Standing Committee on

Biotechnology
(sub-committee of Standing Committee on Patents)

2015

International Association for the Protection of Intellectual Property
AIPPI General Secretariat ¦ Toedistrasse 16 ¦ P. O. Box ¦ CH-8027 Zurich
Tel. +41 44 280 58 80 ¦ Fax +41 44 280 58 85
enews@aippi.org ¦ www.aippi.org

Date: 7th October 2015

REPORT
Standing Committee on

Biotechnology (sub-committee of Standing Committee on Patents)

Chair: Claire BALDOCK
Responsible Reporter: Ralph Nack

1) Report on the activities of the Standing Committee during the reporting period

A meeting of the Standing Committee on Biotechnology and Plant Breeders rights (Q114) took place at the Toronto Congress on 15th September 2014 and was attended by members from UK, France, Germany, Japan, India and USA. The Committee considered possible workshops for the Rio Congress in 2015 and working questions for the Milan Congress in 2016.

A particular topic discussed at the meeting was patenting in the field of stem cell technologies, and in particular whether the AIPPI resolution adopted at the Berlin Meeting in 2005 still reflected the AIPPI position, given the considerable case law developments in the interim. This matter continued to be explored in subsequent telephone conferences of the Committee on 21st January and 9th February 2015 where it was the opinion of the Committee that the existing resolution was broad enough to reflect the current position and did not need replacement but there were nuances which might be usefully reflected in a position paper on the subject. Permission was sought from the RGT for the Committee to prepare such a paper and approval was duly received. This is now a work in progress for the coming year.

Further telephone conferences of the Committee also took place on 10th June 2015 to gather more general information for the current report.

The event of greatest significance during the reporting period of the Committee has been its amalgamation, as a sub-committee with the newly formed Pharma and Biotechnology Standing Committee. We see this as a positive development and are very much looking forward to the collaboration. Some of our members participated in a first conference call of the new committee on 24th June 2015. The Biotechnology Sub-Committee will nevertheless continue to have its own meetings and produce its own report.

2) Key issues/developments relevant to the Terms of Reference of the Standing Committee (arising during the reporting period or coming up)

We include herewith a report of legal developments in IP in the biotechnology and plant variety fields during the reporting year.

2.1 Report in the Biotechnology field

EUROPE

(A) EPO Enlarged Board of Appeal referrals

G02/13 and G2/12 (Broccoli II and Tomato II)

The Annual Report of the former Special Committee Q114 of August 2014, advised of EPO Enlarged Board of Appeal (EBA) referral G02/13 (Broccoli II) which concerned whether a product produced by an excluded essentially biological process is also excluded from patentability.

The Questions referred to the Enlarged Board were:

1. Can the exclusion of essentially biological processes for the production of plants in Article 53(b) EPC have a negative effect on the allowability of a product claim directed to plants or plant material such as plant parts?

2. In particular:

(a) Is a product-by-process claim directed to plants or plant material other than a plant variety allowable if its process features define an essentially biological process for the production of plants?

(b) Is a claim directed to plants or plant material other than a plant variety allowable even if the only method available at the filing date for generating the claimed subject-matter is an essentially biological process for the production of plants disclosed in the patent application?

3. Is it of relevance in the context of questions 1 and 2 that the protection conferred by the product claim encompasses the generation of the claimed product by means of an essentially biological process for the production of plants excluded as such under Article 53(b) EPC?

4. If a claim directed to plants or plant material other than a plant variety is considered not allowable because the plant product claim encompasses the generation of the claimed product by means of a process excluded from patentability under Article 53(b) EPC, is it possible to waive the protection for such generation by "disclaiming" the excluded process?"

In November 2013, an Amicus brief prepared by Q114 and filed on behalf of AIPPI, took the position that such plants should remain patentable to avoid conflicting with long-standing principles applied to product-by-process claims and in particular, conflict with earlier Enlarged Board Decision G01/98 and Article 4(2) of EU Directive 98/44/EC, both of which permit the patenting of plants and animals if the technical feasibility of the invention is not confined to a particular plant or animal variety.

On 25th March 2015 the EBA handed down is decision in G2/13, as well as its decision in parallel referral G2/12 (Tomato II) which dealt with the same issue.

In summary, the EPA concluded that such products should be patentable regardless of the process by which they were produced, even if the only method available at the filing date for generating such a product is an excluded essentially biological one.

The EBA noted that there were a number of ethical, social and economic aspects to the patent eligibility of products produced by essentially biological processes, many of which had been raised in observations by third parties. However, the EBA emphasised that their role was to interpret the EPC rather than "engage in legislative policy". In addition, it was noted by the EBA that those nations (e.g. The Netherlands and Germany) which consider that plant products obtained by essentially biological processes *should not* be patent eligible, have specified as such in their own legislation. These national provisions are supplemental to those which exclude essentially biological processes from patent eligibility.

Alongside taking these factors into account, the EBA provided an extensive discussion of the possible interpretations of the provision which excludes "essentially biological processes" from patent eligibility (A. 53(b) EPC). In light of these interpretations and considerations, the EBA concluded that the exclusion of essentially biological *processes* from patentability should not be understood to exclude plant *products* from patent eligibility.

