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QUNO
Occasional Paper 18

Thinking Aloud on Disclosure of Origin

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October 2005

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What do we all mean by "disclosure of origin"?

"Disclosure of origin" has become a collective term for certain requirements to be incorporated into patent law. These requirements vary widely in terms of the weight and nature of the legal, administrative or informational burdens placed on patent applicants and owners. Accordingly, it is convenient to describe three types of disclosure requirement.

Version one – "voluntary disclosure"

The least burdensome of these types is to encourage the disclosure of genetic resources and/or traditional knowledge relevant to an invention being patented. Its omission would not disqualify the patent application from being accepted, being granted, or being subsequently enforced. In other words non-compliance gives rise to no legal consequences. Such disclosure aims to serve the purpose of enhancing transparency in terms of international commercial transfers of genetic resources and traditional knowledge.

Version two – "mandatory disclosure"

A closely related incarnation of disclosure of origin would be to make this requirement mandatory, with failure to disclose or dishonest disclosure having one or some of the following consequences: the patent application would not be accepted; it would be rejected during the prosecution stage; if granted it would not be enforceable; or if granted it would be revoked with possible criminal sanctions for wrongdoers.

The burden of compliance is placed on the patent applicants and the patent granting offices. The role of provider country governments would be to monitor compliance and take legal action in cases of alleged non-compliance.

In the case of both types of disclosure requirement, what is being proposed, one presumes, is that the country providing the resource should be disclosed whether or not it is the country of origin. In other words, it is the country of *source* that should be disclosed.

Version three – "proof of legal acquisition"

A somewhat different version of the disclosure of origin requirement would tie the patent system more closely to the CBD's access and benefit sharing (ABS) provisions, in particular to the ABS regimes operating in those countries *directly* providing the genetic resources and/or traditional knowledge. One way to implement this is to require patent applicants to submit with their application official documentation from provider countries proving that genetic resources and – where appropriate – associated TK were acquired in accordance with the ABS regulations including conformity with

such obligations as prior informed consent, with the terms mutually agreed between providers and the recipients, and with the need to comply with CBD Article 8(j) on the knowledge, innovations and practices of indigenous and local communities.

To harmonise the rule and make the requirement operate more effectively, there could be an international certification of origin system. The Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization refer to 'a legally recognized certification of origin system as evidence of prior informed consent and mutually agreed terms'. The idea here is that if provider countries were to agree on some common requirements and procedures, standardised certificates of origin could be used which all national and regional patent offices would recognise.

Which is better?

Personally, I feel sceptical about the first two types of disclosure requirement, and, *with certain qualifications* would advocate the third. On the basis of past experiences, imposing an obligation on patentees to disclose in the specification the origin of genetic resources and/or traditional knowledge relevant to the invention would produce modest results in terms of (i) improving patent quality, and of (ii) preventing the unauthorised appropriation and commercialisation of biodiversity.

One reason is that so many resources and so much traditional knowledge related to patents are acquired or is learned about without having to go to any of the countries of origin or source. Therefore, the measure would apply to quite a small number of patents.

More seriously (in the sense that the first problem is common to all three types), the inclusion of such information may not be very relevant to the standard criteria of novelty and inventive step and so their absence may not be noticeable to patent examiners or to anybody else including NGOs. Besides, it may prove difficult to agree on what exactly should be the relationship between the invention and the biogenetic resource and/or associated traditional knowledge for disclosure of origin to apply. In many cases, knowledge and material relevant to an invention may be manifold. Should all sources of knowledge and material be compensated no matter how distant and tangential? This might be hard to justify and to achieve a consensus upon.

It may be worth noting too that if all countries of origin had to be disclosed this might require access to biogeographical information that may not be readily available. Aside from this practical issue, one may reasonably wonder, if we are dealing with *origin* as opposed to *source*, how several countries that could legitimately claim to be countries of origin of the same resource might wish to respond to the patenting of an invention based upon it.

Proof of legal acquisition seems to have more promise as an effective measure in terms of encouraging equitable processes and outcomes to the economic benefit of both providers and users. Admittedly, the fact that so many resources and so much traditional knowledge related to patents are acquired or is learned about without having to go to any of the countries of origin or source would also limit its application.

But linking the patent right to the legality of the acquisition of the relevant resources or knowledge appears to have some practical advantages.

