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INVENTIONS IN CONNECTION WITH BIOLOGICAL MATERIAL - AN ABSTRACT FROM THE INTERNATIONAL PERSPECTIVE

A) INTRODUCTION

The issue of whether inventions in connection with biological material are capable of being protected by registrable rights has been subject to extensive controversy and continues to be so today. The law in this field is extremely diversified - to a certain extent even confusing - and contains numerous international treaties and legislative instruments.

This is not only due to the fact that inventions in connection with biological material have been subject to extensive ethic, moral and philosophical controversies worldwide; many commentators and experts are of the opinion that such controversies are to a certain extent futile, since too many political and social factions have been extensively involved. It is also the result of multinational and regional treaties and regulations which have all added to the already complex and somewhat obscure subject matter.

Therefore, the following article will try to shed some light on the most striking aspects of the protection of ideas that consist of or contain biological material and to take a short look at some issues of exploitation. The headings of this article follow the structure of legislative instruments governing the subject matter which may be arranged as follows:

Biotechnological inventions are, with significant exceptions, generally patentable if they fulfill the general criteria for patentability. Although patents are the main form of protection for ideas in connection with biological material, patent law is not the main subject of this article and shall therefore not be considered here in detail. Animal and plant varieties are exempt form protection by patent law, whereas plant varieties are, under certain circumstances, protectable by *sui generis* rights.

B) BIOTECHNOLOGICAL INVENTIONS

I. International influences on the protectable subject matter

1. The TRIPS Agreement

On the international level, the Agreement on Trade-related Aspects of Intellectual Property Rights (the "**TRIPS Agreement**") requires all member states of the WTO to introduce minimum levels of protection for inventions with respect to biological material. Since many of the more notable jurisdictions in the world (in terms of the size of their economies) are party to the WTO, the TRIPS Agreement is the single most important international legislation governing this issue.

Pursuant to Art. 27 Subs. 3 (b) of the TRIPS Agreement, member states may exclude from patentability plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and

microbiological processes. As we will see later, the EU has made use of the possibility to exclude animal and plant varieties and essentially biological processes. However, member states shall provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof.

The converse of the above approach is that micro-organisms and non-biological (i.e. technical) and microbiological processes are patentable. The issue of what biological material and microbiological processes are shall be discussed below under the Biotechnology Directive which applies to EU Member States only.

Another factor that may influence the protection of biological subject matter by patent law is the exclusion of diagnostic, therapeutic, and surgical methods for the treatment of humans or animals from patentability (Art. 27 Subs. 3 (b) of the TRIPS Agreement). National courts are obliged to properly construe this provision which provides room for a wide range of interpretations. UK courts, for instance, have held that only methods of *direct* treatment of the human or animal body are exempted from patentability.

2. The Paris Convention

The Paris Convention for the Protection of Industrial Property (the "**Paris Convention**") is another piece of international legislation governing some aspects of biological inventions. It protects and applies to industrial property, i.e. patents, utility models, industrial designs, trademarks, service marks, etc. In this context, the Paris Convention affects patents in connection with biological subject matter in its member states; it does not affect plant or animal varieties.

Among other regulations, it provides for national treatment, i.e. a member state to the Paris Convention must offer the same protection to the nationals of other member states as it gives to its own nationals. Additionally, the Paris Convention contains a provision with respect to the priority date, i.e. an application for a patent in one member state shall not prejudice later applications in other member states. Therefore, the later application is to be treated as having the priority date of the earlier one in the other member state. Unlike the TRIPS Agreement, the Paris Convention does not provide for a minimum protection of inventions in connection with biological material and has therefore little impact upon the subject matter of inventions.

II. Regional influences

1. The Biotechnology Directive

EU legislation affects the protection of biotechnological inventions by Directive 98/44/EC of 6 July 1998 on the legal protection of biotechnological inventions (the "**Biotechnology Directive**") and the respective national laws transposing its provisions into national law. The Biotechnology Directive governs the patentability (to be more precise: the subject matter) and scope of protection of biotechnological inventions. It introduces special defenses and compulsory and cross licenses, but does not alter the basic requirements of patentability, namely novelty, inventive step and industrial application. These are governed by the European Patent Convention (outlined below) and by national laws.

