

“Equitable Sharing” of Benefits of Biodiversity-based Innovation: Some Reflections under a Neem-tree

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I. The development of biodiversity-based innovation as a “cooperative trade-off” between industrialized and developing countries

AS EVERYBODY knows, much advanced innovation in the pharmaceutical sector, as well as in the agricultural field (concerning seeds, in particular) is based on germoplasm (often referred to as “biodiversity”), i.e. a “wealth”, rarely and exceptionally surviving in Industrialized Countries (IC), which has been fundamentally preserved by farmers of Developing Countries (DC) “for cultural reasons which may escape those of us who equate wisdom to economic calculus”.¹

Rather obviously, such innovation is typically based on cooperation between IC and DC. The former possesses the technology which enables them to develop new products for mass consumption (more advanced and efficient drugs and healthier and more resistant and/or abundant food) from the germplasm provided by plant and animal genetic resources preserved, and provided, by the latter. And, of course, such innovation can be patented by its developers. In particular, it is well known that patenting of “an invention based on biological material of plant or animal origin” is expressly granted by European Directive No 98/44, and is commonly admitted in most non-EU countries, including US and Japan.

Thus, thanks to patent protection, the biodiversity-related innovation—chiefly concerning the pharmaceutical and the agricultural industry— can yield potentially very high benefits both in strictly economic terms (return

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1. Ricolfi, “Biotechnology, Patents and Epistemic Approaches”, to be published in *Rev. Biolaw and Business*, 2002.

from sales and/or royalties in regime of exclusivity) as well as in techno-scientific progress (further impulse to R&D activities) and industrial and commercial advancement.

II. "Equitable sharing upon mutually agreed terms" of results of R&D and commercial and other utilization of biodiversity-based innovation- the framework

Just a few words to summarize the basic legal framework of the problem I wish to address here, namely that of the "equitable sharing" of benefits accrued from biodiversity related innovation.

This problem, as everybody knows, is specifically addressed by the Rio de Janeiro 1992 Convention on Biodiversity, which first of all acknowledges the States' sovereign rights to exploit their biological and genetic resources² and, therefore, dictates that the said States shall have the "authority to determine access to their genetic resources"³.

The Convention sets, as a fundamental goal, "the fair and equitable sharing of the benefits arising out of the utilization of genetic resources"⁴.

The justification for such sharing seems obvious: providing the germplasm cannot be assimilated to the simple "physical" supply of a material. *That* material indeed is the result of —and thus embodies— the DCs' traditional knowledge and labour in maintaining the agricultural and environmental conditions for the preservation of germplasm and in identifying pharmaceutical and/or nutritional properties of local plants. Embodies, in other words, a *know-how* which - although *not* qualifying *per se* as an "inventive contribution" in the meaning of patent law and thus not validly supporting a claim of "joint inventorship"⁵ - represents the fundamental pre-condition of all the subsequent R&D work carried on by the biodiversity recipient industries. (Incidentally, the same reasons lead to affirm that the DCs' right to the "fair and equitable sharing of benefits" should *not* be made dependent on either the validity of patents, nor from their duration— not even from their existence (the industry's choice to patent or not to patent is irrelevant). Such right should simply be related to the *fact* of development and exploitation of biodiversity-based industrial products).

Now, to achieve the goal of that equitable sharing, the Convention provides that "*Each* Contracting Party shall take legislative, administrative or

2. See, Arts. 2 and 3.

3. Art.15

4. Art.1. The principle is supported also by aforesaid EC Directive 98/44: see, "whereas" 56 (and 11).

5. See here Professor M. Blakeney's remarks in *Bioprospecting and the Protection of Traditional Medical Knowledge of Indigenous Peoples: An Australian Perspective*, in 19 *EIPR* 298-303, particularly 299-300 (No. 6, 1997).

policy measures, as appropriate, and in accordance with Articles 16 and 19, with the objective of sharing in a fair and equitable way the results of research and development and the benefits arising from the commercial and other utilization of genetic resources with the contracting party providing such resources. *Such sharing shall be upon mutually agreed terms.*”⁶ Hence, a straightforward encouragement to implement the objective under a “cooperative”, not confrontational approach, benefiting also—maybe first of all—the DCs⁷.

III. “Sharing” of what?

Now, such approach can be, and is typically pursued within a contractual perspective. In the current experience, the contractual perspective — usually based on a licence for exploitation of biological material granted by a rural community of a DC to a firm of an IC—allows the IC biodiversity recipient industries, typically enjoying a much higher contractual power, to attribute to the biodiversity-providing local communities *just a financial return*, be it a lump sum and/or royalty, from commercial exploitation of the new biodiversity based drug or food produce⁸.

