Report Q114

Biotechnology and Plant Variety Rights

Names and Functions of Committee Members

Chair	Claire Baldock	United Kingdom
Co-Chair	Thomas Bouvet	France
Secretary	Peter Ludwig	United States of America
Members	Gabriel di Blasi	Brazil
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	Takashi Fujita	Japan
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	Juergen Meier	Germany
	Edgar Krieger (Plant Varieties)	Germany
	Gesheng Huang	China
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	Magnus Dahlman	Sweden
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A.

Summary

Current and Future Issues

Herein Committee Q114 provides an update on IP Developments in the Biotechnology sector in Europe, including France and Hungary, USA, China, Australia, Japan, Brazil and India. The live issues going forward into the next year include:

- Whether patents in the field of stem cell technology will become more available in Europe following the final outcome of the CJEU referral in C-364/13 (see Section B(1), subsection c(ii) herein)

- Whether the products of processes currently deemed to be "essentially biological" by the European Patent Office will remain patentable in Europe following the Enlarged Board of Appeal referral in G02/13 (see Section B(1)a herein).

- Whether the Guidance issued by the USPTO in March 2014 concerning patent eligible subject matter will be maintained in its present form or whether the recent public consultation will result in a change of approach (see Section B(2) herein).

- Whether the policy changes at the Chinese Patent Office regarding assessment of insufficiency and inventive step will ease the passage for biotechnology patents in China (see Section B(3) herein).

- Whether criteria for the granting of Patent Term Extensions in Japan will change following Appeal to the Supreme Court in respect of Genentech's patents for bevacizumab (Avastin) (see Section B(7)i herein).

Deadline for any action

There are no specific deadlines for action at present.

Action Recommended

Other than monitoring the live issues identified above and in Section B of the report, Q114 does not have any actions to recommend to the Bureau at the present time.

Report on the Committee Activities

Reporting against priorities set for the period

Q114 met in Helsinki 2013 and the meeting was attended by a majority of the members. At the meeting certain objectives were agreed. These included action relating to Enlarged Board referral G02/13 and interim meetings by teleconference during the forthcoming year (see below).

Activities of Special Committee during the period

Following agreement of the Committee members at their meeting in Helsinki and with approval of the Bureau an Amicus brief was prepared by Q114 and filed at the EPO on behalf of AIPPI by the deadline of 30th November 2013 (see Section B(1) herein).

Meetings of the Committee took place by teleconference on 4th/5th March 2014 (two calls required due to the various time differences of the members) and members reported on local issues in their country. The updates provided are included in Section B of this report.

Recommendations

The Committee does not have any specific recommendations for action at present other than monitoring the various matters summarized above. However, the Committee intends to be proactive in identifying opportunities for supporting and promoting Intellectual Property Rights, including Plant Variety Rights, Internationally on behalf of AIPPI and to be ready to step in with actions as necessary. Interim meetings by teleconference will of course be planned at our meeting in Toronto.

B.

1. Europe – Claire Baldock & Thomas Bouvet

a) Broccoli case, EPO Enlarged Board of Appeal – Referral G02/13

In November 2013 an Amicus brief prepared by Q114 was filed at the EPO on behalf of AIPPI in the case of Enlarged Board of Appeal referral G02/13. Known as the "Broccoli" case, the referral concerns 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 the filed brief the AIPPI took the position that such plant products 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. The current balance of rights between holders of plant patents and of plant variety rights was supported.

The case remains pending before the Enlarged Board and Oral Proceedings are set for 27 October 2014. The parties have a deadline of one month before to file further submissions.

b) Supplementary Protection Certificates

Since our Helsinki Report, the CJEU has handed down a number of Judgments concerning Supplementary Protection Certificates. Two deal with situations where more than one SPC per patent might be permitted and a third with to what extent the pharmaceutical product the subject of the marketing authorisation must be "specified" in the basic patent.

