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NEW VARIETIES OF PLANTS

**WIPO-UPOV SYMPOSIUM ON
INTELLECTUAL PROPERTY RIGHTS
IN PLANT BIOTECHNOLOGY**

organized by
the World Intellectual Property Organization (WIPO)
and
the International Union for the Protection of
New Varieties of Plants (UPOV)

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PLANT BIOTECHNOLOGY DEVELOPMENTS IN
THE INTERNATIONAL FRAMEWORK

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It is my great pleasure to join Ambassador Jara in welcoming you here this morning on behalf of Dr. Kamil Idris, in his capacity as Director General of WIPO.

WIPO is delighted to be co-hosting this Conference today. For us, it represents an opportunity to explore some of the complex issues relating to intellectual property in the context of plant biotechnology. I share Ambassador Jara's trepidation in approaching these issues, not only because they are inherently complex, but also because, I think it is fair to say, they have developed, at least on the international stage, in a way that leaves much to be desired in terms of the clarity with which the issues have been defined and the relationship of the issues to each other and to other areas of public policy.

For WIPO, plant biotechnology evokes first and foremost the patent system. It may be noted at the outset that, throughout its evolution over the last several hundred years, the patent system has applied in essentially the same way, more or less without exception, to all forms of technology. It is unlike copyright, where there are often technology-specific provisions and sectoral- or industry-specific provisions. It is also unlike plant variety protection, which is limited to a specific subject matter. In view of the technology-neutral evolution of the patent system, does the area of plant biotechnology raise any special questions that require specific attention and a deviation from the general rule of neutrality to technology or sector? The main currents of discussion internationally suggest that there are four such issues and I should like to touch on each of them in outline.

The first of the issues is the well-known question of the availability of protection in this area, an issue which is regulated by Article 27 of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) and, more specifically, by Article 27.3(b). This issue is being reviewed in the TRIPs Council and also received a considerable amount of attention in the WIPO-UPOV Conference held one year ago. Article 27.3(b) leaves a large measure of choice to national systems. Various models are possible at the national level. Plants may be excluded from patent protection, but some form of incentive for innovation must be provided specifically in relation to plant varieties, whether that be through patents or through *sui generis* plant variety protection. What seems apparent in relation to the choice available under Article 27.3(b) is that there is a need for more empirical data on the results obtained from the application of different models at the national level, including data on

which models seem to be successful and which, if any, seem to generate problems and for what reasons.

Moving from the question of the availability of protection, a second issue that has generated considerable discussion internationally is the different approaches of the patent system, on one hand, and plant variety protection, on the other hand, to the availability of germ-plasm that may be covered by those rights. The patent system tends to take a relatively narrow approach to this question, and allows only a limited exception for the purposes of research, which is, as a general rule, construed narrowly¹. On the other hand, the plant variety protection system under the UPOV Convention takes a broader approach to the question and allows a wider range of activity in the interests of experimentation, breeding of other varieties and the use of farm-saved seeds for propagating purposes². But these exemptions and these two approaches are situated in the context of completely different systems. In the case of the patent exemption, it applies to a conceptually non-obvious result. The patent right does not withdraw any existing germ-plasm from use. What is withdrawn from use is germ-plasm that has been the subject of a conceptually non-obvious modification or application. Plant variety protection, on the other hand, is directed to what are, arguably, well-known or obvious techniques, where the nature of the innovation is more incremental and builds more upon the basis of preceding varieties. The level of the innovation warrants a proprietary right that is less extensive.

Does this difference in approach to the operation of the research or experimentation and breeding exceptions matter? In general, there are two responses given to this question around the world. One response, which is to be found to some extent in the European Directive on the Legal Protection of Biotechnological Inventions³, seeks to compensate for the narrowness of the patent research exception by making available a compulsory licence of the patent “where a breeder cannot acquire or exploit a plant variety without infringing a prior patent”. The other response eschews regulation of the relationship between the two sorts of rights and their differences and leaves the interface between the rights to be determined by the market,

¹ See, as one example of an approach to the research exemption at the national level, *Madey v Duke Univ.*, 307 F.3d 1351 (Fed. Cir. 2002), cert. denied 156 L.Ed.2d 656 (2003).

² See Article 15, International Convention for the Protection of New Varieties of Plants (“the UPOV Convention”) (1991 Act).

³ See Article 12 of Directive 98/44/EC of 6 July 1998 on the Legal Protection of Biotechnological Inventions

notably by leaving it to economic agents to negotiate access to dependent or associated rights through voluntary licences. Licensing practices are, in most countries, subject to regulation in the event of abuse of dominant position through antitrust or anti-competitive practice legislation.

