

Report Q114

Biotechnology (including plant varieties)

Names and Functions of Committee Members

Chairman	Charles GIELEN	The Netherlands
Co-Chairwoman	Claire S. BALDOCK	United Kingdom
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1) Prejudicial questions on EU Biotech Directive to ECJ (Charles Gielen, The Netherlands)

The case *Monsanto/Cefetra* c.s. in which the Court in The Hague decided to refer questions of interpretation of the EU Biotech Directive is still pending before the European Court of Justice. The final questions as referred to the ECJ read as follows:

- 1) *Must Article 9 of Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions be interpreted as meaning that the protection provided under that article can be invoked even in a situation such as that in the present proceedings, in which the product (the DNA sequence) forms part of a material imported into the European Union (soymeal) and does not perform its function at the time of the alleged infringement, but has indeed performed its function (in the soy plant) or would possibly again be able to perform its function after it has been isolated from that material and inserted into the cell of an organism?*
- 2) *Proceeding on the basis that the DNA sequence described in claim 6 of patent no EP 0 546 090 is present in the soy meal imported into the Community by Cefetra and ACTI, and that the DNA is incorporated in the soy meal for the purposes of Article 9 of Directive 98/44 and that it does not perform its function therein:
does the protection of a patent on biological material as provided for by Directive 98/44, in particular Article 9, preclude the national patent legislation from offering (in parallel) absolute protection to the product (the DNA) as such, regardless of whether that DNA performs its function, and must the protection as provided under Article 9 of the Directive therefore be deemed to be exhaustive in the situation referred to in that article, in which the product consists of genetic information or contains such information, and the product is incorporated in material which contains the genetic information?*
- 3) *Does it make any difference, for the purpose of answering the previous question, that patent no EP 0 546 090 was applied for and granted (on 19 June 1996) prior to the adoption of Directive 98/44 and that such absolute product protection was granted under national patent legislation prior to the adoption of that directive?*

4) *Is it possible, in answering the previous questions, to take into consideration the TRIPS Agreement, in particular Articles 27 and 30 thereof?*

In the meantime the following countries filed submissions with the ECJ: United Kingdom, Portugal, Italy and The Netherlands. Argentina became a party to the Dutch proceedings and is therefore also party to the ECJ-case. The ECJ will soon fix a date for a hearing.

2) Upov 1991 adherence (Charles Gielen, The Netherlands)

Since last year only two new member adhered to the Upov 1991 Treaty, namely and Georgia on November 29 2008 and Slovakia on June 12, 2009 bringing the total number of members to 43. The number is still growing but a number of countries adhering to the 1978 Act are still not adhering to the 1991 Act of Upov.

3) Plant breeders rights; general (Thomas Bouvet)

It is interesting to note that the website of the Community Plant variety Office (www.epvo.europa.eu) contains a case law database giving access to relevant decisions issued in various member states. 18 decisions are reported since 1 January 2008 (including decisions of the Community plant variety Office).

The Court of First Instance of the European Communities issued a decision on 19 November 2008 (T-187/06) in matter Ralf Schröder v. CPVO; it concerned a Community plant variety right.

This decision addresses the interesting issue of:

- the level of evidence necessary to prove that a reference variety (used to assess the distinctness of the variety for which protection is sought) is a matter of common knowledge; it is decided by the CFI that the detailed description of the reference variety mentioned in UPOV document TG/1/3 is one of the aspects which should be taken into consideration, and that the factors mentioned in article 7(2) of Regulation n° 2100/94 does not contain an exhaustive list; in other words, witness statements obtained by the UPOV could be used to prove that a reference variety is of common knowledge;
- the level of review, by the CFI, on decisions of the UPOV Board of appeal; it is decided that although the review must be limited for technical issues like assessing distinctness, the review could be detailed on issues like assessing whether a reference variety is one of common knowledge.