This decision is to be welcomed as it provides clarity for both patent applicants and plant breeders and

preserves the previous commercial balance between those parties. It is also in line with the position taken by AIPPI in its Amicus brief.

(B) Supplementary Protection Certificates

(i) **Arne Forsgren v Österreichisches Patentamt (Case C-631/13)**

This case concerned an SPC application for a product that was authorised for use as a carrier protein in a polysaccharide conjugate vaccine. The purpose of conjugating a polysaccharide antigen to a carrier protein is to elicit an enhanced immune response to the polysaccharide antigen (absent conjugation to a carrier protein, polysaccharides tend not to elicit a memory response).

The basic patent in this case claimed Protein D, which is expressed on the surface of non-typeable Haemophilis Influenzae ("NTHi"). Forsgren sought to obtain an SPC for Protein D on the basis of the MA for 'Synflorix', a polysaccharide conjugate vaccine for immunisation against Streptococcus pneumoniae.

The referring court in Austria found that in 'Synflorix' Protein D has two independent effects: a) eliciting an immune response against NTHi; and b) enhancing the immune response against Streptococcus pneumonia. However, the MA for 'Synflorix' merely stated that the role of Protein D was a carrier protein for the main antigen (i.e. pneumococcal polysaccharides).

The CJEU decided that:

- the fact Protein D was covalently bound to other ingredients in the approved medicinal product did not preclude the possibility of the grant of an SPC for Protein D;
- Article 3(b) of the SPC Regulation precludes the grant of an SPC for an active ingredient whose effect does not fall within the therapeutic indications covered by the wording of the MA;
- A carrier protein conjugated with a polysaccharide antigen by means of covalent binding may be categorised as an "active ingredient" (within the meaning of Article 1(b) of the SPC Regulation) only if it is established that it produces a pharmacological, immunological or metabolic action of its own which is covered by the therapeutic indications of the marketing authorisation.

This case therefore leaves open the possibility that carrier proteins may be classed as "active ingredients" for the purpose of SPC applications. However, it is left to the national courts to determine whether a carrier protein has "a ph`armacological, immunological or metabolic action of its own" and whether such action is "covered" by therapeutic indications set out in the MA.

(ii) Pharmaq v Intervet (E 16/14) – 9 April 2015

This case concerned a vaccine for immunising farmed fish (salmon and trout) against a virus causing pancreatic disease. Intervet obtained an SPC based on its basic patent which claimed a particular strain of the virus (F93-125) and all strains which share similar genotypic and/or phenotypic characteristics and react serologically with F93-125 and its marketing authorisation ("MA") for its vaccine, "Norvax" which was granted in 2011. The active ingredient in Norvax is inactivated F93-125. However, the SPC was granted in terms corresponding to the broad language of the patent claims (effectively covering all strains of the virus) rather than the narrow language of the MA (which covered only one specific strain). Furthermore, sales of Norvax in the period prior to the grant of the MA amounted to more than €70M, based upon special approval exemptions in Norway and Ireland between and a provisional MA granted in the UK.

Pharmaq developed its own competing vaccine based on a strain different to F93-125 and belonging to a different sub-type and challenged the validity and scope of Intervet's SPC in the District Court of Oslo. The grounds relied on by Pharmaq included that the SPC was granted in breach of Article 3(d) of the SPC Regulation because the MA was not the first MA to place the product on the market and that pursuant to Article 4 the scope of the SPC cannot extend beyond the active ingredient covered by the MA. The Oslo Court sought an advisory opinion on these matters from the EFTA Court. The EFTA Court has jurisdiction with regard to EFTA States which are parties to the EEA Agreement (at present Iceland, Liechtenstein and Norway). For those states, the EFTA is equivalent to the CJEU although its decisions are not binding on the CJEU.

The EFTA Court ruled that whether the special approval exemptions and provisional MA would be considered to be the first MAs for Norvax will depend upon the technical nature of those authorisations and whether they were granted under Article 8(1) or 26(3) of the Veterinary Medicines Directive (2001/82/EC). Article 8(1) allows provisional use of an immunological veterinary medicine without an MA in the event of serious epizootic disease and where there is no suitable medicine available. Article 26(3) allows, an authorisation to be granted in exceptional circumstances subject to a requirement that specific safety monitoring and reporting procedures are adopted. The EFTA Court considered that an authorisation granted under Article 26(3) would count as an MA for the purpose of the SPC Regulation, but that provisional use allowed under Article 8(1) would not. Whether the marketing of Norvax prior to 2011 was done under Article 8(1) or 26(3) was left for determination by the Oslo court.

As to the scope of the SPC, the EFTA Court ruled that if the SPC is granted for active ingredients which are not covered by the MA, then it will be invalid (notwithstanding that this is not one of the grounds for invalidity specified in Article 15(1) of the SPC Regulation). However, it suggested that viral strains that are not mentioned in the MA could nevertheless be covered by the MA if they amount to the same active ingredient and have therapeutic effects falling within the therapeutic indications mentioned on the MA. The EFTA Court left it to the Oslo court to determine whether the two strains in issue in this case amount the same active ingredient.