Of course, the contractual framework can allow, and has in fact allowed more advanced schemes, whereby, for instance, the Agreement might place a duty on the “industrial party”, licensee of the biodiversity material and developer and owner of the patent on the new drug or seed, to “grant back” to the “provider” licensor (DC) a non-exclusive license “for research use”⁹. But I would like to remark that, even in this more advanced example,

- (a) the license is “not for any commercial use” and thus it could not be conferred to, and shared with, a locally operating industry;
- (b) it is expressly stated that, whereas the indigenous people are free to continue to make and sell their traditional products, by no means the new drugs developed and patented by the industrial licensor can be deemed as an expression of “indigenous knowledge” ; accordingly

6. Emphasis added.

7. See, below, para. 6, for references.

8. See, e.g., such American contractual models like the Diversa-Yellowstone CRADA—Cooperative Research and Development Agreement—, and INBio-Merck, both involving mere profit-sharing: reference in *AIPPI Yearbook 2001/II, XXXVIIIth Congress, Report of the US Delegation on Question 159 “The need and possible means of implementing the Convention on biodiversity into patents law”*, 388 f.

9. See, e.g., Art. 6.03 of the Agreement between the Peruvian Communities representing the Aguaruna and Huambisa peoples, and a US Company, G. D. Searle & Co., of Monsanto Group, in Professor Charles McManis’ *Recent Publications on Indigenous Knowledge Protection—New Directions in Indigenous Knowledge Protection*, in ATRIP 1999 Collection of Papers, 71.

- (c) there is no provision of any participation of the local communities in the industrial development of the new products. It clearly emerges, indeed, that the biodiversity-related innovation, be it patented or not, will not pertain, even in part, to the indigenous people provider of the biodiversity.¹⁰

I share the view that a purely financial reward—however equitable, and even generous— does *not* match with the concept of “fair and equitable sharing” of “the *results of research and development* and the benefits arising from the commercial and other utilization of genetic resources”, as expressed by the Rio Convention.¹¹ That concept appears wide enough as to embrace participation in that “spread” of applied techno—scientific know-how, and development of new industrial *and* commercial activities, which embody the main socio-economic benefits related with innovation (and which is *not* substitutable by simple “abstract” knowledge, and thus simply by the grant of a sort of “fair use” right, such as foreseen by the Searle-Aguarunas Agreement I referred to above).

Thus, in Professor Jerome H. Reichman’s words “Governments in developing countries should...regulate the manner in which foreign firms obtain access to local germplasm, with a view to sharing in both the technical knowledge that may result and the proceeds of commercial exploitation”.¹² This seems indeed the appropriate balance of interests, the correct trade-off: the DC release to IC their *traditional knowledge* as embodied in the germplasm, and the IC release to the DC their *technical and commercial knowledge* as embodied in the newly developed biodiversity-based products and processes and in their distributive patterns.

This opinion, may I recall, was implicitly *and* expressly shared, *inter alios*, by a number of national (also western) delegations at aforesaid 2001 AIPPI Congress (see, *Summary Report*, loc.cit., at 406 f.; see also the Italian delegation’s position, at 336 : “the conditions aiming at favouring and promoting a local exploitation of patents and the related technology would be more adequate and effective measure to compensate the owners of the genetic resources and to meet the objectives of the C.B.D., than royalties or lump sum payments”).

Conclusively, then, the fulfilment of the goal we are discussing, implies that the provider country be granted the chance to participate, *on its own national scale* (see below), in the industrial and commercial exploitation of biodiversity-related innovation (and thus, particularly, of related patents and know-how). In its turn, such result could typically be achieved either by

10. See, Art.6.05.

11. Emphasis added.

12. “From Free Riders to Fair Followers: Global Competition Under the TRIPS Agreement”, *NYU Journal of Int’l Law and Politics* 11, at 39 (1997).

means of domestic production by local licensees of the patent holder, or by direct working *in situ* by the patentee itself. Indeed, even direct production exclusively performed by the foreign firm would produce —let aside employment-related benefits — a “leakage”, and spread, in the DC, of industrial know-how and capacity: a necessary, although not sufficient, premise for the subsequent development of a domestic industry.

IV. From “agreed dominance” to better balanced terms of trade - A proposal

As hinted—and as several examples show— the risk exists that the goal just defined might not be granted at all within a “purely private” contractual perspective, reflecting the substantial disproportion of contractual and economic power between IC and DC. (A disproportion often enhanced by robust, not always transparent, diplomatic and political pressures of IC governments on DC governments: a not-so-private “third party intervention” in the “private” Agreement).