First, as a legal requirement implemented as an administrative measure rather than as part of the substantive examination it leaves examiners to apply the standard tests of patentability (i.e. novelty, inventive step and industrial applicability) in the normal way. As recent complaints about low patent quality in the United States tend to indicate, this is difficult enough. It is true that improving access to information about traditional knowledge could certainly help improve patent quality. But it is less clear to me that the *geographical origin* of a chemical substance that was subsequently modified by an inventor has anything necessarily to do with determinations of novelty or inventive step. Therefore, expecting a patent examiner to heed such a consideration as part of his work adds to his workload without making his job easier in any other way.

Second, proof of legal acquisition avoids the difficult technical, and arguably somewhat philosophical, question of how closely related the genetic resource and/or traditional knowledge should be to the invention which is the subject of the patent application for the requirement to apply. Bioprospecting and genetic resource export permits issued by governments under their ABS regulations should simply require that *all* patent applications submitted within say 10-20 years of the permit being granted for inventions resulting from the material and information acquired be accompanied by: (i) a declaration from the applicant stating that the relevant ABS rules of the provider country were complied with; and (ii) a copy of the bioprospecting/export permit. Provider countries might wish to consider amending their ABS rules to impose such an obligation (or to make it more explicit).

The patent granting office would record receipt of the application *and* items (i) and (ii). The patent examiner would not even need to be aware of the declaration or permit copy and would be left to examine the application in the normal way. The granting office would notify the competent authority of the provider country that the patent application had been received. It is submitted that such a procedure would not be burdensome for the patent granting office. Again, the country where the patent granting office is located may need to amend its relevant legislation, although it may only require modest reform of the office's internal regulations. However, to be truly effective, the legal means should be made available to allow governments to challenge the patent's legality in the jurisdiction in which it was granted if they consider a foreign patent they were not notified about may have been for an invention resulting from resources or traditional knowledge acquired under their ABS regulations.

The third advantage of proof of legal acquisition is that it can respond to but at the same time move beyond concerns about misappropriation and encourage the kinds of scientific research partnerships that can benefit developing countries rich in biological and genetic resources but still lacking the technological capacity to exploit them effectively. The CBD seeks among other things to encourage fair, transparent and mutually beneficial partnerships between providers and users of benefit to all parties. If life science and biotechnology businesses want access to genetic resources and traditional knowledge they must understand they have to accept the rules of the provider countries. Proof of legal acquisition is hardly an unreasonable or difficult to comply with part of the deal. It may well be a lot easier to comply with than

mandatory disclosure may on occasions turn out to be. And complying with it may be very good for the image of the companies concerned who in doing so will show that they are a business to be trusted.

Admittedly, there are drawbacks with proof of legal acquisition. One of these is that it would not apply to cases of patenting where genetic material and traditional knowledge were acquired not through bioprospecting but ex situ collections and literature searches. On the other hand, mandatory disclosure of origin could still require the source of genetic resources and traditional knowledge to be indicated even if only by citing the relevant journal articles or books. Of course, mandatory disclosure *and* proof of legal acquisition *are not mutually exclusive and may in fact be mutually reinforcing.* Another drawback is that proof of legal acquisition is less appropriate for patents claiming new plant varieties, where that is allowed. ABS regulations tend to be targeted towards pharmaceutical bioprospecting and are not sensitive to the specificities of plant breeding (see below). On the other hand, most seed companies appear to be comfortable with mandatory disclosure[1].

Righting past wrongs – how much difference would disclosure of origin have made?

Proponents of one or more of the above types of disclosure of origin requirement should accept that their earlier implementation may well have made little difference in most of the controversial biopiracy cases. Let us consider some examples to show what I mean.

Hoodia

Certain groups of San (Bushmen) living in South Africa and Botswana eat parts of a plant called hoodia as an appetite suppressant. This helps them to endure long hunting trips in areas of the desert where food is scarce. The South African Council for Scientific and Industrial Research (CSIR), a government institution, investigated the plant, based apparently on some published information and patented certain compounds possessing appetite suppressant activity. Phytopharm is now involved in developing the drug in the hope of turning it into a product for the US and European markets. There are hopes that its sale will be approved in about 2008. The patent specification may well provide the first biochemical description of how the plant produces its commercially promising effect. But the intended use of the plant would hardly be considered as novel by these San groups, who are not mentioned at all in the patent.