This decision provides little guidance as to when two different substances may be considered to be the same active ingredient and therefore does little to resolve the uncertainty as to the extent of protection conferred by SPCs for biologic products where the competing products ("biosimilar" or "biobetter") may display structural and functional differences.

(C) Human embryonic stem cells

(i) CJEU Decision C-364/13

In our report of August 2014 we reported on the opinion handed down by the Advocate General (AG) of the CJEU in C-364/13.

The case in question concerned two UK patent applications of International Stem Cell Corporation (ISCC) which relate respectively to a method of producing human stem cells by stimulating human oocytes to divide into "parthenotes" and the use of these to generate synthetic corneas.

The question before the court was:

"Are unfertilised human ova whose division and further development have been stimulated by parthenogenesis, and which, in contrast to fertilised ova, contain only pluripotent cells and are incapable of developing into a human being included in the term "human embryos" in Article 6(2) of Directive 98/44EC on the Legal Protection of Biotechnological Inventions?"

and the AG had concluded:

"Unfertilised human ova whose division and further development have been stimulated by parthenogenesis are not included in the term "human embryos" in Article 6(2)(c) of Directive 98/44/EC of the European Parliament and of Council of 6th July 1998 on the legal protection of biotechnological inventions as long as they are not capable of developing into a human being and have not been genetically manipulated to acquire such a capability".

On 18th December 2014, the CJEU handed down its final Decision affirming the AG's earlier conclusions.

Supporting the Decision was the evidence provided to the court that mammalian parthenotes can never develop to term because, in contrast to a fertilized ovum, they do not contain paternal DNA, which is required for the development of extra-embryonic tissue.

On this basis it could be that a "*parthenote*" was not an embryo within the meaning of Article 6(2) of the Directive if in the light of the current scientific knowledge, the ovum does not, in itself, have the inherent capacity of developing into a human being.

In the case at issue, the applicant had amended the claims to exclude any further genetic manipulation step which might facilitate the parthenote having the capacity to develop into a human being. On this basis the claims and method could, in principle, be patented.

While this decision is to be generally welcomed, since it opens up the possibility of obtaining patents for a variety of stem cell technologies previously excluded under the earlier CJEU Decision C-34/10 (Brustle), it leaves open the possibility that future technical developments will permit parthenotes to fully develop into humans, in which case stem cells derived from them may again be excluded from patentability.

(ii) UKIPO Practice

Following the C-364/13 Decision, on 25th March 2015 the UKIPO issued a new practice note on inventions involving human embryonic stem cells. This note replaces previous guidance on the subject incorporating the new provision:

"an unfertilised human ovum who's division and further development have been stimulated by parthenogenesis does not constitute a "human embryo" within the meaning of that provision [i.e. Article 6(2)(c) of the Directive], if, in the light of current scientific knowledge, it does not, in itself, have the inherent capacity of developing into a human being".

Accordingly, we expect UKIPO practice with respect to inventions relating to parthenotes to be in accord with the current CJEU position on the issue.

(iii) EPO T1441/13

In September 2014 the EPO Technical Board of Appeal (TBA) issued a decision concerning an invention relating to a method of producing islet cells from primate pluripotent stem cells.

Since, at the priority date of the application the only described method for obtaining the primate pluripotent stem cells for use in the method involved destruction of an embryo, the claim could not be allowed following EPO Enlarged Board Decision G02/06 (WARF) and CJEU Decision C-34/10 (Brustle).

The applicant entered a disclaimer:

"wherein said pPS cells are not obtained by means of a process in which human embryos are destroyed".

The claim was rejected according to the principles of Enlarged Board Decision G02/10 whereby the subject matter remaining in the claim after the introduction of the disclaimer must be explicitly or implicitly, directly and unambiguously disclosed to the skilled person using common general knowledge, in the application as filed.

The Board considered that the non-destructive methods remaining in the claim were not clearly and unambiguously disclosed in the application as filed and thus the disclaimer offended Article 123(2) EPC (added matter). Interestingly, the Board accepted that using a method of pre-implantation genetic diagnosis published in 2001, it was possible that a single blastomere cell could be obtained from day 3 cleaving embryos without destroying the embryo but reasoned that the claimed method required more than this, i.e. *in vitro* culturing and expansion of hES cells (derivation) and there was no evidence that this could be achieved until the publication of a paper by Chung *et al* on Single Blastomere Biopsy in January 2008.

A further claims request was entered by the applicant with the alternative disclaimer:

"wherein the method does not involve use of a human embryo for industrial and commercial purposes".

The disclaimer was rejected for lack of clarity and being contradictory on the basis that the mere seeking of patent protection meant it must have an industrial and commercial purpose. It was also rejected under Article 123(2) for added matter because it related to downstream uses and not the claimed subject matter *per se*.

(iv) EPO T1808/13 Brustle

In February 2015 the Technical Board of Appeal of the EPO handed-down its final decision in the case of European Patent EP1040185, the European equivalent of the German patent of Brustle, considered by the CJEU in C-34/10.

The claims as granted related to a non-tumorigenic cell composition obtained from mammalian embryonic stem cells but, following G02/06, included the disclaimer:

"with the proviso that the method does not include the destruction of human embryos".

