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MEASURES NECESSARY FOR THE BALANCED CO-EXISTENCE OF PATENTS AND PLANT BREEDERS' RIGHTS – A PREDOMINANTLY EUROPEAN VIEW –

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MEASURES NECESSARY FOR THE BALANCED CO-EXISTENCE OF PATENTS AND PLANT BREEDERS' RIGHTS
A PREDOMINANTLY EUROPEAN VIEW –

Joseph Straus*

I. INTRODUCTION

The world is full of anomalies. The discussion of the issue of interface between patents and plant breeders' rights, at least as recently addressed by the Administrative and Legal Committee of UPOV, seemingly is no exception. Thus, it concerns in particular the situation where, for example, the development of genetic engineering can result in a plant variety which will be protected as plant variety, by a plant breeders' right, but will also contain an invention protected by patent (e.g. patented genetic element). What has been entirely left out is the situation where a plant variety can be protected by patents *and* plant breeders' rights. The focus, thus, seems to be on Europe and its actual or potential followers, where plant varieties are excluded from patent protection, but where at the same time generic inventions in plants can be patented. On the other hand, the United States (US) system, with its even three protection forms, i.e. utility patents, plant patents and plant variety certificates, as presented by Professor McManis, is not under investigation. Since the debate is around access to patented germplasm, which is indispensable for developing new varieties of plants satisfying the UPOV protection requirements and guaranteed under the UPOV system by "breeder's exemption" enshrined in UPOV Article 15 (1) (iii), but presumably not available under the patent system, the question may be raised, why the US situation is not addressed at all. Is there no need for access to germplasm containing patented elements (e.g. genes?) or is the access available despite patents on plant varieties, plants and plant elements?

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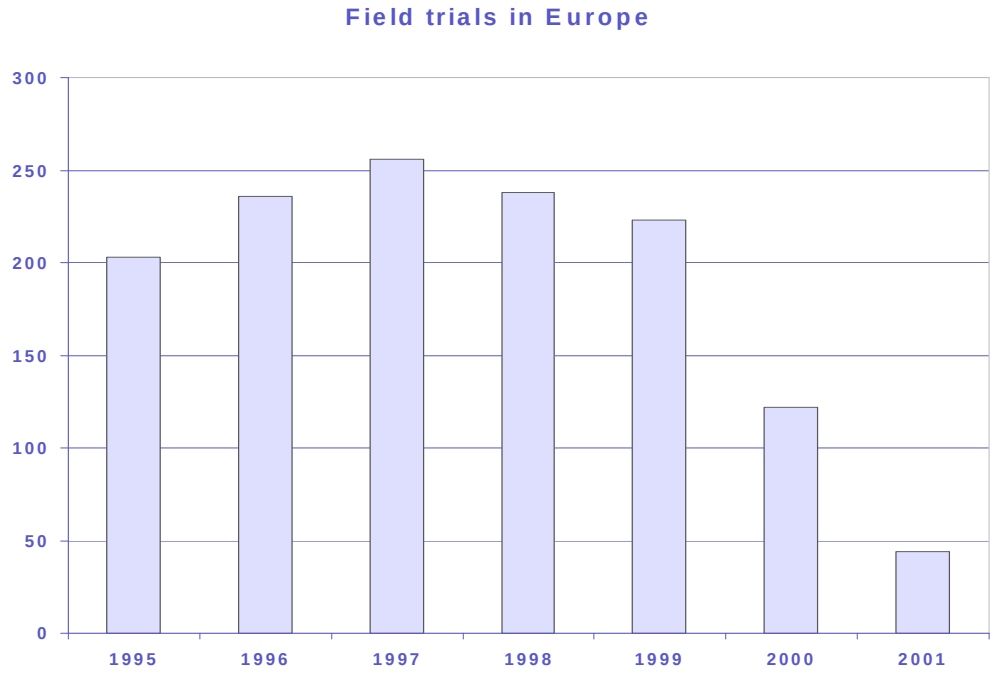
II. WHY AN ANOMALY IN THE CONTEXT ADDRESSED?