Art. 1 of the Biotechnology Directive provides that EU Member States protect biotechnological inventions under national patent law. The notion of "biotechnological invention" is not defined in the Biotechnology Directive itself. Art. 3 of the Directive, however, sets out that for the purposes of the Biotechnology Directive, inventions which are new, involve an inventive step and are susceptible of industrial application shall be patentable even if they concern a product consisting of or containing biological material or a process by means of which biological material is produced, processed or used.

In reference to the above, "biological material" under Art. 2 of the Biotechnology Directive means any material containing genetic information and capable of reproducing itself or being reproduced in a biological system. "Microbiological process" means any process involving or performed upon or resulting in microbiological material. A process for the production of plants or animals is essentially biological (and therefore not patentable) if it consists entirely of natural phenomena such as crossing or selection.

It is understood that genetic manipulation, for example, is a technical process and genetically modified plants and animals may - without prejudice to the principles of immorality of inventions which shall not be discussed at this stage - demand patentability, as arguably most of the research carried out in relation to biological subject matter involves a degree of human intervention and is therefore technical in nature. This is subject to the proviso that plant varieties which were obtained by way of genetic engineering are not patentable. Recital 32 of the Biotechnology Directive sets forth that "if an invention consists only in genetically modifying a particular plant variety, and if a new plant variety is bred, it will still be excluded from patentability even if the genetic modification is the result not of an essentially biological process but of a biotechnological process".

It should be noted that biological material which is isolated from its natural environment or produced by means of a technical process may be the subject of an invention (and therefore patentable) even if it has previously occurred in nature. Essentially biological processes for the production of plants or animals and the human body, at the various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene, cannot constitute patentable inventions.

2. The European Patent Convention

It is important to stress that the European Patent Convention 1973 (the "**EPC 1973**") is an intergovernmental treaty that is distinct from the European Community and that its membership extends beyond members of the EU. Therefore, its applicability extends well beyond the borders of the EU. It is basically concerned with the grant, validity and preconditions of patents, the entitlement to European patents and procedural matters with respect to the application for and grant of European patents, whereas matters of infringement, enforcement, revocation, renewal and litigation are governed by national law.

National laws in turn have been brought in line with the EPC 1973 which sets out, among other things, the basic substantive rules of patentability of inventions, i.e. novelty, inventive step and industrial applicability and which contains some provisions with respect to the exclusion of certain subject matter from patentability. The substantive rules of

patentability are not the subject of this article and shall not be considered here in detail. It should be noted, however, that the patentable subject matter with respect to biological material has been modified by the TRIPS Agreement and the Biotechnology Directive, as described above, in their respective member states. Duration of all patents granted by the EPC 1973 is 20 years as of the date of application.

The EPC 1973 has been reformed by way of a new Convention (the "**EPC 2000**") which has not yet come into force, but will do so by December 31, 2007 at the latest. The EPC 2000 will not change existing patent law substantially; in fact there will be only marginal changes to the language of the EPC 1973, but virtually no amendments of substantive provisions, especially with respect to biological inventions. The provision governing patentable inventions (Art. 52 (2) EPC 2000), for example, adds a new phrase which reads "*European patents shall be granted for any inventions, in all fields of technology*…", without bringing any changes on patentable subject matter.

One issue that warrants attention here is that Art. 52 (4) EPC 1973 sets out that methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practiced on the human or animal body lack industrial applicability and are as such excluded from patentability. By contrast, Art. 53 (c) EPC 2000 takes a more direct approach: it simply says that such methods are excluded from patentability.

3. Exploitation of IP rights and its limitation

The EC Treaty is another piece of legislation which may impact inventions in connection with biological material. Most importantly, Art. 81 (1) EC contains competition provisions which may limit the exploitation of IP rights, in this case patents, if such exploitation consists of agreements between undertakings which may affect trade between EU Member States and which have as their object or effect the prevention, restriction or distortion of competition within the common market.