The claims were revoked by the Opposition Division on 28th June 2013 because the disclaimer added matter contrary to Article 123(2). Similar to the reasons given in subsequent decision T1441/13 discussed above, the application as filed only disclosed a method involving embryo destruction such that subject matter left once destructive methods were disclaimed could not be regarded directly and unambiguously derivable from the application as filed.

The Appeal Board confirmed that an invention starting from established cell-lines which had originally been obtained by embryo destruction, was in contravention of Article 53(a), as were stem cells obtained from a cloned human embryo.

On the question of the disclaimer, the position of the Opposition Division that this was added matter, was upheld and the patent was remitted to the Opposition Division with claims to non-tumorigenic embryonic stem cells, other than human, only.

This decision, as with T1441/13 above merely confirms that while, in principle, disclaimers may be introduced to exclude subject matter from a claim which cannot be patented for moral reasons, in accordance with Article 53(a) EPC, in practice the need to adhere strictly to the criteria for allowance of disclaimers in general, makes this an unreliable route for overcoming Article 53(a) exclusions.

FRANCE

A) Patentable subject matter, TGI Paris, 3 July 2014, *Evinerude* v. *Philippe Giraudeau and Aair Lichens*

The tribunal de grande instance de Paris, in a judgment of 3 July 2014, clarifies the exclusion of discoveries from patent-eligible subject matter.

Philippe Giraudeau is the inventor and the applicant of French Patent â 01 03485, entitled "*Measuring of environmental levels of polychlorinated dibenzodioxins and of polychlorinated dibenzofurans by using lichens as dosing material*".

The patent teaches how to measure air pollution, by exposing lichen to ambient air in different places, collecting and analysing these lichens in order to determine their content in polychlorinated dibenzodioxins or polychlorinated dibenzofurans compounds, and comparing the results of the tests performed on lichens located in specific places with an "*average value of atmospheric impregnation*" calculated from measurements performed on lichens taken from a wider geographical area. The single claim of the patent as granted is drafted as follows: "*This invention consists in using lichens exposed to chlorinated compound-emitting sources and used as transplants or crops to perform quantitative measurements of polychlorinated dibenzodioxins or polychlorinated dibenzofurans compounds, and to assess the impact on the environment*".

The *tribunal* revokes the patent on the grounds that it covers a discovery.

The *tribunal* recalls that, while a mere discovery cannot be patented, a practical application (such as the practical application of a law of nature) may be patent-eligible: "*A mere discovery cannot thus be patented. Indeed, the discovery exists before the human intervention whereas the invention is its fruit. So the discovery brings nothing new to the state of the art since the discovery stands at the stage of the pure knowledge. However, if the subject-matter of a discovery is not patentable, a practical application*

may result in granting a patent."

In this case, the *tribunal* held that the single claim of the patent covers the principle of using lichens to measure pollution by polychlorinated dibenzodioxins and polychlorinated dibenzofurans and that, since the process steps (alone eligible for protection) were not claimed, the patent covers a discovery and not a patent-eligible process: "*As drafted, the single claim of the patent does not cover the process steps but only the assertion that steps can be performed to assess the impact on the environment, which is not a process invention*."

B) Indication of the origin of natural resources in patent applications

A draft bill is being discussed in Parliament: Draft submitted to the *Senat* on 25 March 2015. Articles 18 and 20 of the draft Bill make amendments to the Environmental Code concerning the use of genetic resources and associated traditional knowledge.

One of the provisions of the Bill provides that the origin of natural resources must be indicated in patent applications (Art. 18).

ITALY

Inaugural Report from Italian Member

1. Implementation of EU Directive 98/44/EC

The Directive 98/44/EC on the legal protection of biotechnological inventions was adopted in Italy in January 2006. In 2010, the law was incorporated in a separate section of the Industrial Property Code (IPC), i.e. Section IV bis.

Italian law on biotechnological inventions presents some differences from the Directive 98/44/EC.

Most relevant are:

- Art. 6 of the EU Directive excludes from patentability uses of human embryos for industrial or commercial purpose. IPC excludes every use of human embryos, including embryonic stem cells lines (Art. 81-quinquies.1.3 IPC). Thus, contrary to considerandum 42) of the Directive (and recent case law from EPO and European Court of Justice), the Italian law seems to exclude from patentability also inventions for therapeutic or diagnostic purposes which are applied to the human embryos and are useful to the same.
- Art 5.3 of the EU Directive states that the industrial application must be disclosed in the patent application only for a sequence or a partial sequence of a gene. Art. 81 quarter d) IPC states that function and industrial applicability must be concretely indicated and described for an element isolated from the human body or otherwise produced by means of a technical process.
- Art. 5 of the EU Directive states that the industrial application of a sequence or a partial sequence of a gene must be disclosed in the patent application. Italian relevant provision states that the specific function, which has to be industrially applicable, of a gene or fragments thereof must be indicated, described and specifically claimed (Art. 81 quinquies.1.c IPC).