The CSIR and Phytopharm found themselves criticised by international NGOs and also by a San organisation. The main criticism was that neither had at any time seen fit to contact the San to explain the situation and enter into negotiations with them on the sharing of benefits. In 2001, the CSIR responded by negotiating a memorandum of understanding which led in 2003 to a benefit sharing agreement that sets up a 'San Hoodia Benefit-Sharing Trust'. The Trust will receive milestone payments and royalties from the CSIR to be distributed to the San people. (In the meantime, various

[1] See Walter Smolders, Disclosure of Origin and Access and Benefit Sharing: The special case of seeds for food and agriculture, QUNO Occasional Paper 17, QUNO, Geneva, October 2005 available on www.quno.org

hoodia products are being sold by herbal medicine companies and can be ordered on the Internet).

The patent specification gave the name of the plant but not its source, and did not refer to the relevant traditional knowledge. Since this knowledge was part of the prior art, it ought to have done *whether or not the knowledge was "traditional"*. Citing relevant prior art is supposed to be conventional practice. But having said that, the existence of Article 8(j) of the CBD can be used to argue that special efforts should be made to cite traditional knowledge and that indigenous groups with the knowledge ought to be consulted irrespective of whether they had directly passed the information to the researchers. In this case, the knowledge was discovered through a search of the published literature. With mandatory disclosure, the inventors would have had to disclose the South African origins of the plants and the TK, and arguably the Botswanan origins as well depending on whether the requirement concerns *source* or *origin*. As for proof of legal acquisition, it is difficult to know how it would apply given that the plants used in the research probably came from South Africa and the TK was known about by a literature search. This would depend on South Africa's own ABS regulations and how they deal with domestic usage and patent filing.

The neem patents

The neem tree (Azadirachta indica) has been the subject of a considerable number of patents. The inventions described in virtually all of the neem-related patents used public domain traditional knowledge as a starting point. They have aroused considerable controversy, especially in India, where most of the traditional knowledge holders are from. There have been at least two patent challenges: (1) to a European Patent Office (EPO) patent for fungicidal effects of neem oil (Patent No. 436 257 B1) owned by W. R. Grace & Co., and (2) to a US patent for a storage stable azadirachtin formulation (Patent No. 5124349) also owned by W. R. Grace. The challenge to the former patent succeeded in 2000 when the European Patent Office revoked the patent on the grounds of lack of novelty and inventive step. The revocation was confirmed on appeal.

In considering whether disclosure of origin would have made a difference in such cases, we need to be cognisant that neem trees can be found in in-situ conditions in various tropical countries, including in Africa. Consequently, India and its neighbouring countries have no special claims to neem on the basis of being the country or countries of origin. In any case, it cannot be assumed that the trees from which the scientists acquired the biological material used in the invention were acquired directly from India. Moreover, traditional *and* scientific uses of neem seeds have been widely published and do not by any means all originate from India or its neighbouring countries.[2] So if neem-related patents are being granted it is either because the inventions disclosed are non-obvious in the light of, or an inventive step beyond, the published information available to the patent examiners, or alternatively because the granting offices do not provide sufficient access to the relevant literature. The present author is sceptical that disclosure of origin can adequately address the problems of undemanding inventive step thresholds and inadequate prior art searching.

[2] Van Latum, E.B.J. and R. Gerrits (1991) Bio-pesticides in developing countries: prospects and research priorities. *Biopolicy International* no. 1. African Centre for Technology Studies.

Enola bean

In 1999, a US patent was granted on a field bean cultivar dubbed 'Enola' by its 'inventor' Larry Proctor.[3] Proctor's company Pod-Ners has been using the patent to block the sale of imported beans with the same colour as the one described in the patent, whose description would cover several not very novel traditional bean varieties. The patent claims not only a certain yellow-coloured Phaseolus vulgaris bean seed, plants produced by growing the seed as well as all other plants with the same physiological and morphological characteristics, but also the breeding methods employed. Two things are extraordinary about this patent. The first is that many bean cultivars exist and the specification provides no evidence that none of these cultivars possess the same characteristics falling within the patent's rather broad claims.[4] The second is that Mr Proctor employed conventional crossing and selecting breeding methods that are in no way novel. Yet the patent prevents others from using the bean *and* other beans with similar characteristics in their own breeding programmes. None of this would necessarily matter if the owner had not decided to assert the patent aggressively. Soon after receiving the patent, Proctor sued a company called Tutuli that had been importing Mexican yellow bean cultivars called Mayocoba and Peruano from that country since 1994, and with customs inspectors disrupting supplies Tutuli began to suffer financially as did Mexican farmers that had been selling their beans to this firm. His company has since then filed lawsuits against various other small bean companies and farmers. The patent is being challenged by the International Center for Tropical Agriculture (CIAT), which holds the largest collection of bean varieties and claims that six of its 260 yellow bean accessions very closely resemble Enola and may well fall within its claims. CIAT's Director, Dr Joachim Voss reportedly called the patent 'both legally and morally wrong' and claimed to have 'solid scientific evidence that Andean peasant farmers developed this bean first, together with Mexico'.[5]

To sum up, then, the patent should not have been granted due to lack of novelty. In other words, there was a perfectly good reason for the patent not to have been awarded. The problem here is poor quality patent examining, and, one can also argue, the failure of the US to exclude conventional plant breeding and conventionally bred plant varieties from the ambit of the patent law.