The details are as follows:

(i) Georgetown University (C-484/12)

Georgetown University sought to obtain seven SPCs for different combinations of Human Papilloma Virus (HPV) antigens and the individual antigens, based upon its basic patent EP0647140. Two of these SPCs (for HPV-6/HPV-11/HPV-16/HPV-18 and HPV-16/HPV-18) have been granted and four remain pending, but the present decision relates to the rejection of Georgetown's application for an SPC for HPV-16 alone on the basis that Article 3(c) of the SPC regulation permits only a single SPC to be based upon a basic patent.

The CJEU decided that Article 3(c) does not preclude an SPC being granted for a single active ingredient where, based on the same basic patent, an SPC has already been granted for that active ingredient as part of a combination product, provided the individual ingredient is protected as such by the basic patent. Rather unusually, this is contradictory to the Advocate General's Preliminary Opinion.

Although the CJEU decision does neatly address the specific situation encountered by Georgetown, it does not comment on whether multiple SPCs could be based on a single basic patent under different circumstances, and somewhat frustratingly refrains from clarifying the requirements for an active ingredient to be protected as such by the basic patent.

(ii) Actavis v Sanofi (C-443/12)

Sanofi's EP0454511 patent related primarily to the antihypertensive agent ibersartan, and includes a dependent claim directed to a pharmaceutical composition comprising ibersartan and one of a selection of generically defined additional therapeutic agents, including diuretics. Having obtained marketing approval for ibersartan, Sanofi obtained an SPC for this medicinal product and following the separate approval of CoAprovel (a composition comprising ibersartan and the diuretic hydrochlorothiazide) a second SPC was granted.

Actavis challenged the validity of the second SPC on the basis that the combination of ibersartan and hydrochlorothiazide was not specifically recited in the patent and that a second SPC should not be granted from a single basic patent, and two questions were subsequently referred to the CJEU.

The CJEU decided that Sanofi's second SPC (issued for the combination product CoAprovel) was invalid because, having obtained a first SPC directed to a single patented active ingredient, a Proprietor may not validly obtain a second SPC for a combination product containing the active ingredient in combination with another active ingredient which is not protected as such by the

basic patent. In agreement with the Georgetown University decision discussed above, the CJEU here left open the possibility for a second SPC to be granted from a single basic patent if the combination with another active ingredient is protected as such by the basic patent.

Having decided that Sanofi was not entitled to a second SPC, the CJEU again declined to discuss the criteria for deciding whether a product is protected by a basic patent in force under Article 3(a) of the SPC regulation.

(iii) Eli Lilly v HGS (C493-12)

HGS obtained an SPC for its anti-Neutrokine-a antibody belimumab, based upon a claim directed to an isolated antibody or portion thereof that binds specifically to Neutrokine-a. Before the UK Court Eli Lilly objected to the SPC on the basis that the antibody which formed the active ingredient was not protected by the basic patent in force (EP0939804), as required by Article 3(a) of the SPC regulation, because the structural features of the antibody which formed the active ingredient were not specified in the wording of the claims.

The CJEU addressed the following question after a referral form the UK Judge:

> "*Whether Article 3(a) of Regulation No 469/2009 [the SPC Regulation] must be interpreted as meaning that, in order for an active ingredient to be regarded as 'protected by a basic patent in force', within the meaning of that provision, the active ingredient much be identified in the claims of the patent by a structural formula, or whether the active ingredient may also be considered to be protected where it is covered by a functional formula in the patent claims."*

The CJEU ruled that it is not necessary for the active ingredient to be identified by a structural formula in order to satisfy the requirement of Article 3(a) that the active ingredient is 'protected by a basic patent in force'; a functional definition of the active ingredient is, in principle, enough to obtain an SPC, provided it can be concluded that the claims of the patent, interpreted in light of the description, relate to that active ingredient "necessarily and specifically".