On a general level, IP rights may be exploited by way of self-exploitation (i.e. the inventor manufactures and markets the product based on his invention himself), assignment, license and operation of law (e.g. upon death or insolvency). National and EC Competition law has generally assumed the role of limiting the exploitation of IP rights, since national and international IP legislation abandoned this role.

If we look at Art. 81 (1) EC, an anti-competitive agreement may come into existence where, for instance, the parties to a license agreement divide up the markets or sources of supply, fix purchase or selling prices or limit or control production, markets, technical development, or investment. However, a few block exemption regulations have been introduced by the EU in order to limit the scope of this article and to render the exploitation of IP rights somewhat more liberal.

The two most important block exemption regulations for this matter are Commission Regulation No 772/2004 (the "**Technology Transfer Regulation**") and Commission Regulation No 2790/1999 (the "**Vertical Restraints Regulation**"). The Technology Transfer Regulation applies to technology transfer agreements which are patent, know-how, software copyright or a mixed patent, know-how or software copyright licensing agreements.

Assignments of above mentioned rights can be technology transfer agreements as well if a part of the risk associated with the exploitation of the technology remains with the assignor.

Pursuant to the Technology Transfer Regulation, Art. 81 (1) EC does not apply to technology transfer agreements between two undertakings permitting the production of contract products in the following cases: if the undertakings party to the agreement are competing undertakings, the block exemption applies on condition that the combined market share of the parties does not exceed 20% on the affected relevant technology and product market. If, however, the undertakings party to the agreement are not competing undertakings, the block exemption applies on condition that the market share of each of the parties does not exceed 30% on the affected relevant technology and product market. The above mentioned exemptions are subject to the proviso that the agreement does not contain any hardcore restrictions (the so-called black list) or excluded restrictions (the so-called grey list which contains terms that may be permissible but need to be assessed on a case-by-case basis).

The Vertical Restraints Regulation applies to vertical agreements, i.e. agreements or concerted practices entered into between two or more undertakings each of which operates, for the purposes of the agreement, at a different level of the production or distribution chain, and relating to the conditions under which the parties may purchase, sell or resell certain goods or services. It also applies to vertical agreements containing provisions relating to the assignment to the buyer or use by the buyer of intellectual property rights, provided that those provisions do not constitute the primary object of such agreements and are directly related to the use, sale or resale of goods or services by the buyer or its customers.

The Vertical Restraints Regulation provides an exemption from Art. 81 (1) EC for vertical agreements if the market share held by the supplier does not exceed 30% of the relevant market on which it sells the contract goods or services. In the case of vertical agreements containing exclusive supply obligations (i.e. any direct or indirect obligation causing the supplier to sell the goods or services specified in the agreement only to one buyer inside the EU for the purposes of a specific use or for resale), it is the market share of the buyer that must not exceed the threshold of 30% of the relevant market on which it purchases the contract goods or services.

The Vertical Restraints Regulation contains a list of hardcore restrictions (just like the Technology Transfer Regulation) which must not be violated if the Vertical Restraints Regulation is to be applied. If none of the above Regulations apply, it does not mean that the agreement is automatically void; it simply means that Art. 81 (1) EC is fully applicable and the agreement has to be assessed against the criteria of Art. 81 (1) EC with the possible individual exemption under Art. 81 (3).

C) PLANT VARIETIES

The system of plant variety rights gives plant breeders protection of new plant varieties. Plant varieties are outside the scope of patent-based protection for various reasons: agriculture was long seen as a non-industrial activity and thus incapable of being protected by the patent law regime. As most breeds were obvious to persons skilled in the art, new ideas in connection with plant varieties lacked the inventive step required by patent law. Therefore, a *sui generis* system which suits the characteristics of plant varieties had to be introduced.