4) Developments at EPO-level (Claire Baldock, UK)

The last report of Special Committee Q114, prepared for the Boston Congress in September 2008, drew attention to three legal developments in Europe relating specifically to biotechnology patents. These were case referral G02/06 pending before the Enlarged Board of Appeal of the EPO on the patentability of human embryonic stem cells, two further pending Enlarged Board referrals on the meaning of "essentially biological process" in relation to processes for the production of plants and animals and developments in the assessment of industrial applicability for biological molecules, in particular the T0989/05 decision of the EPO and the case of Eli Lilly v Human Genome Sciences in the English High Court. The only one of these matters on which there has been a further development since then is the embryonic stem cell referral. The Enlarged Board handed down it's decision in November 2008. There do not seem to have been any other legal developments of interest which are specifically biotechnology related at the EPO in the intervening months.

Outcome in G02/06

The case concerned a European patent application filed by the Wisconsin Alumni Research Foundation (WARF) in which the claims were directed to a cell culture comprising primate embryonic stem cells which were cultured in a way that they could divide and proliferate while being kept

from differentiating for at least a year. Although not a step recited in the claim, it was described in the patent application that the culture was obtained by taking cells from a human embryo and inducing them to proliferate in vitro. They were thus maintained in culture in a state in which they would not exist in nature. The Enlarged Board had to consider whether the patenting of such an invention was prohibited by Rule 23d(c) EPC (now renumbered Rule 28 (c) post implementation of EPC 2000) which declares that “uses of human embryos for industrial and commercial purposes” are considered unpatentable. In this evaluation the Board had to consider the facts that the step of recovering a cell or cells from the embryo was not recited in the claim and that subsequent to the filing of the application other methods had been developed for preparing such cells which did not involve the use of an embryo.

In answering the questions referred to it, the Enlarged Board considered that it was necessary to look at the teaching of the application as a whole rather than just the strict wording of the claims in deciding whether WARF's invention fell within the prohibition on patents concerning industrial or commercial uses of human embryos on moral grounds. In this regard, it was critical that, based on the teaching of the patent application, WARF's invention could only be carried out by destroying human embryos to harvest embryonic stem cells. Thus, when considering the exclusion from patentability on moral grounds, the invention “as claimed” (which did not mention harvesting of cells from embryos) could not be viewed in isolation from the means of putting the invention into effect (for which destruction of the embryo was an essential feature). On the question of the later finding that WARF's invention could be put into effect without the need to destroy human embryos, the Board considered this to be irrelevant, since the “new” method not involving destruction of embryos did not form part of the teaching of WARF's application as filed. Thus, WARF's invention was found to be in breach of Rule 23d(c) and was not patentable.

The Decision is a disappointing one and not one encouraged by this committee in its Amicus brief to the Enlarged Board in 2006, which brief followed an AIPPI resolution drafted by the Committee and passed at the Berlin ExCo meeting in 2005 approving human embryonic stem cell patentability. However, in the final paragraph of the Decision, the Board took care to clearly state that G 02/06 is not concerned with the patentability in general of inventions relating to human stem cells or stem cell cultures. Rather, G 02/06 only holds unpatentable the category of inventions concerning products (in this case human stem cell cultures) which can only be obtained by a method involving destruction of a human embryo. It is not ruled that stem cell inventions per se are immoral, and hence unpatentable. Thus, there does not seem to be any reason why G 02/06 should prevent patenting of adult stem cells, or even induced pluripotent stem cells. Given the speed with which this technology advances the impact of this decision in commercial terms may not be great.

5) Olanzapin-decision Federal Supreme Court (Ralph D. Kirsch, Germany)

One recent decision of interest in Germany is not a true biotech decision – but it seems so important for the pharmaceutical industry that it is worth reporting.

In its decision “Olanzapin” of December 16, 2008 (X ZR 89/07) the Federal Supreme Court (BGH) dealt with the question of how a generic chemical formula as state of the art can affect novelty of a more specific formula that falls under this generic disclosure.

Generic formula as prior art

The active agent “Olanzapin” is comprised in the neurolepticum Zyprexa® of the pharmaceutical company Lilly Industries Ltd., which is protected by the German patent DE 691 12 895 (i.e. the German part of the corresponding EP patent EP 0454436). There is a huge market for this drug worldwide. The German patent was declared invalid by the Federal Patent Court (BPatG) in 2007 in the first instance due to a nullity suit initiated by companies that make generics.