In making this ruling, the CJEU referred extensively to Article 69 EPC, which specifies that the extent of protection conferred by a European patent shall be determined based upon the claims interpreted on the basis of the description and the drawings. Since the provisions of the EPC are outside the jurisdiction of the CJEU, the CJEU declined to provide any further guidance to national courts as to the manner in which they should determine the extent of protection conferred by the claims of a patent granted under the EPC.

On 18 July 2014 the UK High Court then handed down its judgment in the matter taking into account the CJEU Decision. The Judge was very critical of the Decision in failing to clarify exactly what sort of disclosure is required for the patent to relate to the active ingredient "necessarily and specifically". However, he concluded that if the CJEU has decided that a functional definition of an active ingredient in the claim did not preclude the granting of an SPC, then it could not have intended that a structural definition must appear as well.

Further, in requiring the claims to relate implicitly but necessarily and specifically to the active ingredient the CJEU merely intended to exclude from SPC eligibility active ingredients which fall within the scope of a claim merely due to the inclusion of open "comprising" language. In arriving at this interpretation the Patents Court has effectively limited the CJEU's ruling to that previously handed down in Medeva (C-322/10) where the CJEU rejected the infringement test and confirmed that the active ingredient must be specified in the wording of the claims in order to be considered protected by the basic patent in force under Article 3(a) of the SPC regulation.

Based on this reasoning, HGS would be entitled to an SPC for a functionally defined antibody binding neutrokine-α. This may not be what the CJEU intended. Lilly have been given leave to appeal.

c) Stem cell issues

(i) T 2221/10 Culturing stem cells / Technion

On 4 February 2014, the Boards of Appeal of the European Patent Office examined the patentability of inventions which make use of publicly available human embryonic stem cells, initially derived by a process resulting in the destruction of the human embryos.

The Board ruled that, under the framework of Art. 53(a) EPC and Rule 28(c), it is necessary to evaluate all the steps which constitute a necessary precondition for carrying out the claimed inventions:

> *"The Board interprets this statement of the Enlarged Board of Appeal as meaning that for the purpose of Rule 28(c) EPC, all steps preceding the claimed use of HES cells which are a necessary precondition for carrying out the claimed invention, have to be considered."*

The panel found such inventions to be unpatentable, even if they do not directly involve the destruction of human embryos, which instead takes place at a preceding, but necessary, stage:

> *"In consequence, the claimed invention depends entirely on the use of HES cells, either obtained by de novo destruction of human embryos (cf. points 8 and 9, above) or by using established HES cell lines which initially were obtained by methods involving the destruction of human embryos (cf. points 10 to 29, above), both of which are excluded from patentability under the provisions of Article 53(a) EPC in combination with Rule 28(c) EPC.*
>
> *Therefore appellant's sole request is not allowable."*

The decision shares the same perspective adopted by the EU Court of Justice in Case C-34/10 (*Brüstle v Greenpeace*):

> *"But, although judgements of the ECJ are not legally binding on the EPO or its boards of appeal, they should be considered as being persuasive."*

(ii) CJEU Decision C-364/13

In our Helsinki Report, mention was made of a new CJEU referral C-364/13. In the case of International Stem Cell Corporation v Comptroller General of Patents.

The case in question concerns 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 applications were refused by the UKIPO on the basis of the CJEU finding in the case of *Oliver Brustle v Greenpeace eV* that, amongst other things, an embryo could be:

> *"a non-fertilised human ovum whose division and further development have been stimulated by pathenogenesis, insofar as it is capable of commencing the process of development of a human being".*

This finding has been criticized as factually flawed, because cells generated by parthenogenesis and which are not from a fertilised egg are pluripotent and lack the essential elements for development of a human being.

The applicant lodged an appeal to the High Court of England and Wales arguing that the Brustle case should not be followed since parthenotes were not embryos as they could not develop into human beings. Mr Henry Carr QC, sitting as Deputy Judge, therefore referred a further question as follows to the CJEU:

> *"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 beings included in the term "human embryos" in Article 6(2) of Directive 98/44EC on the Legal Protection of Biotechnological Inventions?"*

On 17th July 2014 the Opinion of the Advocate General (AG) was issued. While not the final decision of the CJEU, such preliminary opinions are usually predictive of the outcome.

