delay while domestic ABS policy issues are debated.

This is an unhealthy and wasteful dynamic. Moreover it has other disturbing consequences. Firstly it builds distrust between parties making the resolution of conflicting views more difficult and creating frustration. Secondly, this frustration leads to another consequence: positional bargaining. This manifests itself in claims which a party knows or should know are unacceptable to others. Moreover, it allows claims to be advanced that represent overreach, ie that are wrong, exceed the authority of the institutional body concerned or are unachievable. An example of this would be a claim in the WIPO IGC that the patent criteria should be amended in respect for inventions based on genetic resources to add additional criteria relating to evidence of prior informed consent (PIC) and mutually agreed terms (MAT).

The descent into positional bargaining has other consequences. Proposals offering real solutions are inadequately considered or are simply rejected. An example of this is the Swiss proposal to enable countries to stipulate what should be required in patent applications without risk of falling foul of the interaction between the Patent Law Treaty (PLT) and the Patent Co-operation Treaty (PCT)[6]. Switzerland proposed in the PCT an amendment of PCT Rule 4.17bis.1

[6] See WIPO PCT/R/WG/4/13, Proposals by Switzerland Regarding Declarations of the Source of Genetic Resources and Traditional Knowledge in Patent Applications**.** Would introduce a new paragraph at (g) that would allow national law to require in accordance with PCT 27(1) applicants to declare:

- (i) the source of specific genetic resources for inventions directly based on such resources or that the source is unknown; and
- (ii) the source of traditional knowledg for inventions directly based on such resources or that the source is unknown.

that would have allowed countries to establish a disclosure requirement in patent applications and conform to the requirements of the PLT. This proposal was rejected almost out hand by some delegations and the only compromise available was deferral of consideration. The policy content of the proposal ie to tell what you knew, or did not know, in a patent application is not new, insofar as it reflected the basis of the EU position on disclosure in the TRIPS Council in 2000 and was in turn supported in-principle, by some other developed countries.

The sleeping Issue

When enough countries, or enough of an economic market, adopt a rule or practice that rule or practice becomes normative. This is the basis of international customary law. While a number of countries in Europe have introduced or are introducing national disclosure options or requirements, this is not sufficient to have such an affect. However, when that is added to, the requirements introduced by India, those changes to patent law recently announced by China and those contained in Brazil's new draft ABS law[7] then a new situation emerges. The more valuable an invention is, the more likely it will be patented internationally in markets that require some form of disclosure. Thus high value patents based on genetic resources are more likely to be subject to national disclosure requirements. It follows therefore that high value patents based on genetic resources and any associated traditional knowledge are, or are about to be, subject to disclosure. Meeting any instance of such a requirement in any one jurisdiction means that the fact and content of disclosure is then generally known. This has significant implications and is generally not acknowledged in debates within the CBD.

Defusing the tension and returning to effective consideration: a Strategy

Having asserted that an unhealthy dynamic exists around this issue and in the principal fora in which it is played out and having given some examples of its consequences., we now turn to a strategy for its resolution. The first step is to break this dynamic.

Since the dynamic is sustained by an absence of effective action,if that absence is filled by effective action in any one area, then the whole dynamic evaporates. The logical place for this to happen is within the CBD.

Underlying the formal communications between the CBD and WIPO by the COP is the recognition that the conventions must operate in a mutually supportive manner. Any action within the CBD must therefore not enter into the responsibilities of WIPO and its family of IP conventions nor be inconsistent with TRIPS obligations.

This is not difficult. It can be done, and indeed, the Montreal Annex contains relevant text where it says (with bracketing removed and some words inserted):

It also sought to amend PCT Rule 4.17 to allow parties to include such declarations at the international stage of PCT applications.

7. Author's personal conversations with Brazilian officials inSao Paulo in late 2009.

"**(e) Disclosure requirements**

"*Recognizing* that intellectual property rights play an important role in the fair and equitable sharing of benefits arising from the use of genetic resources, their derivatives and associated traditional knowledge, and that these rights need to be supportive of and do not run counter to the objectives of the Convention

Option 1

1. (*Users of genetic resources must disclose in*[8]*)* patent applications whose subject matter is directly based on genetic resources and/or associated traditional knowledge shall disclose the country providing genetic resources in accordance with the Convention or source of such genetic resources and/or associated traditional knowledge as well as information on prior informed consent and evidence that provisions regarding prior informed consent, mutually agreed terms and benefit-sharing have been complied with, in accordance with the national legislation regulations and/or requirements of the country providing the resources in accordance with the Convention."[9]

The first thing to note about this formulation is that it does not amend the existing patent system in any way. It does ensure however that lawfully obtained genetic material has that fact made known transparently and globally through the patent system and it's associated patent data search mechanisms. Accordingly it demonstrates the existence of primary legal certainty: permanently and free of charge to any and all interested parties.

Such action creates a comparative market value advantage for inventions based on lawfully obtained material and is a powerful step in compliance.

The second thing to say about this step is that there is a long-standing precedent for this approach within the patent world. Formal, legislated disclosure mechanisms were introduced by the Bayh-Dole ACT 1980 which requires that when contracts for the commercialisation of federally funded research are made, such contracts must contain a requirement the federal funding is disclosed in any patent applications. This also allows the US government to track the commercialisation of federally funded research and to readily and objectively identify where research dollars are most productive. Moreover we are unaware that this provision has given rise to any burden of litigation.

Thirdly, a comprehensive legal opinion provided to the authors states categorically, that contrary to some suggestions presented on this point, national requirements for CBD disclosures in patent applications are fully consistent with existing international law treaties. Moreover it concludes that such requirements should be understood as permissible, substantive conditions on entitlement to

[8] Inserted to show how such a step does not need to involve any alteration to the patent system

[9] The removal of brackets was undertaken subjectively to more clearly demonstrate the point.

apply for patent rights and to own patents, designed to prevent misappropriation of genetic resources or traditional knowledge.[10]

What then would be the effects of such a step? Firstly, it would remove the justification for taking comprehensive action within TRIPS and WIPO on the grounds that disclosure is an IP issue and the CBD would or should not take action on the issue.

Secondly, it would allow the WIPO IGC to act more effectively within its new mandate. Instead of competing with CBD or TRIPS it would be free to focus on compliance supporting measures that would provide support to the implementation of contractual obligations established by the CBD (or its forthcoming Protocol) as part of its consideration of the content of mutually agreed terms.

Moreover, it could more clearly see its role as working to better harmonise existing and future disclosure requirements in national patent legislation. This would entail the application of its specialist expertise and more likely result in productive and practical outcomes. This is especially pertinent when considering the increasing range and significance of national patent laws providing for disclosure of information about the origin and sourceof genetic resources used in inventions and any associated traditional knowledge.

Finally, by taking immediate action within the CBD or the International Regime the CBD is well placed to consider the primacy of national sovereignty over genetic resources and consider that while patents are an option in the commercialisation process, providers and users need to have the flexibility to choose other alternatives - if that suits their mutual interests better. For example in the nutraceutical and cosmetic fields greater benefits may flow from going down the trade-secret path than patenting. Similarly, some flexibility in the level of detail published in a patent application may be required for conservation or commercial confidentiality reasons. This is best left to the parties involved.

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[10] Permission to cite this advice currently pending.