Remarkably, the Federal Supreme Court (BGH) decided in the following appeal proceedings that the patent indeed is valid. The judges decided that in this case novelty of the specific structural formula of Olanzapin was not taken away by the more generic disclosure that was state of the art

and that also covered Olanzapin in generic terms. The Court confirmed validity of the German part of the EP patent so that the patent was upheld. The reason for that is as follows: according to German case law the disclosure of a given prior art document can be defined as what a person skilled in the art can extract from the document "directly and unequivocally". According to the BGH there was no indication that the structural formula of Olanzapin could be taken out of the relevant prior art document "directly and unequivocally" so that a person skilled in the art would automatically see Olanzapin as being disclosed by the prior art formula.

This view is reflected in Headnote c) of the decision:

c) "In principle, the disclosure of a chemical structural formula does not disclose single compounds that fall under this formula."

Obviously, this BGH decision strengthens the position of pharmaceutical companies who are dependent on a strong patent protection of their compounds.

6) Developments in the United States (Jeffrey P. Kushan)

Several important cases are pending that will affect biotechnology invention patenting standards and practices.

First, the Federal Circuit heard oral arguments in the case of *Prometheus Labs. v. Mayo Collaborative Services* (No. 2008-1403) on August 5, 2009. The *Prometheus* case was directed to the question of whether a claimed method of treatment that exploited a scientific correlation between the blood concentration of a metabolite and a desired therapeutic treatment window were ineligible to be patented as non-statutory subject matter. The lower court held the claims unpatentable under 35 U.S.C. § 101, relying significantly on cases involving claims directed to natural phenomena. A decision is expected in Fall 2009.

Second, the Federal Circuit recently granted rehearing en banc in the case of *Ariad Pharmaceuticals, Inc et al., v. Eli Lilly and Company* (No. 2008-1248). In April of 2009, the Federal Circuit reversed a district court finding that *Ariad's* patent was valid and infringed, and the district court's award of damages against *Lilly*. The panel, inter alia, held the patent invalid for a lack of an adequate written description. In its August 21, 2009 order vacating the decision of this Federal Circuit panel, the court directed parties to brief the following two questions:

- a. Whether 35 U.S.C. § 112, paragraph 1, contains a written description requirement separate from an enablement requirement?"
- b. If a separate written description requirement is set forth in the statute, what is the scope and purpose of the requirement?"

The written description standard under 35 U.S.C. § 112, first paragraph, has played a significant role in many biotechnology patent cases. The Federal Circuit's review of whether this standard exists independent of the enablement requirement may have a significant impact in biotechnology patent law.

Third, the U.S. Supreme Court granted certiorari to review the Federal Circuit's recent en banc decision of *In re Bilski*, 545 F.3d 943, 88 U.S.P.Q.2d 1385 (Fed. Cir. 2008) concerning patent eligible subject matter in a case involving computer process inventions. The Supreme Court will review the question whether the Federal Circuit's standard – which requires that a process involve a transformation of physical matter or be linked to a specific machine – is the appropriate test for patent eligibility of computer-related and business process inventions. Because the Supreme Court's pronouncement will address the boundaries of § 101 and patent eligibility of process inventions, it may have effects in the biotechnology and life sciences area.

Fourth, the Federal Circuit is reviewing two cases brought by patent applicants against the Patent and Trademark Office (PTO).

In July of 2009, the Federal Circuit vacated its earlier decision in *Tafas and GlaxoSmithKline vs. Doll*, and granted en banc review of the decision of the district court. The *Tafas* case concerned a challenge to new PTO rules that would have placed limits on the filing of continuation applications and requests for continued examination, as well as constraints on claiming. The original en banc order was subsequently stayed on motion by the PTO, which indicated that the Obama Administration was reviewing the case, and was awaiting appointment of a new Director. The Federal Circuit recently reactivated the schedule for briefing following the confirmation of David Kappos as the new Director and Undersecretary for Intellectual Property. It is unclear what the ultimate disposition of this appeal will be given the ongoing review of the PTO of its pending examination policies.