Distinguishing the technical evidence before the court compared to that in Bustle and conscious of changes in scientific understanding since that Decision, the AG held :

> *"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 capacity".*

On the basis of the ruling, since the claims at issue excluded any subsequent manipulation of the parthenotes they could be patented. While not currently binding on the CJEU, the Opinion is encouraging in that, if followed, it opens up the possibility of obtaining patents for a variety of stem cell technologies previously excluded, including cell stem cells not capable of developing into a human being even if not a parthenote. The Committee will review the position again when the actual CJEU decision is issued.

2. USA – Peter Ludwig

USPTO IMPLEMENTS NEW GUIDANCE FOR DETERMINING SUBJECT MATTER ELIGIBILITY FOR PATENTING

In March 2014 the United States Patent and Trademark Office (USPTO) published a Guidance to implement a new procedure to address changes in the law relating to subject matter eligibility under 35 USC§101 in view of recent court decisions including the June 13, 2013 US Supreme Court decision in Association for Molecular Pathology v. Myriad Genetics, Inc. and in Mayo Collaborative Services v Prometheus Laboratories Inc.

The Guidance is for use in examining any claim "…reciting or involving laws of nature/natural principles, natural phenomena and/or natural products." and reflects a significant new procedure for examining a broad range of claims for patent eligibility. While the Supreme Court decision in Myriad applied only to naturally occurring DNA ("We merely hold that genes and the information they encode are not patent eligible under §101 simply because they have been isolated from the surrounding genetic material") the Guidance has broader scope and includes claims that call for:

> *" chemicals derived from natural sources(e.g. antibiotics, fats, oils, petroleum derivatives, resins, toxins etc.); foods (e.g. fruits, grains meats ,and vegetables); metals and metallic compounds that exist in nature; minerals; natural materials (e.g. rocks, sands, soils); nucleic acids; organisms (e.g. bacteria, plants, and multicellular animals); proteins and peptides; and other substances found in or derived from nature."*

The Guidance includes a three question flowchart. The answers to the questions are supposed to assist Examiners on determining whether the claim under Examination is drawn to patent eligible subject matter. The questions are set forth below.

Question 1. Is the claimed invention directed to one of the four statutory patent-eligible subject matter categories: process, machine, manufacture or composition of matter?

Question 2. Does the claim recite or involve one or more judicial exceptions?
Judicial exceptions include abstract ideas, laws of nature/natural principles, natural phenomena and natural products. If there is any doubt that the claim recites a judicial exception the claim requires further analysis under questions 3.

Question 3. Does the claim as a whole recite something *significantly different* than the judicial exceptions.

The Guidance says that a *significant difference* can be shown e.g. by including elements or steps in addition to the judicial exception that apply the judicial exception in a significant way e. g. by adding more to the judicial exception.

Factors that weigh toward and against eligibility are set forth. The factors are to be used in analysing a claim for eligibility. Examples in which the various factors are applied and analysed with respect to sample claims are presented.

The Patent Office hosted a public forum on May 9, 2014 to receive public feedback from organizations and individuals on the Guidance. The Patent Office will issue an update to the Guidance after it has considered public feedback and the developing case law. The Office requested written comments from the public by July 31, 2014.

Q114 did not prepare a response in view of separate response by US group through AIPLA. The Committee will, however, monitor the USPTO response to the consultation.

3. China – Gesheng Huang

There have not been many significant new decisions available during the past year. However, there are important policy changes at the Chinese Patent Office regarding assessment of insufficiency. It is expected the Examination will be less rigorous in this respect but that absence of data may give rise to finding of lack of inventive step. However, comparative data submitted after filing is admissible to prove inventive step. The Committee will monitor how the new policy is applied going forward.