2. Declaration to be provided for national Italian patent applications.

IPC foresees that some procedures/declarations should be activated/required for Italian patent applications (Art. 170-bis IPC):

1. a declaration of origin of the animal or plant biological material (State of origin and biological organism from which it has been isolated) on which the invention is based (see also Considerandum 27 of the Directive and Art. 1 of the Convention on Biological diversity);
2. a free informed consent of the person donating human biological material that is object of the invention or used in the invention; c) a declaration that guarantees on the fulfilment of obligations relating to modifications for of genetically modified microorganism or organism contained in the biological material that is object of the invention or used in the invention.

In the absence of such declarations, the Italian Patent Office asks for them and/or for filing observations (art. 173.7 IPC). The application is refused only if there is lacking of patentability requirements. The lacking of such declarations should be annotated in the Italian Register, not implying refusal. In addition, such lacking of documents is not even ground for nullity of a granted patent.

3. Administrative sanctions (Art. 170 *ter* IPC)

Everyone who uses biological material of human origin, being aware of the fact that it was collected or used for patent purposes without the express consent is punished with a fine from € 100,000.00 to 1,000,000.00 (Art. 170-ter.1 IPC). Everyone who falsely certifies the origin of the biological material of animal or vegetable origin or the compliance with the requirements of the law regarding genetically modified organism or microorganism is punished with a fine from € 10,000.00 to 100,000.00 (Art. 170-ter.2 and 3 IPC).

AUSTRALIA

Recent Patent Office Decisions

Pharmaceutical substances involving recombinant DNA (rDNA) technology

Two recent decisions from the Australian Patent Office, *ImmunoGen, Inc.* [2014] APO 88 (19 December 2014) and *Novartis Vaccines and Diagnostics S.r.l.* [2015] APO 2 (2 February 2015) clarify the breadth of the scope of PTE provisions as they relate to pharmaceutical substances involving recombinant DNA (rDNA) technology.

Briefly stated, the decisions make clear that:

1. The relevant claims do not need to be limited to products made by rDNA technology.

A process claim can support a PTE for a pharmaceutical substance which is, or comprises a component, made using rDNA technology, even where the claim does not explicitly recite recombinant process steps or that the product/component is recombinantly-produced. and where the rDNA process *per se* is not novel or the subject of a separate patent;

2. A product-by-process claim is not required.

A claim defining a process for producing a pharmaceutical substance is substantially indistinguishable in scope from a claim to a product made by that process. However, it remains prudent to include product-by-process claims.

3. Whilst rDNA technology must be relevantly involved, the specific rDNA processes themselves need not be the novel and inventive subject matter

Patentability of isolated nucleic acid – High Court of Australia hears Myriad Appeal

On 16 June 2015, the High Court of Australia (Australia's highest court) heard the long anticipated appeal from the unanimous decision of a 5-judge bench of the Full Federal Court to allow Myriad's claims to isolated nucleic acids.

The question before the High Court is whether the invention claimed in claims 1-3 of Australian Patent No. 686004, owned by Myriad Genetics, is a "manner of manufacture" within the meaning of s 6 of the Statute of Monopolies, as required by section 18(1)(a) of the *Patents Act 1990*. The test for "manner of manufacture" was defined by the High Court in *National Research Development Corporation v Commissioner of Patents* (1959) 102 CLR 252 (NRDC) which remains the leading case on subject matter eligibility in Australia and has, for over 50 years, been consistently applied to various evolving technologies from IT to biotechnology.

The NRDC test requires that the claimed invention involve an "artificially created state of affairs" (i.e. something which, but for human intervention, would not exist) in a field of economic utility.

The Appellant's arguments relied heavily on the reasoning of the US Supreme Court in *AMP v Myriad Genetics,* asserting that the isolated nucleic acids are in substance identical to the corresponding sequences in nature.

Myriad's submissions emphasized that isolated nucleic acids are chemically, structurally and functionally different from the naturally occurring nucleic acids and have new applications which do not apply to the sequences as found in nature.

It appears from the High Court proceedings that the Court's consideration will be confined to claims to isolated nucleic acids, leaving aside any broader question of patentability of isolated biological material.

The decision is expected later this year.

CHINA

Legislative Activities

1. **SIPO issued *Measures for the Deposit of Biological Materials for the Purposes of Patent Procedure***

On October 30, 2014, SIPO issued the *Draft Measures for the Deposit of Biological Materials for the Purposes of Patent Procedure* (hereinafter referred as *Measures*), for collecting opinions from the public.

On January 16, 2015, SIPO approved the *Measures* which has taken effect on March 1, 2015. The *Measures* contains 20 articles, specifying requirements on procedure issues relating to deposit of the biomaterial and submission of sample of biomaterial.

1. **The State Council decided to amend *Regulations on the Protection of New Plant Varieties***

On July 29, 2014, the State Council decided to amend the current *Regulations on the Protection of New Plant Varieties*. Correspondingly, the *Implementing Rules of Regulations on the Protection of New Plant Varieties* was at the same time amended.

1. **SIPO issued the fourth *Draft Amendment of Patent Law of China***

The current *Patent Law of China* (PLC) does not protect methods for diagnosing and treating diseases of animals. However, the fourth draft amendment is going to patent protection on methods for diagnosing and treating diseases of farmed animals, as a kind of respond to development and need of relevant cultivation industry.