The market approach and market mechanisms have the obvious advantage of not being industry- or technology-specific in approach. In this regard, it is pertinent to recall that the quantity of technology dealt with by the patent system is of a completely different order to the quantity of technology that is dealt with by the plant variety protection system. In 1999, for example, there were 4.37 million patents in force around the world, according to the Trilateral Statistical Report⁴. That is a number that is of a completely different order to the number of plant varieties, which I think you will find is more in the vicinity of 50,000 titles in force at any given time, and naturally so, since the patent system applies to all technologies. In similar fashion, the number of patent applications worldwide in the year 2000 represented about 750,000 new inventions (measured by first filings). In view of the magnitude of economic activity represented by patent applications, one needs to exercise the greatest of care before creating specific regulations related to one particular sector or technology.

A third area that has incited considerable attention internationally is the cluster of issues that are related to access to genetic resources and benefit-sharing. These issues are not limited to plant genetic resources, but they have a major application to plant genetic resources.

The first thing that needs to be said about this area is that access to genetic resources is first and foremost a question of physical property. Any regulatory attention, whether of a legislative or an administrative nature, given to the question should in the first place address the question of physical property and physical access. How do intellectual property rights come into the question at all? Well, they become relevant as a consequence of the use of genetic resources to which access has, or may have, been granted. That use may give rise to an invention that is susceptible of protection by an intellectual property right.

Three main questions have been discussed internationally in connection with intellectual property and access to genetic resources. The first of those is whether there

should be a sharing of benefits by the owner of an intellectual property right in respect of that right if it involves or is based upon genetic resources to which access has been given? The Convention on Biological Diversity (CBD) has provisions that require Contracting Parties to “take legislative, administrative or policy measures, as appropriate, ... with the aim 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.”⁵ On the basis of the work of the Ad Hoc Open-ended Working Group on Access and Benefit-sharing, the Conference of Parties of the CBD adopted the Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization.⁶ A Second Meeting of the Working Group will take place in December 2003. While the issues are complex, it is apparent that it is very short-sighted to regard intellectual property as a form of plunder of genetic resources. It is, because of licensing, in fact an efficient mechanism for returning benefit to the owner of genetic resources.

A second question that arises in this context is whether intellectual property rights that might be acquired with the use of genetic resources to which access has been given limit the further use of those genetic resources in a way that is harmful to public policy? This is a question that is, in particular, being considered in the context of the International Treaty on Plant Genetic Resources for Food and Agriculture of the Food and Agriculture Organization of the United Nations (FAO) and the development of the material transfer agreement for the purposes of that treaty. This work is just underway.

A final question in this area is whether the intellectual property system, in general, or the patent system, in particular, is a useful instrument for implementing the policy of legal access to genetic resources? This is the well-known question of disclosure of the origin of genetic resources used in an invention. Should there be a provision in patent law that would require the disclosure of the source or origin of any genetic resources that are used in an invention for which patent protection is applied and, if so, what is the nature of this requirement and what is the nature of any legal remedy that might be applied in the event that the requirement is not complied with? It is very important to contextualise these questions.

⁴ Trilateral Statistical Report 2000 available at <http://www.uspto.gov/web/tws/sr-2.htm>

⁵ Article 15.7, Convention on Biological Diversity

They are not questions of patent law, but questions of genetic resource policy. At the request of the CBD, formulated in the Bonn Guidelines⁷, WIPO prepared a technical study⁸ on various issues related to the patent system and the policy of legal access to genetic resources, which has now been approved by the Member States of WIPO for transmission to the next Conference of Parties of the CBD.

There is a final area. It would be very remiss of me not to mention a fourth issue which, like most of these issues, is related to, but not exclusively concerned with, plant biotechnology. It is the question of traditional knowledge. Traditional knowledge can and does exist in relation to plant genetic resources as it exists in other domains and spheres. At WIPO, the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC) has been considering this question very carefully. Recently, the WIPO General Assembly decided to extend the mandate of the IGC. It decided that the IGC's work should continue on all issues, including genetic resources, that have been before the Committee and that its work should focus in the future, in particular, on the international dimension of these questions. It further decided that no outcome should be excluded for the work of this Committee. The IGC next meets in March 2004 and its work program over the next two years is expected to be solid and vigorously pursued.

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⁶ Decision VI/24

⁷ "The Conference of Parties

...

4. Invites the World Intellectual Property Organization to prepare a technical study, and to report its findings to the Conference of the Parties at its seventh meeting, on methods consistent with obligations in treaties administered by the World Intellectual Property Organization for requiring the disclosure within patent applications of, *inter alia*:
- a. Genetic resources utilized in the development of the claimed inventions;
 - b. The country of origin of genetic resources utilized in the claimed inventions;
 - c. Associated traditional knowledge, innovations and practices utilized in the development of the claimed inventions;
 - d. The source of associated traditional knowledge, innovations and practices; and
 - e. Evidence of prior informed consent."

⁸ Draft Technical Study on Disclosure Requirements related to Genetic Resources and Traditional Knowledge (document WO/GA/30/7Add.1) available at http://www.wipo.int/documents/en/document/govbody/wo_gb_ga/index_30.htm.