4. Australia – Andrew Blattman

(i) Apotex Pty Ltd v Sanofi-Aventis Australia Pty Ltd & Ors, December *2013* [2013] HCA 50

The High Court has considered the issue of patentability of claims to methods of medical treatment. The High Court held that a method of medical treatment of the human body can be a "manner of manufacture", and, therefore, a patentable invention within section 18(1)(a) of the *Patents Act 1990* (Cth).

The High Court has also clarified that claims directed to treatment of a disease by a known pharmaceutical substance (having prior therapeutic uses) are limited in scope to the deliberate or conscious treatment of that disease. A claim in this form is only infringed if the purpose of the administration is the unknown use which is claimed. There will be no incidental or accidental infringement by administration for the treatment of other diseases

Methods of medical treatment can thus be patentable and avoiding particular uses on the pharmaceutical labelling, so-called “skinny labelling”, may allow a generic to avoid infringement.

(ii) *Cancer Voices Australia v Myriad Genetics Inc*,; case before Federal Court. Decision expected September

On 15 February 2013, the Federal Court of Australia confirmed the patentability of isolated nucleotide sequences (genes) in Australia. The decision relates to the patents held by Myriad Genetics (Myriad) over the BRCA1 and BRCA2 genes, which are used in the diagnosis of breast and ovarian cancer. Cancer Voices Australia, a national organisation representing cancer patients, sought revocation of these gene patents.

The Federal Court ruled that the "isolated" nucleic acid that formed the BRCA1 and BRCA2 genes claimed by Myriad existed independently of their originating cells. Accordingly, by definition, the "isolated" nucleic acid did not exist within a cell like "naturally occurring" nucleic acid. The human intervention of isolating the nucleic acid from its "naturally occurring" state constituted "an artificially created state of affairs" and so was a "manner of manufacture" within the meaning of the Patents Act 1990 (Cth).

The Federal Court decision is currently under appeal to the Full Federal Court on the grounds that the court, at first instance, erred in its conclusion that isolating the gene constitutes a manner of manufacture.

(iii) Consultation paper issued by Australian Patent Office on gene patenting and morality issues.

There is no exclusion to patentability re subject matter (nothing similar to Art. 53 EPC).

5. Hungary – Arpad Peto

(i) Biotech provisions in Hungarian law

The Hungarian Patent Act, as regards regulations concerning biotech inventions, is fully harmonized with the EPC (namely, the meritorious regulations of the EU Biotech Directive are included in the Patent Act in a word by word translation).

(ii) Post grant limitation

The Hungarian Patent Act, unfortunately, is not at all harmonized with EPC as regards Art. 105a, 105b and 105c enabling proprietors to voluntarily limit their patents after grant.

There is no opportunity for post-grant amendment to redress the situation in Hungary for a national right, even though the law should be harmonized with EPC, where limiting amendment could be allowed. Our Hungarian Q114 Committee member has called the attention of the Intellectual Property Office to this irregularity and was informed that the HIPO did not think that it was under law harmonization obligation in this respect but was ready to start a discussion on the necessity of this legal institution within the profession. Such discussion has not started yet.

This defect of the Hungarian Patent Act seems to be a serious drawback for SPC proprietors, the SPC's of whom are being attacked on the basis of the Medeva decision.

(iii) SPC case law

An invalidity action has been started against a combination SPC (telmisartan + hydrochlorothiazide) on the basis of the Medeva decision C322/10. In Hungary, as there is no telmisartan alone SPC, the only relevant argument on the invalidity of the SPC is that the second ingredient is not "specified" in the claims.