Now, to avoid such risk, it is imperative: A) to ensure the substantive compliance of the Agreement between recipients and providers of biodiversity with basic legal principles, internationally acknowledged, supporting *that* goal of equitable sharing. And, to this end, B) that the “cooperative” approach recalled above be implemented not just in a “purely private” perspective, but *dans le cadre* of procedural guarantees capable to build a mutually satisfactory equilibrium of interests, not a simple reflection of the existing imbalance of power between the parties.

As for A), reference should be made both to Rio Convention and TRIPS. As recalled, the Rio Convention empowers “Each contracting Party to adopt legislative, administrative or policy measures aimed to achieve the fair sharing of results of R&D and the benefits arising from the commercial and other utilization of genetic resources.”¹³ Same Article provides that such adoption must take place “in accordance” with Articles 16 and 19 of the Convention. Now, on the one hand, Article 16 engages the parties to the Convention — including provider (DC) and recipient (IC) countries — to cooperate, subject to national legislation and international law, in order to ensure that *patents and other IPRs* “are supportive and do not run counter to its the objectives”¹⁴. On the other hand, Article 19 provides that all parties to the Convention “shall take *all practical measures* to promote and advance priority access on a fair and equitable basis by Contracting Parties, *especially developing countries, to the results and benefits arising from biotechnologies based upon genetic resources provided by those Contracting Parties*”.¹⁵

13. Art.1; emphasis added.

14. Emphasis added.

15. Emphasis added.

On the TRIPS' side, same allows members "in *formulating or amending* their laws and regulations, (to) adopt *measures* necessary to promote the public interest in sectors of vital importance to their *socio-economic and technological development*".¹⁶ And also, specifically, it allows members to institute compulsory licences on IPR's holders.¹⁷

It seems to me that such framework allows the provider country to adopt a set of *ad hoc* measures requesting holders of local biodiversity-based innovation to establish a production *in situ* of the developed results or, in default, to licence to domestically located industries production and sale of products covered by biodiversity-based patents and know-how. According to such scheme, should the patent owner refuse either to produce locally or to appoint a local licensee of its choice, the biodiversity providing country could grant a *compulsory license*, which, according to TRIPS rules¹⁸ should be non- exclusive, non – discriminatory, based on fair terms (fair, of course, *also* to the provider country in view of its essential contribution to the developed innovation). Moreover, such licence should fundamentally focus on the supply of *that* local market — thus excluding, if not marginally, any export activities of the licensee¹⁹.

May I shortly anticipate a rather obvious reflection, which I will articulate in next paragraph? The hypothesis just formulated—the adoption, by the biodiversity providing DC, of a set of measures whereby the patentee is required to work the new products locally, and only in default of such working is subject to a compulsory license, expresses not a unilateral view of DCs' interests, but rather a reasonable *compromise* with ICs' interests, in that that it safeguards IPRs-linked competitive advantage more than the straightforward imposition of a compulsory license.

V. Article 27.1 TRIPS repeals "local working requirement" for patent protection - not a real obstacle to the proposed solution

The outlined proposal, aimed to grant truly "fair and equitable sharing" of the results and benefits— of *all* kinds— related to industrial exploitation of biodiversity, might be rejected as apparently inconsistent with the wide, although still debated, recognition that the TRIPS (as well as the

16. Art. 8.1; emphasis added; see also, Art. 7.

17. See, Art. 31 ("Other Use Without Authorization of the Right Holder"): a provision which should be read in the light of aforesaid Arts.8.1. and 7. Carlos M. Correa, *Intellectual Property Rights, the WTO and Developing Countries* (2000); see also, B. Remiche & H. Desterbeq, "BREVET ET GATT: quel intere^t?" *Rev. droit intellectuel-L'ingenieur-conseil* 81, at 94 (1996); IIDD, "Les brevets pharmaceutiques dans les accords du GATT:l'enjeu?" *Rev.int.dr.econ.* 7, at 43-46 (1996).

18. See, Art.31.

19. Art.31 (6).

subsequently amended national patent laws) has repealed the long-time established principle of “local working requirement” for patent protection at national level, i.e., the duty to produce the patented goods in the country where patent protection is sought²⁰.