Patent Invalidation case relating to patent named "Treatment With Anti-Erbb2 Antibodies"

Patentee: GENENTECH, INC.

Third Party: Domestic Individual

Case Brief

The patent relate to the pharmaceutical preparations of ErbB2 antibody (i.e., "Herceptin") and the manufacture method thereof, with the Patent No. ZL200610008639.X. In February, 2014, a domestic natural person requested for invalidation against this patent to Patent Re-examination Board of SIPO (hereinafter referred to PRB). After Examination, the patent was wholly invalidated by PRB for lack of inventiveness in Invalidation Decision No. 23948.

Specifically, the case related to the limitation effect of the medicine container and label on the medicine product claims and the limitation effect of the administration feature on the medical use. The PRB believed the medicine container and the information about the indication and administration method and the like recited in the label belonged to common technical means in the prior art, and meanwhile, the skilled person is motivated to change the administration subject whereas the specification did not recite which unexpected technical effects could be brought by the change of the administration subject.

Comments

The involved Patent directed to “Herceptin”, which is the first anti-cancer drug targeted to molecule. The cure rate for breast cancer is up to 95%, and the saleroom is over 7 billion dollars. The patentee of this patent is the industry giant in the international bio-medical art and has filed about 40 patent applications concerning this anti-cancer drug. The involved patent is the core patent among them. This case explicated the strategies and methods for examining the inventive step of product claims and medical use claims defined by features of drug administration in the art of medical and biological art, and thus provided certain guides for how to reasonably control the examination standard on those kinds of claims and how to execute the standard consistently.

COSTA RICA

Technical Regulations: RTCR 440: 2010.

Regulations for the Registration and Control of Biological Drugs, Executive Decree N°37006-S from November 15, 2011 is going through public consultation in order to enforce a series of amendments in the Regulations. Specifically, certain definitions of the Regulations are being amended, such as the concept for Biological Medicines: “4.48. Biological medicine: Pharmaceutical product made with bio-based materials such as microorganisms , organs and tissues of animal or plant origin, cells or fluids (including blood or plasma) of human or animal origin, and biotechnological cell constructs (cell substrates , whether or not recombinant including primary cells)”. In addition, the documentary requirements for the registration of these products before the Health Authority are being clarified and/or augmented. Once the public consultation period has elapsed, the Health Authority will review all commentaries and will issue a final text for approval. In that case, the amended Regulations could be in force in about one year.

JAPAN

No further developments in the reporting year but see report of Pharma Standing Committee.

INDIA

No further developments in the reporting year.

MEXICO

No further developments in the reporting year.

USA

We learned just at the point of completing this report that the USPTO have issued further patent eligibility guidelines following the public consultation. No commentary has appeared yet.

2.2 Report in the plant breeders rights field

EUROPE

(A) Farm saved seeds: CJEU, 25 June 2015, C-242/14, Saatgut-Treuhandverwaltungs c. Vogel

By decision of 25 June 2015, the CJEU answered the questions referred to it by the Landgericht Mannheim (Germany) on 9 May 2014.

The issue relates to the derogation from community plant variety right provided by Art. 14 of Regulation N° 2100/94 known as the farmer’s privilege or farm-saved seeds.

Article 14(1) of Regulation No 2100/94, entitled ‘Derogation from Community plant variety right’, provides that “*Notwithstanding Article 13(2), and for the purposes of safeguarding agricultural production, farmers are authorised to use for propagating purposes in the field, on their own holding, the*

product of the harvest which they have obtained by planting, on their own holding, propagating material of a variety other than a hybrid or synthetic variety, which is covered by a Community plant variety right."

This derogation is limited to given species (Art. 14(2) and subject to conditions contained in Art. 14 of the basic Regulation and in Regulation No 1768/95. In particular Farmers are required to pay an equitable remuneration to the holder (Art. 14(3)).

If those conditions are not met, the farmer "*may be sued by the holder to enjoin such infringement or to pay reasonable compensation or both*" and whosoever acted "*intentionally or negligently shall moreover be liable to compensate the holder for any further damage resulting from the act in question*" (Art. 94 of basic Regulation.

The questions referred to the CJEU related to the time when the farmer is due to pay the equitable remuneration; and thus acted the expiration of which the holder can start the actions to obtain compensation of its damage.

The CJUE (Second Chamber) ruled as follows: "***In order to be able to benefit from the derogation provided for in Article 14 of Council Regulation*** *(EC) No 2100/94 of 27 July 1994 on Community plant variety rights from the obligation to obtain the authorisation of the holder of the plant variety right concerned,* ***a farmer*** *who has planted propagating material obtained from a protected plant variety (farm-saved seed) without having concluded a contract for so doing with the holder* ***is required to pay the equitable remuneration due under the fourth indent of Article 14(3) of that regulation within the period that expires at the end of the marketing year during which that planting took place, that is, no later than 30 June following the date of reseeding***."

(B) Nullity proceedings in respect of Community plant variety rights, CJUE, 21 May 2015, Case C 546/12, Ralf Schräder v. CPVO

This appeal is against the judgment of the General Court of the European Union in *Ralf Schräder v. CPVO* of 23 January 2009. The main issue relates to the onus of proof and the power of the Board of Appeal of the CPVO to act on its own motion in proceedings for the annulment of a Community plant variety right initiated by third party according to Art. 20 of Regulation N° 2100/94. The CJEU criticizes the decision taken by the court of first instance of the European Union.