Concentrating on Europe at this point in time provokes at least two comments: On the one hand, by adopting the Directive 98/44/EC on the Legal Protection of Biotechnological Inventions in July 1998,[1] the European Union has introduced a regime for protecting innovations in plant area in which the scope of protection of a patent has experienced substantial changes in favour of plant breeders and farmers, and where even a statutory research exemption exists in most patent laws. On the other hand, Europe is actually free of any transgenic plants outside laboratories and some few green houses! Consequently, also free of any commercial use of transgenic germplasm, thus free of innovative and useful products or processes based on genetic engineering. In other words, the question of interface and balance between patents and plant breeders' rights as posed, for the time being in Europe is predominantly not a practical but rather a virtual one, i.e. a prospective issue. This is well revealed by the fact that in 2001 in Europe less than 50 field trials with transgenic crops were performed, down from the peak of more than 250 in 1997.



Source: E. Magnien, EU-Commission

During the same period of time venture capital investments in agricultural biotechnology in the European Union practically disappeared.

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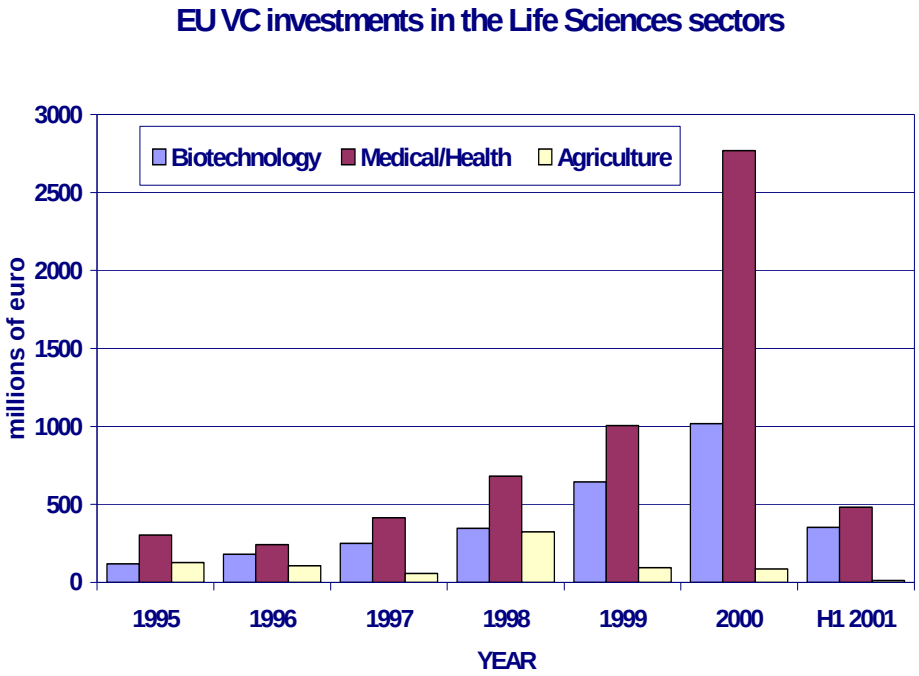
[1] OJ EC No. L 213/13 of 30.7.98.



Source: E. Magnien, EU-Commission

The actual European situation, which can be fully realised only when compared with that of the US, Canada, China or Argentina, where millions of acres have been planted with genetically modified crops,[2] has very little if at all to do with the principles or standards controlling patent protection or plant breeders' rights, but rather exclusively with the regulatory legal framework and the public acceptance of genetically modified crops. Of course, I am not supposed to address these aspects of exploitation of potentials of plant biotechnology, but only wish to draw attention on the impact, which this fundamental difference between Europe and its main competitors in global markets may have on the competitiveness of Europe in the future. One should not overlook that not only Bt-soy beans, Bt-corn or Bt-cotton are at stake, also not the flavour saver tomatoe, but also such technologies as for instance transgenic trees with altered lignification. A product, which may end up in enormous benefits for the environment but, which may equally affect producers of agri-chemicals and the paper prices world-wide.[3]

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2 Cf. Stikeman, New Markets for Biotech – Developing Countries turn to genetically modified crops, Technology Review July/August 2001, 29 ss. (at 30); Huang et al., Plant Biotechnology in China, 295 Science 675 (2002); USDA 2002 crop acreage report, 20 nature biotechnology 422 (May 2002).