I will discuss this objection on the “toughest” ground, so to say, for a supporter of that proposal, namely accepting, in principle, that the systemic coordination between Article 5A (.2) of Paris Convention (“incorporated bodily into the TRIPS agreement”²¹), by virtue of Article 2.1. TRIPS²² requires that default of local working of the patent cannot any longer be considered as an abuse *per se*. According to this (not universally shared) position, patentees—while retaining the right to manufacture, hence actual capability to implement the relevant know-how, in their own homeland or in any other country where they find most convenient to operate—would incur in a patent “abuse” as per Article 5 A.2. Paris (and thus to be subject to a compulsory licence according to same Article 5 A.2.) *only* if they should not provide, even by mere export, “enough” products to the country where they hold the patent—including the biodiversity providing country.

At this point, it would seem that no legal means—aside from a rather “expropriatory” Government use” (Article 31,1st al)—nor legal argument could prevent that the IC’s patentees validly impose to (*pardon*, agree with) the DC rural communities, under a party-to-party private Agreement, just a monetary compensation, denying the DC any participation to the industrial development of the innovative products realized, thanks to the biodiversity its people preserved and provided, and thus dealing same biodiversity providing country as a simple territory of import.

And obviously, if it were so, it would be vain to observe that, however officially justified under the ennobling tag of anti-protectionism, an across-the-board application of Article 27.1 of TRIPS would in fact allow the IC, holders of the relevant patents, to replicate (renew) *the typical colonial scheme of trade*, whereby the developing country “exports” its “raw materials”, and the industrialized countries “returns” their finished goods. A trade-off, of course, that—let aside any other considerations,²³ would substantially delay

20. See, Art. 27.1.

21. J.H. Reichman & C. Hasenzahl, “Non-voluntary Licensing of Patented Inventions: Historical Perspective, Legal Framework Under the TRIPS Agreement, and an Overview of the Practice in Canada and the United States”, Draft, UNCTAD/ICTDS, II,C,2, text at Fn.62 (2002).

22. J. Straus, “Implications of the TRIPS Agreement in the Field of Patent Law”, in Beier-Schricker (eds.), *From GATT to TRIPS*, 18 *ICC Studies* 204 (1996).

23. Such as those related to employment (and thus, also to the development of a “working class” progressively conscious of its labour, and civil, rights) as well as to the traditionally strong price imbalance between DC “raw materials” and IC “finished products”.

the spreading and acquisition of industrial know-how amongst developing countries, and thus keeps same in a long-term condition of economic and technical dependence²⁴.

So what?, one might indeed reply. *Dura lex, sed lex(internationalis)*. But, as hinted, I do not think that the reference to Article 27.1 TRIPS, although impressive, “settles the question”—even accepting, as I said, those “harder” premises about the present meaning of Article 5 A. 2 Paris Union (i.e. after its “bodily incorporation” into the TRIPS, and its consequently necessary harmonization with same Article 27.1, even without turning to any “Government use” and/or to any “wiggle rooms”(“grey”) areas of the TRIPS, i.e. to the (much disputed) “gaps in TRIPS standards that provide developing countries with flexible compliance options”²⁵.

My argument is simply rooted in systemic logic, and is articulated as follows:

- (a) Article 31 TRIPS admits, although exceptionally (in view of the specific goals, and upon the specific conditions set therein) the direct, straightforward imposition of measures such as compulsory licenses, so heavily interfering with the fundamental patentees’ right to freely choose how to exploit their “monopoly”,
- (b) the provision of a working requirement intrinsically amounts to a *much less sensible “wound” to patentee’s exclusive right* than the blunt and straight provision of a compulsory license. Since the intensity of that “wound” must be appreciated *vis-a-vis* patentee’s competitive advantage, it seems self-evident that working the patent locally “on one’s own” (or through a local co-venturer/licensee of one’s own choice) would cause—in comparison with a straightforward imposition of a compulsory license directly “breeding” a future competitor—a more diluted and slow “leakage” of industrial and commercial know-how, and thus a less intense reduction of patentee’s “time lead” (as secured by the patent).

Therefore, if a) and b) are true, the consequence is that:

- (c) even (and indeed, *a fortiori*) Article 27.1 should be read, in coherence with the aforementioned rules, Articles 8.1, 7, 31 of TRIPS (and in consistency with Rio Convention, Articles 1,16,19), as the provision of a *general principle* which, even in default of an express (formal) reserve, can be exceptionally derogated when necessary in order to

24. See also, Vandana Shiva and Radha Holla-Bar, “Piracy by Patent: The Case of the Neem-Tree”, in Mander and Goldsmith (eds.), *The Case Against the Global Economy and For a Turn Toward the Local* 157 (San Francisco, 1996).