One of the used arguments supporting validity of the SPC was the recent "relaxed" interpretation of the Medeva decision in the light of the Eli Lilly decision disclosed under 1B above. Another applied defense strategy was based on the special Hungarian situation, namely, that the basic patent the SPC is based on is a special pipeline patent which, in turn, is based on a New Zealand patent. The NZ patent has been post-grant restricted to have the combination definitely specified in the claims. This amendment has a retroactive effect. An attempt to post-grant "correct" the Hungarian patent the SPC was based on the retroactive NZ restriction having been made. However, as it was detailed above, in accordance with the Hungarian Patent Act, there is presently no possibility for effecting post-grant voluntary "amendment" of patents, only within the framework of revocation actions, otherwise, the patentee voluntarily only can abandon whole claims or the whole patent. An attempt was made to convince the authorities that the "alteration" that needs to be introduced herein because of the strict interpretation of the Medeva decision, on the basis of the retroactive NZ restriction, should qualify as a "correction" of the basic Hungarian patent on which the combination SPC is based (and which is a pipeline patent based on the NZ patent).

At the first instance, despite the above arguments, the HIPO has invalidated the subject combination SPC on the basis of the Medeva decision. The Hungarian member will continue to report on the further progress of these proceedings, if any.

6. France – Thomas Bouvet

(i) Dosage regime: Court of appeal of Paris, Pole 5 Ch. 1, 12 March 2014, Eli Lilly v. Teva Santé

In the above case it was held that claims regarding dosage regimes are not patentable subject matter because dosage is set by the doctor prescribing the drug. The claims also lacked inventive step because the dosage claimed was very broad and its technical effect was not explained.

(ii) New law

Act No. 2013-715 of 6 August 2013 allowing research on embryos and embryonic stem cells

Act № 2013-715 of 6 August 2013 has replaced the pre-existing regime of prohibition save express authorisation, which was set up in 1994 and maintained under the 2004 and 2011 Acts, by a system of authorisation under strictly regulated conditions.

The new Act (amending Article L. 2151-5 of the French Health Public Code) will permit research on human embryos and embryonic stem cells provided it meets all of four criteria:

- the scientific relevance of the research project is established;
- the research is part of a medical purpose;
- there is no alternative to the use of embryos or embryonic stem cells;
- the research project and the conditions for implementing the protocol respect all the ethical principles on research on embryos and embryonic stem cells.

The research is carried out on surplus embryos conceived *in vitro* in the context of medically assisted procreation and for which there is no longer a parental project.

The consent of the couples who conceived the embryos must be obtained.

The requirement of prospects of "major therapeutic advances" specified in the 2004 Act or “major medical advances" specified in the 2011 Act is abandoned in favour of simple "medical purpose."

The *Agence de la biomédicine* (the French Biomedicine Agency) issues authorisations after verifying compliance with legal requirements.

The import and export of human embryonic stem cells also require the authorisation of the *Agence de la biomédecine*.

(iii) Draft law No 1548 of 13 November 2013 on the future of agriculture, food and forest

The act intends to supplement Art. L. 613-2-2 of the French Intellectual property code as follows (see part in bold):

> *"Subject to the provisions of Articles L. 613-2-1 and L. 611-18, the protection conferred by a patent on a product containing or consisting of genetic information genetic information shall extend to any matter in which the product is incorporated and in which the genetic information is contained and performs the indicated function.* ***This protection does not apply in case of adventitious or accidental genetic information in patented seeds, propagating material of plants, seedlings and plants or parts of plants.****"*

The draft act also intends to supplement Art. L. 623-4 of the French Intellectual property code as follows (see part in bold):

> *I.-Any plant variety may be protected by a title called a "plant variety certificate" that gives the holder an exclusive right to produce, reproduce, package for the reproduction or multiplication, offering for sale, sell or market in any other form, export, import or possess for one of these purposes propagation material of the protected variety.*
> *II.-Where the products referred to in 1 ° and 2 ° of this II were obtained by the unauthorized use,* ***other than incidental or accidental****, of propagating material of the protected variety, the exclusive right extends unless the breeder has had reasonable opportunity to exercise his right on the product in question:*
> *1 on the harvest material, including whole plants and parts of plants;*
> *2 on the products directly obtained from harvested material of the protected variety. (…)*

Both of these changes will once again weaken the IP rights. The effect will be monitored.

7. Japan – Takashi Fujita

(i) Patent term extension cases

There is much activity in Patent Term Extension (PTE) cases in Japan. Four appealed "Patent Term Extension" cases at IP high Court were referred to "Grand Panel Division".