3 Cf. on this Chiang, From Rags to Riches, Transgenic trees may improve the efficiency of pulp production without detrimental environmental and ecological effects, according to new results from field trials, 20 Nature Biotechnology 557 s. (June 2002), and Pilate et al., Field and pulping performances of transgenic trees with altered lignification, 20 Nature Biotechnoogy 607 ss. (June 2002).

III. SOME ADDITIONAL REMARKS ON THE US SITUATION AND THE TRIPS RULES

Prior to addressing the rules which in Europe control the interface of interest, some remarks on the information contained in Professor McManis' presentation seem advisable:

First, since Professor McManis left the US for Europe, the Court of Appeals for the Federal Circuit (CAFC) in *John M.J. Madey v. Duke University* case[4] held, *inter alia*, in respect to the "experimental use defense" under the US patent law, that

> "..., regardless of whether a particular institution or entity is engaged in an endeavour for commercial gain, so long as the act is in furtherance of the alleged infringer's legitimate business and it is not solely for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry, the act does not qualify for the very narrow and strictly limited experimental use defense. Moreover, the profit or non-profit status of the user is not determinative."

Consequently, if the US Supreme Court will not overturn the case law of the Federal Circuit, the experimental use defense will hardly ever provide the possibility to, without the consent of the patentee, use patented plant germplasm for further breeding purposes. Since access to plant germplasm, be it patented or protected by PBRs, is of key importance for further innovation in plants, be it based on rDNA technology or on conventional plant breeding, or a combination of both, and since the US is the place with the most advanced use of transgenic patented crops, one should not lose sight of the special importance which US developments may have in general on technical and scientific progress in this area.

Secondly, Article 27(3)(b) TRIPS Agreement allows WTO Members to exclude from patentability *plants* and essentially biological processes for their production other than non-biological and micro-biological processes. Since, however, under Article 28(1)(b) TRIPS Agreement, in case of process patents, the patentee has the right to prevent third parties not only from the act of using the patented process, but also from the acts of: using, offering for sale, selling, or importing for these purposes, at least the product obtained directly by that process, *plants* have to be protected as direct products of patented non-biological and micro-biological processes in WTO Members. In other words, plants, i.e. plant germplasm, produced by various patented recombinant DNA methods (non-biological!), can only be used with the consent of the respective process patent owner, unless rules of national or regional legislation complying with Articles 30 and 31 TRIPS provide otherwise.

In this latter context it should be recalled that under Article 30 TRIPS

> "...limited exceptions to the exclusive rights conferred by a patent [are allowed], provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interest of the patent owner, taking account of the legitimate interests of third parties."

Moreover, Article 31 TRIPS controls the conditions under which WTO Members may allow the use of a patent without the authorization of the right holder. It should suffice to

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[4] Decision of October 3, 2002 (Case 01-1567) explicitly confirming its previous case law, i.e. in Embrex, 55 USPQ 2d at 1163, and in Roche, 221 USPQ at 940, case.

note in the context of interest that such use may also be authorized in order to permit the exploitation of a patent ("the second patent") which cannot be exploited without infringing another patent ("the first patent"), if the following additional conditions are met:

"(i) The invention claimed in the second patent shall involve an important technical advance of considerable economic significance in relation to the invention claimed in the first patent;

(ii) The owner of the first patent shall be entitled to a cross-license on reasonable terms to use the invention claimed in the second patent; and

(iii) The use authorized in respect of the first patent shall be non-assignable except with the assignment of the second patent."

IV. THE ATTEMPTED BALANCE UNDER EU-REGIME

As pointed out at the outset, under the European regime, on the one hand, plant varieties are strictly excluded from patent protection (Article 53 (b) EPC, Article 4(1)(a) EU-Directive) but, on the other hand, inventions concerning plants are patentable if the technical feasibility of the invention is not confined to a particular plant variety (Article 4(2) EU-Directive).[5] On the basis of Recitals 29 to 30 of the Directive, it has to be observed that plant varieties, i.e. plant groupings within a single botanical taxon of the lowest known rank,[6] are defined by their whole genome and are protected by plant variety rights. However, plant groupings of a higher taxonomic level than the variety, defined by a single gene and not by the whole genome, may be protected by patent if the relevant invention incorporates only one gene and concerns a grouping wider than a single plant variety.