The Federal Circuit will also hear arguments on October 7, 2009, in the case of *Wyeth v. Doll*, involving a challenge to the PTO's interpretation of the law governing patent term adjustment for PTO delays. In *Wyeth*, the district court held the PTO's method of determining patent term adjustments inconsistent with the statute. In particular, it held that the PTO had improperly calculated patent term adjustment periods for patents by not crediting delays that occurred during the first three years of pendency of the application.

7) Gene patentability (Andrew Blattman, Australia)

Current Situation in Australia

- For an invention to be patentable in Australia it must be for a manner of manufacture within Section 6 of the Statute of Monopolies. This serves to exclude from patentability inventions which are "contrary to law" or "generally inconvenient". In respect of the requirements of manner of manufacture, it is for Parliament, not the courts or the Patent Office, to decide whether matters of ethics or social policy are to have any impact on what is patentable.[1]
- In light of the manner of manufacture requirement under Australian Law, it is not possible to secure patent protection in respect of genetic technologies as they exist in nature. However, gene sequences are patentable in Australia as "isolated" gene sequences, provided the remaining conditions of s18 are satisfied (ie. novelty, inventive step, utility). [2]
- In addition, the Australian Patent Office Manual of Practice and Procedures (Manual) provides specific guidance as to the current patentability requirements; "a gene can be claimed as the gene per se (as long as the claim does not include within its scope the native chromosome of which the gene forms part) or as the recombinant or isolated or purified gene." [3]

Reforms

- The patentability of genes has been of concern in Australia since before the inception of the Patents Act 1990 (Cth) (Patents Act) [4]. More recently, in 2002, the Attorney-General of Australia requested the Australian Law Reform Commission (ALRC) examine the laws and practices governing intellectual property over genetic materials.[5] The ALRC Report 99 https://www.utsonline.edu.au/webapps/discussionboard/do/message?action=list_messages&forum_id=352391&course_id=4841&nav=discussion_board_entry&conf_id=3301&message_id=16966531-edn19 [6], inter alia, stated "inventions involving genetic materials and technologies should be assessed according to the same legislative criteria as other inventions." In addition, the ALRC concluded that if there had been a time to recommend that gene sequences should not be patentable, that time was in the past. Consequently, the reforms proposed by the ALRC were directed at improving the existing system, for example, providing for an experimental use exemption and encouraging a more active role for the Australian Competition and Consumer Commission (ACCC).[7] Although the ALRC report was tabled in Parliament, no legislative action was taken.
- In 2006 the Australian Advisory Council on Intellectual Property (ACIP) made a recommendation for an experimental use exemption.[8] In August 2007, the Commonwealth Government accepted the recommendations in principle and proposed to amend the Patents Act to introduce an experimental use exemption reflecting the recommendations and in consideration

of international obligations (ie. TRIPS Article 27.2).[9] However, no legislation has been drafted as yet.

Current Parliamentary Inquiry

• In November 2008, the Senate commissioned the Senate Committee on Community Affairs to conduct an inquiry into inter alia the patentability of gene sequences, and report by the last sitting day of 2009 (December 2009).[10] Specifically, the inquiry is addressing the impact of the granting of patents in Australia over human and microbial genes and non-coding sequences, proteins, and their derivatives, including those materials in an isolated form, with particular reference to:

- (a) the impact which the granting of patent monopolies over such materials has had, is having, and may have had on:
 - (I) the provision and costs of healthcare,
 - (II) the provision of training and accreditation for healthcare professionals,
 - (III) the progress in medical research, and
 - (IV) the health and wellbeing of the Australian people;
- (b) identifying measures that would ameliorate any adverse impacts arising from the granting of patents over such materials, including whether the Patents Act 1990 should be amended, in light of the any matters identified by the inquiry; and
- (c) whether the Patents Act 1990 should be amended so as to expressly prohibit the grant of patent monopolies over such materials.

