THE IU: TIME TO DRAW THE LINE ON IPRS

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Negotiations on the International Undertaking (IU) on Plant Genetic Resources for Food and Agriculture have reached a critical point. Without dramatic progress on key issues at the upcoming meeting in April, the Undertaking is likely to disappear from view once and for all. At stake is the world's access to a central component of biodiversity: the food that feeds us. In the final rounds of the negotiations, all parties must face up to the real issues that have been blocking progress for so many years: intellectual property rights and benefit sharing.

In the June 2000 issue of Seedling, GRAIN published an article on the renegotiation of the International Undertaking (IU) on Plant Genetic Resources for Food and Agriculture. The IU is a 20-year old voluntary agreement, implemented though the UN's Food and Agriculture Organisation (FAO), that aims to rewrite the rules of the North-South game with respect to the conservation, exchange, and benefits from the world's crop germplasm.

For too long the South's agricultural biodiversity has been flowing freely into the hands of the North, which then exploits it and patents it with no returns to the South. Several years ago, the IU was opened up for renegotiation in order to turn it into a legally-binding instrument and bring it in line with the Convention on Biological Diversity (CBD).

In the article "Last chance for an open access regime?" GRAIN argued that governments must take these negotiations much more seriously, because the world's crop gene pool is fast being privatised by corporations in countries that allow for monopoly rights on life forms. Such monopoly rights include patents and plant variety protection. Since then, a Contact Group of government representatives that carry out these negotiations has met three times: in August 2000 in Teheran (Iran), in November 2000 in Neûchatel (Switzerland), and in February 2001 in Rome (Italy). The meeting in Teheran made a good deal of progress on different fronts -- which fired people with enthusiasm -- but the one in Neûchatel almost caused a total breakdown of the talks over the controversial issues of sharing of the benefits from crop genetic resources and whether to allow property rights over them. The most recent meeting in Rome did move the process forward -- albeit in slow motion -- but it did so by avoiding a lot of the contentious articles and issues.

The next meeting of the Contact Group is now set for late April in Spoleto (Italy). Most observers now concur that unless agreement on a number of core issues is reached there, the negotiations will grind to a halt. This will mean that the chance to set up a multilateral system for that part of the world's biodiversity that feeds us -- the genes in crops and other food plants -- will vanish. But if countries do come to some common understanding during that session, then the expectations are that a new Undertaking could be agreed upon before the year is over.

The central aim of the negotiations is to establish a multilateral system in which as many countries as possible agree to common rules on conservation, exchange and benefit sharing in relation to crop genetic resources. The most important and controversial question on the table is whether and to what extent the international community should allow intellectual property rights (IPRs) on the crop genetic resources included in the system. To many observers, the answer seems obvious. If the main objective of the Undertaking is to enable the free flow of crop germplasm -- which all parties agree is central for any agricultural development and crop improvement efforts -- then a clear ban on IPRs should not even be questioned. The very nature of IPRs, which are exclusive commercial monopoly rights, limits access to genetic resources when applied to life forms.

But inevitably, pressures from various quarters make the equation more complicated. Industrialised countries are keen to keep patent options wide open, for the benefit of their biotech and breeding corporations. Their message to the South basically boils down to: "Please don't limit our access to your rich biodiversity for the benefit of humanity. But we reserve the right to patent and monopolise it whenever an interesting commercial application appears in our labs."

The other hot issue is the question of how to share the benefits generated through the commercial use of the materials covered by the IU. An agreement was reached in principle last year that holders of patents on "new" crop varieties and other plant material developed as a result of facilitated access to the system's germplasm should pay back some "equitable royalty" to the international community. This proposal actually came from the industry association ASSINSEL (International Association of Plant Breeders). On the surface, it might seem like a fair thing to do: to ensure that part of the profits that the North makes on the South's germplasm flow back to the South. But there is a lethal trap built into this scheme. Money will only come out of it if all countries accept the principle of IPRs on life. The more patenting, industry says, the more financial benefit. The countries that are echoing this position in the IU negotiations are actually advocating a strategy which will reduce access to biodiversity for everybody. This defeats the very objective of the IU. What is often forgotten in the FAO talks is that by allowing -- promoting, in fact -- the patenting of crop germplasm covered by the IU, a steadily increasing flow of valuable material will actually leave the multilateral system to become the private intellectual property of a few powerful corporations. This is the very gene-drain from the public to the private sectors that the IU negotiations are meant to reverse.