The scope of protection conferred by Articles 8 and 9 of the Directive is, in principle, far reaching and covers, in case of product patents on biological material possessing specific characteristics, any biological material derived from the patented one through propagation or multiplication in an identical or divergent *form and possessing those same characteristics* (Article 8 (1)). Protection of a product containing or consisting of genetic information extends to all material in which the *genetic information* is *contained and performs its function* (Article 9).

In case of product patents, the protection extends to biological material directly obtained through that process, as well as to any other biological material derived from the directly obtained one through propagation or multiplication in an identical or divergent form and possessing those same characteristics (Article 8 (2)). It follows from Articles 8 and in particular 9 that an infringement of such patents can only be at hand if the material at issue

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[5] Cf. also the interpretation of Article 53 (b) EPC by the Enlarged Board of Appeal of the EPO, 2000 OJ EPO 111 – Novartis II, which goes along the same lines. For more details cf. the Report from the Commission to the European Parliament and the Council: "Development and implications of patent law in the field of biotechnology and genetic engineering" of October 7, 2002, Doc. COM (2002) 545 final, pp. 19 ss.

[6] Article 2(3) of the Directive explicitly refers to the plant variety definition of Article 5(2) Council Directive (EC) 2100/94 of 1994 on Community plant variety rights, which itself, is entirely in line with the UPOV plant variety definition.

still *contains* the patented genetic information and that information still *performs its function* (Article 9) or still possesses the *same characteristics*. This seems an important clarification, an in fact limitation, specifically if considered in the context of experimental use exemption.

In view of the key role, which access to plant germplasm, be it patented or protected by plant breeders rights, plays for further plant innovation, the so-called *experimental use exemption*, set forth in many national patent laws, is instrumental.

Whereas the US Patent Act (35 U.S.C.) does not dispose of a general statutory research exemption, patent acts of EU Member States disposing of such provisions have their common roots in Article 27 (b) of the Community Patent Convention (CPC), as adopted by the Agreement Relating to Community Patent of 1989.[7] Under Article 27 (b) CPC, the right conferred by a Community Patent does not extend to

> "Acts done for experimental purposes relating to subject matter of the patented invention."

Following a Resolution to the CPC, in which the EC Member States resolved to harmonize their laws with the CPC and notwithstanding the fact that the CPC did not enter into force, all Members of the EU, except Austria, have introduced into their patent acts provisions on research exemptions.[8]

The first court decision to clearly stick to a new European standard of interpretation of the research exemption rule under the influence of Article 27 (b) CPC of far reaching influence was the UK Court of Appeal 1989 *Monsanto Co. v. Stauffer et al.* case,[9] in which the court held, *inter alia*:

> "Trials carried out in order to discover something unknown or to test a hypothesis or even in order to find out whether something which is known to work in specific conditions, e.g. of soil or weather, will work in different conditions can fairly,...., be regarded experiments."[10]

Most importantly, according to the Court, this quality of trial as an "experiment" *is not affected*, even if they have a commercial end.[11]

The German Federal Supreme Court (BGH) in its C*linical Trials I*[12] *and Clinical Trials II*[13] decisions, eventually, confirmed by the German Federal Constitutional Court,[14]

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7 Originally Article 31(b) of the CPC of 1975.

8 See for details Straus, On the Admissibility of Biological Equivalence Tests, During the Patent Term for Obtaining a Regulatory Approval for Patented Drugs by Third Parties, *A.I.P.P.I. Journal of the Japanese Group* 1998, 211 ss. (214 ss.).

9 [1985] R.P.C. 515.

10 [1985] R.P.C. 542.

11 [1985] R.P.C. 538.

12 1996 GRUR 109 = English translation (1997) IIC 103.