These four cases related to appeals against decisions by the Board of Appeals of JPO to reject the PTE applications under the revised examination guideline (revised at the end of 2011.) for bevacizumab (Avastin).

On 30 May 2014 the Grand Panel revoked Board of Appeal's decisions. The Grand Panel decisions rejected the rational published in the revised examination guideline. The revision of the

guideline was made to reflect the changes required by the Supreme Court decision in April, 2011. Details of the Grand Panel Decisions and the original Board of Appeal Decisions follow below, but in summary the Grand Panel held that for rejecting PTE application, an examiner MUST establish either (1) prohibition of an act to work the patented invention was NOT removed by the approval or (2) the act was NOT covered by the patented claim.

Regarding a patent directed to a medicament (excluding a process patent, and a patent relating to a product by process claim), in the examination of requirement (1) above in relation to the question whether a prior approval has already removed prohibition of an act to work the patent invention, the prior approval and the instant approval should be considered in respect of "ingredients, amounts, administration and dosage, effect, and efficacy" among the elements examined under Pharmaceutical Affaires Law.

The JPO has now appealed to the Supreme Court against the Grand Panel decisions and the Committee will be monitoring the outcome.

I. IP High Court H25 (Gyo-ke) 10195 decided on May 30, 2014 by Grand Panel (PTE)
Appealed for revocation of decision by Board of Appeal
Patentee/Appellant: Genentech Incorporated
(MB: only one of 4 cases is reported herein but reasons are basically same in each. All 4 Grand Panel decisions relate to PTE applications directed to bevacizumab based on two patents (Patent No: 3398382, and Patent No: 395776) and two approvals that differ only in the amount of injection solutions,i.e,100mg/ 4ml and 400mg/ 16 ml.)

1. (Facts)
Patent No: 3398382
Claim 1
Composition for treatment of cancer comprising an effective amount of a hVEGF antagonist which is an anti-VEGF antibody

Approved medicament and Disposition: （bevacizumab: genetically engineered) 21900AMX00910000 (Dated on 18, September 2009.）

Use of the approved medicament specified by the disposal: (Effects /Dosage)
In combination with other anti-malignant tumor agent, usually, intravenous drip injection of 7.5mg/kg(body wt) of bevacizumab to an adult subject suffering from untreatable and unresectable progressive and recurrent colorectal cancer once with administration interval of three weeks or more.

Previous Disposal on April 18, 2007:
"In combination with other anti-malignant tumor agent, usually, intravenous drip injection of 5mg/kg(body wt) or 10mg/kg(body wt) of bevacizumab to an adult subject suffering from untreatable and unresectable progressive and recurrent colorectal cancer once with administration interval of two weeks or more ". (Underlined portion differs from instant disposal.)

2. (From Holdings)

IP High Court revoked the BoA decision to reject PTE application.

1. Examination of PTE application.
For the judgment of PTE application, conclusion should be drawn from applicability of Patent Law Section 67 ^{ter} paragraph 1 item 1 which prescribes grounds for rejection of PTE application. Extended area of a patent right by a previous approval does not necessarily relate with necessity to obtain another approval to work the patented invention.

In order to establish a fact that it was necessary to obtain an approval prescribed by the ordnance to work the patented invention, it is necessary that (1) that prohibition of an act to work the patented invention was removed by obtaining the approval, and (2) that an act of which prohibition was removed by the approval prescribed by the ordnance is covered by the patented invention.

Thus for rejecting PTE application, an examiner MUST show either (1) prohibition of the act was NOT removed by the approval or (2) the act was NOT covered by the patented claim .

Drug to be subject of approval under Section 14 paragraph 1 or paragraph 9 of Pharmaceutical Affairs Law is defined by "appellation, ingredients, amount, administration route/ dosage, effects/ use, side effect or other quality matters, efficacy and safety". Hence, an act of which prohibition is removed by the approval means an act of manufacturing, selling or other similar handling the approved drug which is defined by the above criteria.