The facts can be summarized as follows: On 11 April 2007, Mr. Schräder (sued for infringement of a CPVO) filed an application for annulment of CPVR pursuant to Art. 20 of basic Regulation. Proceedings. By letter of 26 September 2007, the CPVO rejected the application for annulment. On 19 October 2007, Mr. Schräder brought an appeal before the Board of Appeal against the decision on the application for annulment. The Board of Appeal dismissed as admissible, but unfounded, the appeal. Mr. Schräder appealed before the CJEU.

By decision of 18 September 2012 the court of first instance of the European Union reminded that under Article 20(1)(a) of the regulation, the CPVO is to declare the Community plant variety right null and void 'if it is established' that the conditions laid down in Articles 7 or 10 were not complied with at the time of the Community plant variety right.

In this decision, the court set out the principles relating to burden of proof:

"The task of the Board of Appeal is solely to rule, on the application of an interested party, on the lawfulness of a decision of the CPVO adopted under Article 20 (1) (a) of the regulation refusing to declare the Community plant variety right null and void on the ground that it has not been 'established' by that party that the conditions set out in Article 7 or in Article 10 of that regulation were not satisfied at the time when the right was granted.

Since annulment proceedings were initiated not by the CPVO of its own motion, but on the application of an interested party, Articles 76 and 81 of the regulation, read in conjunction with Article 20 thereof, thereby place the onus on that party to prove that the conditions for that declaration of nullity have been met.

In proceedings before it the Office shall examine the facts of its own motion. However, in proceedings relating to a declaration of invalidity, the Office shall be restricted in this examination to the facts, evidence and arguments provided by the parties and the relief sought."

It followed from this decision (criticized) that the CPVO is entitled to examine the validity of a CPVR, notably the novelty requirements, but that "*it shall be restricted, in this examination, to the facts, evidence and arguments provided by the third party*" which has the burden of proving the alleged invalidity.

In its decision of 25 May 2015, the CJEU considered that the Court of first instanced made an error because the Board of appeal of the CPVO can examine the facts on its own motions even when the nullity action is initiated by a third party:

"47- The General Court, consequently, erred in law in holding that the principle of examination of the facts by the CPVO of its own motion does not apply to proceedings before the Board of Appeal."

Yet the CJEU considered that the board of appeal of the CPVO does not have to examine facts on its motion in every circumstance, but only if serious doubts regarding the validity of the CPVR exist:

"Thus, the CPVO has a wide discretion concerning annulment of a plant variety right for the purposes of Article 20 of Regulation No 2100/94, in so far as the protected variety underwent the examination set out in the previous paragraph. Therefore, only where there are serious doubts that the conditions laid down in Articles 7 or 10 of that regulation had been met on the date of the examination provided for under Articles 54 and 55 of that regulation can a re-examination of the protected variety by way of nullity proceedings under Article 20 of Regulation No 2100/94 be justified".

(C) CPVO, Board of Appeal, 15 September 2014, A007/2013, Bloomkwekerij Van Rijn – de Bruijn v. OCVV (Oksana)

By decision of 2 July 2014, the Board of appeal of the CPVO decided on the issue of novelty of a CPVR, pursuant to article 6 of Regulation N° 2100/94, which provides that "*A variety shall be deemed new if, at the sate of application (...) variety constituents or harvested material of the variety have not been sold or otherwise disposed to others, by or with the consent of the breeder (...)*". The issue of consent of the breeder was at stake.

It resulted from the facts that material of the variety had been made available for research purposes at a German institute, which later provided variety constituents to third parties. The owner of the CPVR argued that this disposal had not been made with the consent of the breeder within the meaning of Art. 6 of the basic Regulation.

The Board of Appeal of the CPVO considered that the variety is not novel:

- because it has been established that it was common practice in the former East Bloc countries that Institute could provide plant material to third parties for the spreading of new varieties and
- because the applicant failed to establish that the Institutes were obliged to obtain the consent of the variety's breeder before providing material of the variety to third parties.

The board of appeal of the CPVO does not consider that a written contractual obligation must exist in order for the breeder to keep control over the plant material; but the board considered that evidence of the contrary (*i.e.* of unqualified disposal) had been given in this matter.

FRANCE

A) Decree N° 2015-164, 12 February 2015, Joint Committee of conciliation specific to the field of plant varieties

The French Decree No 2015-164 of 12 February 2015 determines the composition and functioning of the Joint Committee of conciliation specific to the field of plant varieties.

This committee can be seized by parties in the event of dispute between a breeder and its employer when a variety was bred by the employee, including through the execution of his employment contract or in the field of the business activities of the employer.

The rules applicable to this committee are identical to those applying to employees' inventions.

B) Decree N° 2014-869 of 1 August 2014 pursuant to Article L. 623-24-1 of the French Intellectual property code regarding farm-saved seeds

The decree of 1 August 2014 lists the species for which farmers have the right to use on their own holdings , without the authorization of the breeder, the product of the harvest which they have obtained by culture of a protected variety.