[Footnote continued on next page]

followed suit. The following comments on those two Supreme Court decisions should suffice:

In C*linical Trials I*, the Court defined the test (experiment) as

> "... any (planned) act for the acquisition of knowledge, independent of the purpose for which the acquired knowledge is intended to serve eventually."[15]

The Court continued:

> "This implies a finality between any act toward a specific test purpose and the subject matter of the invention. The subject matter of the invention must be the object of the test activity for the purpose of gaining knowledge!"[16]

The Court, moreover, emphasized that the research exemption includes, for instance, any act of use for test purposes, which are performed on the subject matter of the invention in order to determine the effects of a substance or new previously unknown applications. It clearly held that it cannot be of any importance whether the tests serve only to verify the information provided in the patent document, or to obtain further research results and whether they are used to pursue additional objectives such as commercial interests.[17]

It follows from the above that the subject matter of a patented invention, e.g. plant germplasm, *can be used for further breeding purposes without authorization of the patentee*. If the written disclosure in the patent application satisfied the sufficient disclosure requirement only by complementing it by a deposit of biological material (e.g. a construct containing the patented genetic element) in a publicly accessible depository institution, samples of the deposited germplasm, after certain deadlines, will also become accessible to the public and can then subsequently be used for further breeding activities. Whether the commercial use of the final outcome of such activities, e.g. a new plant variety will eventually infringe the respective patent, will ultimately depend on, for instance, whether it will still contain the patented gene and whether the gene – the genetic information – will still perform its function. In case the breeder would succeed in removing that patented genetic information – e.g. resistance, from the propagating material of the new variety, the variety would be outside the scope of the patent. Thus, its commercial use would not constitute an infringement. If, however, the variety would make use of that information, a clear case of dependency would be at issue.[18] In such a case Article 12 EU Directive containing the

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[13] 1997 Mitteilungen der Deutschen Patentanwälte 253 = English translation [1998] R.P.C. 423.

[14] 2001 GRUR, 43.

[15] (1997) IIC 106.

[16] Ibidem.

[17] Cf. (1997) IIC 107.

[18] Lange, Patentierungsverbot für Pflanzenzüchtungen, 1996 GRUR Int. 586 ss. (at 589) made the point: „Wenn es also dem Züchter gelingt, die gentechnisch verankerte und patentierte

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compulsory cross-licensing rule, very much along the lines of Article 31 TRIPS could help, if a contractual license could not be obtained. A problem may be seen in this latter context: which yardstick should/could be used as proof that a specific plant variety constitutes "significant technical progress" compared with the invention claimed in dominant patent? Is the cumulation of these two requirements justified and adequate?

V. CONCLUSIONS

Sustainable innovation in the area of plants is of crucial importance for the well-being of the globe. A few years ago Phillip Abelson the then editor of Science Magazine observed, that

> "Ultimately the world will obtain most of its food, fuel, fibre, chemical feed stock and some of its pharmaceuticals from genetically altered vegetation and trees."[19]

In order to achieve these partly still very remote goals, all involved in plant innovation activities, be it "modern" plant biotechnologists or conventional plant breeders, must be offered a legal framework, which will ensure optimal incentives and working conditions. For all of them, one of crucial conditions for their R & D activities is access to plant germplasm, i.e. entire plant genomes. At present such access seems to be secured under the described European regime, but not in the US system. It is therefore suggested that introduction of appropriate research exemption rules in the respective patent laws is seriously considered. As pointed out at the outset, it should be understood that this is not only an issue which requires a solution in systems where there is an overlap of protection under patents and plant breeders' rights, but exists to the very same extent where plant varieties *per se* are eligible for patent protection!

Moreover, it should be admitted that the European regime as described has not yet been tested in practice. In view of the hope that the interface issue will not remain a virtual one forever, it would seem advisable to clarify these statutory research exemption rules so as to leave no doubt that R & D breeding activities with protected germplasm for developing new plants and plant varieties *per se*, even if for commercial purposes, do neither constitute an infringement of the patent issued on such germplasm, nor an infringement of a plant variety certificate issued on the respective variety.

I should not end without emphasising that no player in the field should claim to be more equal than equal. No free riding at the expense of the other should be tolerated. It would cause imbalance of the system understood as a whole and would, eventually, hamper the badly needed progress in the field.

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> Resistenzeigenschaft wieder ‚herauszumendeln', so muss es ihm erlaubt sein, dieses Sortenmaterial frei in seiner weiteren Züchtungsarbeit zu verwenden (beispielsweise durch Einkreuzung, etc.). Gelingt ihm dies nicht, ist sie weiterhin patentrechtlich abhängig..."

[19] Editorial, 279 Science 219 (1998).