New ideas with respect to plant varieties are protected on the international, regional and national levels. On the international stage, plant varieties are protected by the International Convention for the Protection of New Varieties of Plants (the "**UPOV**"), the original version of which dates back to 1961. Council Regulation (EC) No. 2100/94 on Community Plant Variety Rights (the "**Plant Variety Regulation**") gives breeders the right to apply for a single Community-wide right for varieties which has uniform effect within the whole territory of the EU.

National laws, such as the UK Plant Varieties Act 1997, are not the subject of this article and shall not be considered here in detail. However, as all three regimes are on highly similar terms (and could therefore be discussed together) we shall concentrate on some aspects of the Plant Variety Regulation, unless specific circumstances warrant otherwise.

I. Subject matter

Pursuant to Art. 5 of the Plant Variety Regulation, varieties of all botanical genera and species, including, inter alia, hybrids between genera or species, may form the object of Community plant variety rights. A "variety" is defined as a plant grouping within a single botanical taxon (i.e. "group" of plants) of the lowest known rank, which grouping, irrespective of whether the conditions for the grant of a plant variety right are fully met, can be: (i) defined by the expression of the characteristics that results from a given genotype or combination of genotypes, (ii) distinguished from any other plant grouping by the expression of at least one of the said characteristics, and (iii) considered as a unit with regard to its suitability for being propagated unchanged.

II. Validity

Community plant variety rights shall be granted for varieties that are distinct, uniform, stable and new.

1. Novelty

Novelty is regulated by Art. 10 of the Plant Variety Regulation and is not as onerous as the novelty requirement in patent law. A variety shall be deemed to be new if, at the date of application, variety constituents or harvested material of the variety have not been sold or otherwise disposed of to others, by or with the consent of the breeder, for purposes of exploitation of the variety earlier than one year prior to the application, within the territory of the EU or earlier than four years outside the territory of the EU or, in the case of trees or of vines, earlier than six years prior to the application date.

It should be noted that novelty is not exhausted by prior use of the variety (e.g. sowing and growth), but only by prior sale or disposal for the purposes of exploitation of the variety. The substantial grace periods (which are unusual for other IP rights) also deserve mentioning. Thereby, a person can sell trees or vines up to six years outside the EU without prejudicing the variety's novelty. The phrase that the only disposals and sales to be taken into account are the ones made by the applicant means that sales made by third persons who have independently devised the same variety will not exhaust the variety's novelty.

2. Distinct, uniform and stable (sometimes referred to as the "DUS" or "agro-technical" requirements)

Under Art. 7 of the Plant Variety Regulation, a variety shall be deemed to be distinct if it is clearly distinguishable by reference to the expression of the characteristics that results from a particular genotype or combination of genotypes, from any other variety whose existence is a matter of common knowledge on the date of application. Thus a certain difference is required to bestow distinctiveness on a plant variety, whereby any difference will suffice, whether it be visible differences in outward appearance (e.g. height, size, color, etc.) or physiological differences in the plant variety's chemical or biological structure (e.g. resistance to disease, ability to withstand certain conditions, etc.).

Under Art. 8 of the Plant Variety Regulation, a variety shall be deemed to be uniform if, subject to the variation that may be expected from the particular features of its propagation, it is sufficiently uniform in the expression of those characteristics which are included in the examination for distinctness, as well as any others used for the variety description. Thus a variety has to be sufficiently uniform in those characteristics which make it stable, i.e. nearly all examples of the variety must bear the characteristics that make the plant distinct. Complete uniformity is not required, only a degree a capable breeder skilled in the art can reasonably be expected to achieve.

Stability is governed by Art. 9 of the Plant Variety Regulation which states that a variety shall be deemed to be stable if the expression of the characteristics which are included in the examination for distinctness as well as any others used for the variety description, remain unchanged after repeated propagation or, in the case of a particular cycle of propagation, at the end of each such cycle. In other words, a variety is stable if the characteristics that make it distinct remain unchanged after repeated propagation.