Indeed, Proctor actually disclosed the source of the beans he used. Clearly he did not consider such honesty to be harmful to his legal claim. One can only wonder if he would have disclosed the source had doing so entailed certain legal obligations and consequences. Indeed, it may be that many inventors will be tempted to withhold information or provide false information concerning their invention if doing so enables them to avoid certain onerous legal obligations – if of course they think they can get away with it. If such poor examining is allowed to continue the chances are that they can. But perhaps one should not be too cynical. Companies interested in bioprospecting related research and development may not wish to do things the Pod-Ners way. Why? First, because governments allowing them to bioprospect may decide

[3] US Patent No. 5,894,079 (issued April 13, 1999) ('Field bean cultivar named enola').
[4] In fact, Proctor indicated in his application for a Plant Variety Protection certificate on Enola (that was subsequently granted) that 'the yellow bean, Enola variety, is most likely a landrace from the [Mexican] azufrado-type varieties' (ETC Group (2001) Proctor's gamble (News Release), 17 December).
[5] Quoted in Pratt, T (2001) Small yellow bean sets off international patent dispute. *New York Times*, March 20.

to routinely screen their future patent applications for possible failure to declare legal acquisition. Second, not all companies wish to be exposed and branded as biopirates anyway. Doubt about disclosure of origin, then, should not go so far as to discount all possibility of positive consequences in terms, for example, of improving business practices.

The rosy periwinkle

In the 1950s the rosy periwinkle (Catharanthus roseus), a plant originally found in Madagascar, yielded two anti-cancer alkaloids, vincristine and vinblastine, which have generated huge profits for Eli Lilly since they came on the market around four decades ago. To some this is the classic biopiracy case with Madagascar and its people the unfortunate victim.[6] In fact, while the plant is thought to originate from Madagascar, it exists throughout the tropics and has grown in the Caribbean long enough to be considered as a native plant there. It is many years since the company relied on Madagascar for supplies of the plant, and most now come from plantations in Texas. The Eli Lilly researchers who discovered and patented[7] vincristine and its anti-cancer properties decided to study the plant when a literature search uncovered its use by rural populations in the Philippines. Those at the University of Western Ontario who discovered and patented[8] vinblastine received plant samples from Jamaica that were considered worth testing, again, because people used the plant for therapeutic purposes. In both countries the plant was used by rural communities not to treat cancer but diabetes.[9] Neither of the research teams made any secret in their publications of the fact that they were inspired by traditional knowledge. On the other hand, only the University of Western Ontario team was reliant both upon overseas sources of plant material and unpublished ethnobotanical information when it began research on the periwinkle.

Consideration of these cases gives rise to scepticism that disclosure of origin will make much difference. Admittedly, Jamaica might have stood to gain in the vinblastine case. However, we should not leap to such a negative conclusion without reflecting on the possibility that there may be many unknown cases of 'misappropriation-by-patent' that disclosure of origin would have prevented or at least brought to light.

Conclusions

Is disclosure of origin compatible with TRIPS?

The answer depends on whether we are talking about versions 1, 2 or 3. Clearly there is no problem whatsoever with voluntary disclosure. As for mandatory disclosure, one

[6] Stone, R. (1992) The Biodiversity Treaty: pandora's box or fair treaty? *Science*, 256, p.1624.
[7] See US Patent No. 3,205,220 (issued September 7, 1965) ('Leursidine and Leurocristine and their production').
[8] See US Patent No. 3,097,137 (issued July 9, 1963) ('Vincaleukoblastine'). The patent was assigned by the inventors, Beer, Cutts and Noble, to Canadian Patents and Development Ltd., who made a deal with Eli Lilly allowing the latter company to commercially exploit the invention.
[9] As expressed by three medical researchers at the University of Western Ontario, 'the disease of cancer was certainly far from our thoughts when we learned of a tea made from the leaves of a West Indian shrub that was supposedly useful in the control of diabetes mellitus' (Noble, R.L., Beer, C.T. and Cutts, J.H. (1958) Role of chance observation in chemotherapy: vinca rosea. *Annals of the New York Academy of Sciences*, 76, pp 882-894, p.882).

can easily argue that description of genetic resources and TK is essential for a full disclosure of the invention as normally required under patent law. By helping to describe the prior art against which the purported inventive step needs to be measured such a description ought to be required anyway. But having to describe the geographical source of the genetic resource and undocumented TK would certainly go beyond the extent of disclosure normally considered necessary to assess novelty and inventive step. This point may be used to dispute the TRIPS compatibility of the requirement.