25. J.H. Reichman, *The TRIPS Agreement Comes of Age*, etc., cit. note 72 and accompanying text; *id.*, “From Free Riders to Fair Followers”, cit.12, 27-51, esp.36-39.

achieve the goals set by Article 8.1²⁶, and of course respecting the conditions set by Article 31: *especially so* — this is the core of my argument— where a *much less “intrusive”* set of measures, foreseeing compulsory licences only as *subordinate option vis-a-vis* patentee’s direct working of the invention in the biodiversity providing country, were introduced by such country, making use of the recalled faculties granted under Article 8.1 TRIPS (and under Rio Convention, Article 19).

May I stress, at the cost of repeating myself, that the hypothesis (proposal) outlined above does not violate Article 27.1 TRIPS *as expression of a general principle*. Indeed, the repeal of local working requirements would continue to cover *all other* countries, whereas the exception would concern *only* the biodiversity providing country.

VI. Toward a cooperative, not a confrontational approach

As for B), let me first of all restate that, for all the reasons (7) convincingly and extensively expressed by prominent scholars in addressing the subject of disputes between industrialized and developing countries in matters related to TRIPS rules in the field of Intellectual Property, I strongly share, even *vis-à-vis* the specific problem here discussed, the preference for a “cooperative” rather than “confrontational” approach.²⁷

Under such approach, in particular, possible conflicts arising from DC’s resolution to affirm local working requirements for biodiversity-based patents and to introduce, in default, compulsory licenses on same, and from opposition thereto from IC, should be first carried, for consultation and mediation, before the Council for TRIPS and the WTO Secretariat that services the former, and, if unsettled, eventually settled, under the rules and procedures set by the “Understanding on Rules and Procedures Governing the Settlement of Disputes” (DSU) by the *ad hoc* Panel and, ultimately, by the Appellate Body.

As far as our specific problem is concerned, such strategy appears the most suitable to encourage each party to achieve, on the basis of the legal argument put forth above, a settlement reasonably balanced and respectful of the aforementioned principles of international law.

On the one side, the DC would be guaranteed that the Agreements between its firms and those of the IC would effectively allow the biodiversity providing country to participate in—*really* “fair share”— the overall scientific, industrial and commercial— advancement that its people

26. See also, Remiche-Desterbeq, *BREVET ET GATT*, etc., cit.17, at 98.

27. See in particular, Jerome H. Reichman, “The TRIPS Agreement Comes of Age: Conflict or Cooperation with the Developing Countries?” *Case Western Reserve J of Int’l L* 441 (2000).

so decisively contributed to create. In this way, and only in this way, same country will get a chance to progressively “grow” its *own* R&D capacity and develop (even in view of the time when the patent will be elapsed) a domestic industry and a domestic trade of new biodiversity-based products and processes.

On the other side, substantial benefits could be secured also to the IC’s firms. In return, for accepting to have the innovative products manufactured *in situ*, they would enjoy, as “first choice”, the chance to work themselves their patents *in situ*—directly or through local licensees/ co-venturers of their choice—whereas the compulsory licence to third parties would remain in the backstage, as just the second option to be implemented *only in default* of the patent owner’s own working. Thus, the cooperative approach might avert—let aside discouraging an otherwise possible “free riding” approach by the DCs—that same DCs implement, as first and sole option, a compulsory licence in favour of other (competing) local—or pseudolocal—firms— or even “seize” the patent claiming “Government use”²⁸.

Second, within such “cooperative” framework, the IC firms could well be granted (let aside fiscal facilities, e.g., on its exports from the concerned country) the right to contractually impose to the local licensees/co-venturer of their choice, strict restraints (even beyond what dictated by Article 31(b), TRIPS), to export outside the biodiversity providing country without the patent holder’s authorization.

Third, but hopefully not less important for said IC firms, by accepting to abide to afore-quoted legal principles aimed to ensure a truly equitable sharing of biodiversity-based innovation, they would substantially improve their “social” corporate image, enhancing their own reputation and consensus even at international level. In times of (manifold) drops in corporate ethical image, this factor might provide a good “return”. And not a merely moral one, if it is true what many reputed economists believe: that a more pro-social, and thus more ethical image can accrue also to economic success, providing for a significant competitive advantage.

In its August 17, 2002, issue, page 11, *The Economist* observed, with regard to *corporate* ethics, that “Even in morality, the market rules—in the end”. I suggest to slightly reverse: “even in the market, morality helps—in the end”. (A wishful thinking?).

28. In such perspective, the compulsory licence would express its most useful, “virtual” role: that of a Damocles’ sword facilitating fair voluntary settlements; see also, W. Cornish, *Intellectual Property* 205 (London, 1989).