Submissions were received from individuals and organizations including research scientists, clinicians, patent attorneys and public and private sector organizations.[11] In general, the primary arguments against gene patenting include objections on the basis that inventions involving genetic materials do not satisfy the requirements for patentability under Australian Law; ie. genetic sequences are a discovery rather than invention; and objections to the way in which gene patents are exploited and commercialised. Conversely, arguments in support of gene patenting contend that patent protection is an incentive for innovation and investment.

The report from this inquiry is due in December 2009, and likely will reflect the need for an explicit experimental use exemption [12], however the recommendations with respect of the patentability of gene sequences per se remains to be seen.

8) Developments in France (Thomas Bouvet)

The Cour d'Appel of Paris rendered an interesting decision on 4 March 2009 in a matter between Chiron and Institut Pasteur for infringement of a patent regarding HIV detection kits.

Institut Pasteur alleged that Chiron would have committed acts of contributory infringement of the French designation of its European patent No. 0 178 978 regarding "cloned DNA sequences, hybridizable with genomic ARN of lymphadenopathy-associated virus (LAV)" by selling certain kits for the detection of HIV in blood samples.

The Tribunal de Grande Instance and the Cour d'Appel dismissed Institut Pasteur's claims on the ground that the detection kits of the Chiron companies did not fall within the scope of the patent and that their sale did not amount to contributory infringement.

This decision is the first ever issued by a French court about infringement of a molecular biology patent.

From a legal standpoint, it is interesting for several reasons:

- it reminds that the extent of protection conferred by a patent shall be determined by the terms of the claims and that this rule applies even in relation to a pioneer patent; the Cour d'Appel accepts that the claims of a pioneer patent be drafted in general terms but it specifies that, if the claims are drafted narrowly, the patent, even a pioneer one, has a limited scope;

- it indicates that the patent claims which have been amended during prosecution or opposition proceedings before the European patent office can not, under the pretext of interpretation, be given the extent of claims to which the patentee renounced, as this would prejudice to the security of third parties;
- it reminds the provisions regarding contributory infringement by indicating that:
 - a means must be considered as essential if it contributes to the result of the invention;
 - the means supplied must be suited for putting the invention into effect; in this specific matter, the Cour d'Appel dismissed the action on the ground that the use of the accused detection kits was not suited to obtain the RNA subject matter of claim 11.

9) Developments in Brazil (Gabriel Di Blasi)

Guidelines for Examining Biotech Patent Applications by the Brazilian Patent Office

On 2002 the Brazilian Patent Office (INPI) issued specific guidelines for the examination of biotechnology/chemical-pharmaceutical patent applications which are now under a review process.

The current scenario for applicants in Brazil is uncertain, mainly due to lack of harmonization between the (INPI) and the Brazilian National Health surveillance Agency (ANVISA), which according to the Brazilian Patent Law has to grant a prior consent for the issuance of patents in the chemical/pharmaceutical area. In order to clarify and trying to speed up examinations, the INPI started to discuss the so called "special topics" last year. Out of the selected eight topics, the patentability of polymorphic molecules and second medical use inventions were already discussed. ANVISA has a position against second medical use inventions and polymorphs, although the INPI's position on polymorphism is that it should not be excluded from patentability ab initio. This controversial position by ANVISA shall maintain the lack of definition for the pending patent applications. Patent applications in the chemical/pharmaceutical area cannot be issued without ANVISA's prior consent, thus creating a huge backlog for the exam in biotechnology patents.

Other points that remain to be discussed and that are of special interest in the biotech area are selection patents and the patentability of molecules/sequences which have a naturally occurring counterpart. For selection patents, once again ANVISA and INPI do not share the same opinion. Regarding the patentability of molecules/sequences having naturally occurring counterparts, the Brazilian Patent Law does not classify naturally occurring materials as patentable subject matter, further stating that even when the material is isolated therefrom said exclusion should be applied. However, both the INPI and ANVISA tend to present an impossibly strict view on the matter, excluding even fragments of the said "naturally occurring material" from patentability. This tendency is extremely damaging for applicants claiming DNA fragments and/or isolated proteins which actually are claimed outside the scope of their natural environment.