No IPRs has to be the bottom line. Clear boundaries must be drawn to ensure that intellectual property rights cannot be exercised on the genetic resources covered by the IU. Resolution of this issue lays the cornerstone which the remainder of the negotiations rest upon. The key is the Undertaking's Article 13, which regulates access to the genetic materials covered by the system. At present, governments are contemplating several possibilities for this critical article:

(1) There should be no intellectual property or other restrictive rights on the plant genetic resources in the form received from the Multilateral System. This is the language a

number of industrialised countries are pushing, but is generally recognised as a non-starter, empty of any substance. Any material received from the system could not be protected as such by IPRs anyway -- since the material would not be new -- so this wording would not restrict IPRs at all.

(2) There should be no intellectual property or other restrictive rights on the materials in the form received from the Multilateral System or on their parts and components. This adds some substance. It extends the proposed limitation on IPRs beyond the materials as such to their genes, cells, tissues, etc. However, it still retains the “in the form received” qualifier. Under this construction, if breeders develop new materials from the germplasm received, it would arbitrarily be left to each country to permit IPRs on that material or not, depending on national legislation. This leaves a lot of loopholes, especially as patent offices in some industrialised countries regard the mere act of isolating and purifying a gene as the production of “new” material. It also raises the question of how to ensure that such IPR-protected "new” material remains part of the IU and bound to the facilitated access rules.

(3) There should be no intellectual property or other restrictive rights on the materials received from the Multilateral System, or on their parts and components. The difference here from the previous option is that the qualifier "in the form received" is deleted. In this scenario, any of the germplasm or its parts is clearly marked “hands off!” with respect to IPRs. This is the most reasonable and clear cut construction, because it means that breeding of basic food crops can continue freely throughout the world, with no threats, blockages, extra costs or legal headaches generated by lawyers. It would not ban all plant patenting, as the IU will only cover a limited number of crops. But it would effectively establish an IPR-free zone for the most important food crops.

Governments have to agree on some construction within this span of principles ranging from “all IPR” to “no IPR” as soon as possible. It is common knowledge that IPRs restrict access to genetic resources and undermine the central role of public institutions and local farmers in crop improvement. If they are allowed to be exercised with no restriction on the multilateral pool of germplasm, then the IU has little to contribute -- and probably no real reason to exist. If, on the other hand, the negotiators have the wisdom and courage to look beyond the short-term interests of a few, agree on a multilateral system that is free from monopoly rights and which promotes the conservation and improvement of crop germplasm by all actors, then they will create a valuable instrument for food security at all levels, now and in the future.

The importance of the successful conclusion of the IU renegotiation -- and the need to pressure governments for the best deal for agriculture and plant breeding worldwide (all plant breeding by all actors, not only genetic engineering by a few companies) -- cannot be exaggerated. At stake is the world’s access to a central component of biodiversity: the part that feeds us.

GOING FURTHER

GRAIN, "Last chance for an open access regime?", Seedling, June 2000. http://www.grain.org/publications/jun00/jun001.htm

RAFI, "The Other BioSafety Protocol", GenoType, 20 February 2001. RAFI regularly follows the IU negotiations and produces briefing materials that can be found on their website. http://www.rafi.org

The International Institute for Sustainable Development reports in journalistic fashion from the scene of the IU negotiating sessions. http://www.iisd.ca/biodiv/iu.html

The UK Agricultural Biodiversity Coalition is also actively involved in making press and campaign materials about the IU negotiations available on their website. http://www.ukabc.org/iu2.htm

Official papers from the negotiations are available from the website of the FAO Commission on Plant Genetic Resources for Food and Agriculture. http://www.fao.org/ag/cgrfa/IU.htm

The renegotiation of the International Undertaking on PGRFA

Some observations on the interface between the Multilateral System and IPRs

(by Genetic Resources Action International, January 2001)

Introduction

Together with an increasing number of other NGOs, GRAIN has monitored, participated in, and contributed to. the renegotiation of the International Undertaking. In June 2000, we published an article in which the negotiations towards a new Undertaking were analysed and in which several proposals were made to achieve a strong international instrument that truly benefits the sustainable and equitable conservation and management of PGRFA[1].