The Decree extends the farmer's exemption to certain species of fodder plants, oil plants , plants for use as intermediate crops, protein crops and vegetables, not mentioned by Regulation (EC) No 2100/94 of 27 July 1994.

THE NETHERLANDS

(A) Court of The Hague, 18 March 2015, Taste of Nature v. Cresco

Taste of Nature is the holder of EP No 1 290 938 relates to a plant and a sprout of a plant of the radish species Raphanus sativa with an increased anthocyanin level, and to methods for its production.

Claim 1 reads as follows : "*A Raphanus sativa plant, obtainable by screening Raphanus sativa plants for their ability to produce sprouts with at least some purple coloring, selfing and/or crossing said plants for several generations and selecting progeny having sprouts with purple coloring, characterized in that the sprout of said plant comprises anthocyanins at a level of at least 800 nmol per gram fresh weight of sprout*."

Taste of Nature had initiated preliminary proceedings against Cresco, on the basis of this patent. In 31 January 2012, the Court of The Hague addressed the issue of patentability in light of Article 53, opening lines and (b), of the EPC and, in doing so it clearly refers to EPO Enlarged board of appeal decisions G2/07 and G1/08 i.e. the broccoli and tomato case.

On 18 March 2015, the Court of the Hague on the merits however held that Taste of Nature's patent for red radish plants was invalid since the seeds, sprouts and the plant itself had been made public before the patent was even applied for. Unfortunately, the court did not decide on the issue of patentability in light of Article 53, opening lines and (b), of the EPC.

BRAZIL

Infringement Lawsuit of Plant Varieties Rights

Fibria vs Eldorado

On July 22nd 2015 the Judge of the Brazilian 4th Civil Court of Três Lagoas (State of Mato Grosso do Sul) issued a decision on a very important case concerning cultivars. Parties involved in the litigation are FIBRIA, the world's largest producer of bleached eucalyptus pulp, and its local direct competitor, ELDORADO BRASIL CELULOSE. Because of its importance, the case has been closely watched by the international media.

The litigation started when Fibria received an anonymous message stating that Eldorado had been using an eucalyptus breed of Fibria's IP portfolio, named cultivar VT02, without authorization or license. In order to verify this information, Fibria submitted the breeding and the supposedly cloned eucalyptus breed to a comparison test (DNA) at a Molecular Laboratory. The results, as demonstrated in the lawsuit, indicated a virtual identity of 99.9999% between the two tested eucalyptus breeds. In view of that, Fibria filed an injunction aiming at the disclosure of evidence and seeking a judicial examination of the matter by an expert. In so doing, the damages would be demonstrated and the proofs of violation would be secured

before a lawsuit claiming losses and damages (and other legal measures) could eventually be filed.

Eldorado responded to the accusations stating that that court would have no jurisdiction to rule over that case, which has been rejected by the judge, as the jurisdiction was the one on which the expert's analysis was supposed to take place. Regarding the case's merits, the company mostly stated that cloning a species would involve another kind of environment, different from the one the eucalyptus' fields are located in.

Later, Fibria requested the suspension of the in camera procedures, since the lawsuit had been going under wraps since the beginning. The plea was ultimately accepted under the argument that the sole fact that two of the biggest players in the paper industry were in a judicial controversy was not a good enough reason to keep the lawsuit out of the public domain.

After the trials were carried out, the test results validated that 5 samples, of a total of 6, were genetically identical to Fibria's cultivar VT02. The Mato Grosso do Sul (MS) State Court Judge confirmed the proof and the case has finally reached an end on the first chamber. As for the next step, Fibria should sue Eldorado by means of a lawsuit due to infringement of its plants varieties rights, ultimately based on the evidence that was obtained during the disclosure of evidence.

3) Any recommendation for AIPPI involvement/action (describe what involvement/action is recommended and why, by whom and relevant time frames)

The Biotechnology Sub-Committee does not have any particular recommendations for intervention or specific participation by AIPPI in relation to on-going legal proceedings, government projects or intergovernmental meetings.

4) Plan for the activities of the Standing Committee for the next reporting period highlighting any priorities

It is intended that the Biotechnology Sub-Committee will hold a meeting in Rio providing sufficient members are present and that some or all of those members will attend a meeting of the Pharma Committee. We will continue to monitor developments within our Terms of Reference and hold telephone conferences with members during the reporting period to gather information, as in previous years. Preparation of the position paper on patenting human embryonic stem cell technologies will continue.

Names and Functions of Committee Members

Chair	Claire BALDOCK	United Kingdom
Co Chair(s)	Thomas BOUVET	France
Secretary	Peter LUDWIG	United States
Members	Andrew N. BLATTMANN	Australia
	Olga CAPASSO	Italy
	Magnus DAHLMAN	Sweden
	María DEL PILAR LOPEZ	Costa Rica
	Gabriel DI BLASI	Brazil
	Takashi FUJITA	Japan
	Gesheng HUANG	China
	Israel JIMENEZ	Mexico
	Edgar KRIEGER	Germany
	Jürgen MEIER	Germany
	Hariharan SUBRAMANIAM	India