Reformulation of the Law regulating plant breeder's rights in Brazil

The Brazilian law for plant breeder's rights (Lei de Cultivares No. 9456/97) is in force since April 28, 1997, and is currently under review. The Brazilian Patent Law excludes plants and parts thereof from patentability, therefore plant breeders have to rely on the Law 9456/97 for protection.

The current law in force is not harmonized with the intellectual property law, creating a very complicated scenario in Brazil where gene and plant breeding companies have to devote huge efforts to enforce these two regulations in a concerted way, e.g. when the final product of a breeding process is related to a patented gene/process or when the patented gene is not used directly in the breeding process.

- [1] Anaesthetic Supplies Pty Limited v Rescare Limited (1994) AIPC 91-076, 28 IPR 383
- [2] Kiren-Amgen Inc v Board of regents of University of Washington and another 1995 33 IPR 557. A claim directed to a naturally occurring DNA characterized by specifying the DNA coding for a portion of that molecule would likely be claiming no more than a discovery per se and not be a manner of manufacture. The claims relate to artificially created states of affairs, not to a mere chemical curiosity or a mere discovery of the DNA sequence encoding erythropoietin. Accordingly, the objection of manner of manufacture does not apply to any of the claims.
- [3] IP Australia, Patent Manual of Practice and Procedure Volume 2: National (2009), [2.9.2.5]
- [4] https://www.utsonline.edu.au/webapps/discussionboard/do/message?action=list_messages&forum_id=_35239_1&course_id=_484_1&nav=discussion_board_entry&conf_id=_330_1&message_id=_1696653_1_-_ednref2 Patents Act 1990 (Cth), <http://www.austlii.edu.au/au/legis/cth/consol_act/pa1990109/>;https://www.utsonline.edu.au/webapps/discussionboard/do/message?action=list_messages&forum_id=_35239_1&course_id=_484_1&nav=discussion_board_entry&conf_id=_330_1&message_id=_1696653_1_-_ednref4 Senate Standing Committee on Industry Science and Technology, Report on the Consideration of the Patents Bill 1990 (1990); Commonwealth of Australia, Parliamentary Debates, Senate, 20 September 1990, 2653 (J Coulter); Patents Amendment Bill 1996 (Cth); Commonwealth of Australia, Parliamentary Debates, Senate, 27 June 1996, 2332 (N Stott-Despoja)
- [5] https://www.utsonline.edu.au/webapps/discussionboard/do/message?action=list_messages&forum_id=_35239_1&course_id=_484_1&nav=discussion_board_entry&conf_id=_330_1&message_id=_1696653_1_-_ednref14 Attorney-General and Minister for Health and Ageing, Who Owns Your Genes?, Media Release, 4 December 2002.
- [6] Australian Law Reform Commission, Genes and Ingenuity: Gene Patenting and Human Health, Report 99 (2004) <<http://www.austlii.edu.au/au/other/alc/publications/reports/99/>>
- [7] Australian Law Reform Commission, Summary, Report 99, (2004) <<http://www.alrc.gov.au/inquiries/title/alrc99/recommendations.html>>
- [8] Australian Advisory Council on Intellectual Property, Final Report 2006 <http://www.acip.gov.au/library/ACIP%20Patents%20&%20Experimental%20Use%20final%20report%20FINAL.pdf>
- [9] Government Response, 2007, http://www.acip.gov.au/library/Government%20Response%20to%20ACIP%20Report%20on%20Patents%20&%20Experimental%20Use_Final.pdf
- [10] Senate Community Affairs Committee, Inquiry into Gene Patents Terms of Reference < http://www.aph.gov.au/SENATE/COMMITTEE/CLAC_CTTE/gene_patents/tor.htm>
- [11] Senate Community Affairs Committee, List of Submissions, http://www.aph.gov.au/senate/committee/clac_ctte/gene_patents/submissions/sublist.htm
- [12] <http://www.aph.gov.au/hansard/senate/committee/S12302.pdf>, p.78 (G Humphries)
 "I would guess that this committee is going to recommend that there be an attempt in the law to clarify the right of researchers to access any patent that has been published and to use that knowledge to research and develop things, subject to whatever restrictions it is felt should be applied to the commercial application or exploitation of that knowledge outside the laboratory."