GRAIN remains committed to the successful conclusion of these negotiations. As the process of the renegotiation is now reaching a critical phase, we take the liberty to offer a few observations to delegations meeting at the 5th session of the IU Contact Group from 5 to 9 February.

Towards facilitated access by all

In our judgment, agreement on the design of the Multilateral System for access and benefit sharing is the key to the overall success of the renegotiation. The key to success with the Multilateral System, in turn, is agreement on the interface between IPR protection and the facilitated access mechanism envisaged.

It must be recognised that while most prospective Parties are now bound by the TRIPS agreement, national legislations have very different approaches to IPR protection of plant material. A solid majority of developing countries are striving to limit proprietary control over PGRFA as much as possible. Typically, they exclude plant varieties for patent coverage, offering instead some kind of sui generis protection for plant varieties. In some cases, Farmers Rights or broader Community Rights are being incorporated in legislation in order to balance the different rights

[1] GRAIN, *'Last chance for an open access regime?'*, in: 'Seedling', June 2000, Barcelona. Available at: http://www.grain.org/publications/jun00/jun001.htm

systems and provide for more appropriate management and use of PGRFA at the national and local levels.

Most developed countries have opted, in contrast, to maximise proprietary control over PGRFA. Most of them exercise today a combination of plant variety protection under UPOV and industrial patents on PGRFA parts and components, on breeding tools, techniques and processes, and on plants and varieties as such.

Consequently, the real challenge for the Undertaking negotiation is that it needs to design the Multilateral System to be compatible with *all* these very different national situations. Saying that facilitated access needs to take place "in accordance with applicable property regimes" (Montreux Chairman's Elements) or "be consistent with national law" (present draft) implies compatibility both with those national regimes which permit a high level of exclusive IPRs on plants, and with those which do not.

To succeed in this, we feel that the Contact Group needs to consider more in depth the following 4 points.

1. No limitations of coverage

The basis of the Multilateral System must be a mutual commitment to provide facilitated access to all material of the covered crops in a coherent fashion, regardless of whether a Party has opted for a high level of proprietary control or not. There is a need to clarify that the commitment will indeed apply to all material in the jurisdiction of each Party, whether held by public or private entities, and whether covered by IPRs or not.

Our impression is that delegations still have highly diverging understandings of how the System would operate in this respect. Some for example appear to envisage a general exemption for patented materials, so that whenever a plant breeding product would incorporate components under patent protection, facilitated access rules would cease to apply. Others seem to presuppose a mechanism of 'designation', similar to that used to identify what parts of CGIAR collections fall under the trusteeship agreement with FAO, which would allow Parties to unilaterally decide to exempt any amount of material from coverage.

Obviously, in both cases, the mutual character of the Multilateral System would be lost and there would effectively be no reliable commitments made by Parties.

Excluding patented materials from the System, while at the same time requiring biodiversity-rich countries to make their non-patented diversity condition to the 'facilitated access' rules, would be totally unfair and inequitable.

Regarding 'designation', our impression is that a false analogy is drawn between the CGIAR/FAO agreement and the Undertaking. What seems to be overlooked is that the former is a voluntary agreement by a group of private institutes to put a specific number of *ex-situ* collections under oversight of the FAO. The Undertaking will be of a entirely different character and magnitude. We are speaking about a legally binding treaty whereby governments will agree to mutually reduce barriers to PGRFA exchange on all the major food crops in their entirety. A 'designation' procedure is reasonable in the first case, but entirely unacceptable in the second, simply because it would remove the very basis of agreement, the mutual commitment.

2. No IPRs on materials received

It must be made clear that IPRs can under no circumstances be claimed by a Party or an other recipient on the materials received from the Multilateral System, including any genetic parts and components isolated from such material. It must be emphasized that if the restriction is not extended to genetic parts and components, it will be entirely ineffectual and allow unlimited privatisation of material that is being shared through the System.

Because existing intellectual property treaties, including the TRIPS agreement, do not establish any minimum standards either for novelty or inventive step in patent applications, it is important that the Undertaking clearly spell out what should apply in the Multilateral System. Present jurisprudence in some industrialised countries is extremely liberal and allows, for example, patents on genetic material without any requirement for technical intervention except the isolation of a gene with standard industry methods. This is in fact the legal background to a very large part of biopiracy cases involving PGRFA. If no safeguards are included in the Undertaking, it will in fact condone such practices and give them status of international law.