III. Ownership and duration

The person who bred, or discovered and developed the variety, or his successor in title, shall be entitled to the Community plant variety right. If two or more persons bred, or discovered and developed the variety jointly, entitlement shall be vested jointly in them or their respective successors in title. If the persons completed these acts in the course of employment, the employer is presumed to be the person entitled to grant of the plant breeders' rights pursuant to the relevant provisions of the UPOV.

A minimum protection period of twenty years for most plants and of twenty-five years for trees and vines is required by UPOV from member states. The Plant Variety Regulation extends this period somewhat by protecting potatoes, trees and vines for thirty years and other genera and species for twenty-five years.

IV. Rights and infringement

As with other IP rights, plant variety rights are negative rights and apply in relation to the commercialization of propagating and harvested material (the Plant Variety Regulation refers to propagating material as "variety constituents") and derivative varieties. Propagating

material is not defined anywhere, but potentially includes seeds, seedlings, bulbs, rhizomes, grafts and other such materials. As biotechnology is advanced enough to propagate from a wider variety than from seeds or seedlings (e.g. blooms), material will be treated as propagating material if it is intended to be used as such. Except for ornamentals and fruit, the breeder must obtain relevant regulatory approval before a variety is put on the market.

The rights in respect of propagating material (apart from the naming rights) are set out in Art. 13 of the Plant Variety Regulation and the following acts shall require the authorization of the holder: to produce or reproduce (multiply) the material, to condition the material for the purposes of propagation and to sell, offer for sale, import, export or stock the material for the above mentioned purposes.

The above mentioned rights in connection with propagating material also apply to harvested material obtained through the unauthorized use of propagating material unless the holder has had reasonable opportunity to exercise his right in relation to the said propagating material. Derivative varieties are governed in the Plant Variety Regulation by Art. 13 (5) and (6). The provisions of paragraphs 1 to 4 shall also apply in relation to: (a) varieties which are essentially derived from the variety in respect of which the Community plant variety right has been granted, where this variety is not itself an essentially derived variety, (b) varieties which are not distinct in accordance with the provisions of Art. 7 of the Plant Variety Regulation from the protected variety, and (c) varieties whose production requires the repeated use of the protected variety. The question of whether a plant variety is essentially derived from another variety shall not be subject to further scrutiny here; it should only be noted that a variety is deemed as essentially derived from another variety if it is predominantly derived from the initial variety, it is distinct from the initial variety and it conforms essentially to the initial variety in the expression of the characteristics that results from the genotype or combination of genotypes of the initial variety.

Defenses to infringement can be summarized as follows: acts done privately and for non-commercial purposes, for experimental purposes and for the purpose of breeding, discovering and developing other varieties are not infringing. With respect to Community plant variety rights, there are other defenses under Art. 15 of the Plant Variety Regulation, the discussion of which would exceed the contents of this article.

D) ANIMAL VARIETIES

In short, animal varieties are, due to various reasons, generally not protectable, neither are any inventions with respect to biological material in connection with the human body or parts of it. This is subject to the above elaborations with respect to the TRIPS Agreement and the Biotechnology Directive.

E) SUMMARY

In conclusion, the subject matter can shortly be summarized as follows: ideas in connection with biological material are protectable by the patent law system and by plant variety rights. The patent law system in connection with biological subject matter is heavily influenced by international and regional legislation: the TRIPS Agreement on an international level, the Biotechnology Directive for the EU Member States and the EPC for its member

states (which are not necessarily EU Member States), whereby only the EPC contains elaborations with respect to the general validity of patents (novelty, inventive step and industrial application). The Paris Convention sets out rules with respect to the priority date and national treatment. The exploitation of the rights is, at least in the territory of the EU, largely checked and to a certain extent confined by EU and national competition law.

Ideas in connection with plant varieties, which are *sui generis* rights, are governed by the UPOV, the Plant Variety Regulation and the national plant variety acts for their respective territories. Animal varieties and inventions in connection with the human body are not protectable, subject to the above elaborations.

The contents of this article are intended to provide only a general overview of the subject matter. Specialist advice should be sought for specific matters.