However, a careful application of proof of legal acquisition may provide a more satisfactory resolution. There is no compelling reason at all why the compulsory submission of a document such as a certificate of origin would impose another substantive condition as long as it is not linked to determining the patentability of the invention. After all, examination and renewal fees normally have to be paid by patent applicants and owners, and TRIPS does not prevent them merely because they are not mentioned in the Agreement.

In short, the following interpretation seems plausible: it would not be a violation of TRIPS for countries to require patent applicants (i) to describe the relevant genetic material and TK in the specification and (ii) to submit documentary evidence that the ABS regulations were complied with. But it probably would be to require patent applicants also to disclose the geographical origin of the relevant genetic material and associated TK in the specification itself. Consequently, imposing such a requirement will entail a revision of TRIPS. Alternatively, these requirements could possibly be introduced outside of the search and examination processes as administrative measures. But that would not solve the problem that most patents are filed in the USA, Europe and Japan where there is little enthusiasm to adopt either version 2 or 3. To deal with this, as mentioned earlier, each WTO member should be required to make the legal means available to allow governments or other interested parties to challenge a patent's legality in the jurisdiction in which it was granted.

Is it a good idea anyway?

Versions 2 and 3 could probably operate quite well for resources with health applications, especially pharmaceuticals. The pharmaceutical industry generally bases its new drugs on single compounds. Tracing and declaring the sources of these should not normally be a particularly onerous task if version 2 were the chosen option. For version 3, the task of compliance would be even simpler. The measure would still need to determine the extent to which the obligation would extend to synthetic compounds derived from or inspired by lead compounds discovered in nature. It should be noted that the pharmaceutical industry is not favourable to disclosure of origin, whereas the seed industry, with the possible exception of the bigger firms, is better disposed towards the requirement and is confident that compliance would not present great difficulties. Having made that point, though, the latter industry is not much interested in bioprospecting. And the little interest it has may evaporate if it has to comply with ABS regulations in the same way that pharmaceutical firms have to.

But in the case of plant varieties, which can be patented in some countries, genetic material may come from numerous sources. Consequently, the value of individual resources is relatively low. In addition, the seed industry is much smaller than the

pharmaceutical industry and will never generate as many benefits to share anyway. So for plant varieties developed through conventional breeding methods, any version of disclosure of origin may produce little benefit to developing countries. But in any case, patenting of plant varieties is bad policy. Plant variety protection should be left to UPOV and other sui generis IPR systems.

So perhaps version 3 should apply to genetic resources and traditional knowledge for all applications and business sectors other than food and agriculture. Resources and knowledge in the latter categories should be dealt with under the multilateral system of facilitated access established by the FAO International Treaty on Plant Genetic Resources for Food and Agriculture. Why? because facilitated access to plant genetic resources for food and agriculture of those crop species covered under the multilateral system is to be subject to a standard material transfer agreement (MTA), which will require benefits to be shared from the use, including commercial use, of the resources acquired, and is far more appropriate for scientific, commercial and food security reasons.

One of the practical complications in the version 3 context is that many countries still do not have ABS regulations. If the patent must be accompanied by official documentation from the source country, no authority may exist to provide it. In this case, presumably the requirement for a certification would have to be waived. But if so, what is to stop a company from claiming that a resource was obtained from such a country when it was actually collected illegally from another country with ABS regulations?

Clearly, none of the above proposals is going to prevent all misappropriation of genetic resources and traditional knowledge. And neither are they a substitute for competent substantive examinations of patent applications. However, countries that are net exporters (whether voluntarily or otherwise!) of genetic resources and traditional knowledge probably have more important things to think about than trying to eradicate inappropriate patenting. Such efforts should be no more than a means to such higher ends as technological capacity building, local and national economic development and poverty alleviation. How can disclosure of origin pursue such ends? Proof of legal acquisition, in my view, is the best option first and foremost because it has the potential to link the acquisition and deployment of important business assets (i.e. patents) to sustainable development in a way that versions 1 or 2 can do only in a very indirect way.