The Undertaking at the very least needs to make a unequivocal distinction between the materials received from the System, and new materials developed on the basis of those received. To the extent that a recipient adds new work to a material received, it is up to the legislation of the individual Party to decide whether IPR protection covering that new addition may be warranted. This falls outside the scope of the Undertaking. What must be regulated by the Undertaking, however, is that such protection must never extend to the material originally received, no matter whether it is left in its natural state or broken down into its genetic components. For example, if a seed sample is received, and a gene isolated, which is then incorporated into a new variety, it would be up to the individual Party whether this new variety could be the subject of an IPR, and possibly also the use of the gene in that particular context. But under no circumstances should the gene as such be covered by IPR, as it was already present in the material received.

3. Availability of IPR-protected materials

When IPRs are granted on any material of the covered crops there will be a need for special mechanisms to ensure its availability in the Multilateral System.

With UPOV-type PBR protection, availability for the purposes of the System may not be an insurmountable problem, as the protection does not extend to the genetic makeup of the varieties and there is a general, although restricted, research exemption. There may however be cases, for example in farm-based breeding, where restrictions on replanting will indirectly block research.

Patent protection, however, will in most national legislations block all research and development use without the consent of the patent holder. This is in direct contradiction with the basic access requirements of the Multilateral System. Thus there is a need for an mechanism to ensure compliance in those cases. In effect, the Undertaking must demand that Parties in some way provide a research exemption whenever patents are obtained on PGRFA covered by the System.

It can be noted that the EU, in its Directive on protection of biotechnological inventions, has provided possible models for this by introducing two types of ad hoc measures for very similar purposes. One is a general limitation in the coverage of plant and animal patents to allow on-farm reproduction of the patented organisms. The other is a provision for compulsory cross-licensing between PBR and patent holders in cases where one cannot exercise his rights without infringing those of the other.

It should perhaps also be emphasized that this in no way implies that other rights of the IPR-holder would be restricted. The right to economic compensation if and when new research results in a new commercial product would remain. But not the right to block that research, nor to block the commercialisation of its results.

4. Relation to commercial benefit sharing

The question has legitimately been raised what is the rationale for the royalty payments foreseen in 14.2.d(iv), and what is the relation between those provisions and those limiting IPRs in Article 13. Some have argued that there would be a contradiction between the two Articles.

In our view, the royalty payments should be seen as a compensation to the Multilateral System for private gains realised from commercial products developed on the basis of materials received from the System. The facilitated access offered by all Parties will be an important contribution to those commercial benefits, and some proportion should flow back to the collective providing that access.

As drafted, the royalty system is roughly proportionate to the level of IPR protection granted. It is mandatory where license payments are required on the genetic material as such (patents). It is recommended where license payments are only required on propagation material (PBR). It is zero if the product is put in the public domain or license payments waivered.

The relation between this royalty system and the limits to IPRs in Article 13 is as far as we can see non-existent. What is excluded in Article 13 are IPRs on the material received from the System. What forms the basis for royalty payments in Article 14 are the IPRs granted on new materials developed on the basis of material received. As long as this distinction is upheld, we can see no interference or contradiction.

Conclusion

GRAIN remains committed to contributing to the success of the Undertaking renegotiation. We feel that the negotiation, although difficult, holds the promise of creating the first large-scale implementation of the access and benefit-sharing principles set down in the CBD. Success with the Undertaking would provide an important example for upcoming discussions of benefit-sharing in several other fields of biodiversity.

Yet, unless the fundamental concerns outlined above are fully addressed, we could not recommend any developing country to sign a revised Undertaking. Indeed, it is

doubtful whether an Undertaking failing on these points would even be in the best interest of most developed countries.

If clear lines cannot be drawn limiting the extent to which IPRs can be used in conjunction with facilitated access under the Multilateral System, the Undertaking will in fact constitute a blank check, a license for private interests to gradually appropriate public domain PGRFA, until nothing of value remains. This scenario should be equally worrisome for public research institutions and gene banks in the North as for the governments of the South.

This Paper was drawn up by Genetic Resources Action International (GRAIN) as a contribution to the negotiations on the revision of the International Undertaking on PGRFA.

GRAIN is an international NGO that promotes the sustainable management and use of agricultural biodiversity based on people's control over genetic resources and local diversity.

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