For the judgment of presence or absence of the above requirement (1), the examination should be substantial examination in view of the purport of the establishment of PTE system rather than formal examination based on the elements of "appellation, ingredients, amount, administration route/dosage regime, effects/ use, side effect or other quality matters, efficacy and safety" under pharmaceutical affairs law.

Regarding a patent directed to a medicine (excluding a process patent, and a patent relating to a product by process claim), it is reasonable to understand that an act of working a patented invention in the area where prohibition of the working of the patented invention is removed by a previous approval under Pharmaceutical Affairs Law correspond to manufacturing or selling of the approved drug defined by "ingredients, amounts, dosage regime, effect, and efficacy", that is, the examination items listed above excluding "appellation", "adverse effects and like", and "items relating efficacy and safety".

In the present case, previous approval has NOT removed a prohibition on the approved drug to use " In combination with other anti-malignant tumor agent, usually, intravenous drip injection of 7.5mg/kg(body wt) ,--- once with administration interval of three weeks or more."
Present approval for the first time removed the prohibition of the above use, thus it is clear that present case does not meet the requirement (1) to reject the PTE application.

(2)The court in dicta also mentioned that effect of PTE (Extended Area) is defined by "ingredients", "dosage regime" (administration route, dosage), "effect" and "efficacy". In other

words, extended patent covers basically approved drug or equivalent thereof for approved dosage regime only.

II. Board of Appeals No: 2011-8105 Decided on March 5, 2013.

Reasons of Rejection
(1)
A medicine that is the subject of approval is defined by the details that are stated in the approval certificate, whereas, a patented invention is the creation of technical ideas expressed by the “matters to define the invention” (i.e., limitations in the claim.).

Therefore, in a judgment pursuant to Article 67-3(1)(i), the phrase “to work the patented invention” should not be interpreted as an act of manufacturing and marketing or otherwise handling the approved drug product per se. Rather, it should be interpreted as an act of manufacturing and marketing or otherwise handling a drug product defined by the features of the approved drug product that correspond to claim limitations of the patented invention.
(Please note that above reasoning is basically same as mentioned in the revised examination guideline.)

(2) Application of above reasoning to instant case
Claim 1 may be construed as medicament comprising "anti-VEGF antibody which is hVEGF antagonist" as an effective ingredient and "treatment of cancer" as its use.

Approved medicament is "bevacizumab", that corresponds to "anti-VEGF antibody which is hVEGF antagonist" in claim 1. Further, its use for "untreatable and unresectable progressive and recurrent colorectal cancer" corresponds to "treatment of cancer" in claim 1.

Previous disposal with same disposal number on April, 2007 is directed to a medicament, that is, "bevacizumab" as an effective ingredient for the treatment of "untreatable and unresectable progressive and recurrent colorectal " as its use.
Previous disposal on April 18, 2007:
"In combination with other anti-malignant tumor agent, usually, intravenous drip injection of 5mg/kg(body wt) or 10mg/kg(body wt) of bevacizumab to an adult subject suffering from untreatable and unresectable progressive and recurrent colorectal cancer once with administration interval of two weeks or more ". (Underlined portion differs from instant disposal.)

Thus previous disposal relates to a previous medicament which are equipped with features for the medicament of instant disposal, that is, "bevacizumab" and "untreatable and unresectable progressive and recurrent colorectal cancer", that corresponds to limitations in claimed invention.
Hence, area specified by features of the medicament of instant disposal that corresponds to limitations in the claimed invention, has already been made workable by the previous disposal.

Allegation by Appellant:
More than six years were required to obtain the instant disposal for the specified dosage regimen.
With instant approval it becomes possible to administer bevacizumab in combination with XELOX which is combination regimen of capecitabine and oxaliplatin, thus the instant approval widens the scope of its application.

Conclusion (Board of Appeals)
Since dosage regiment is not recited in the claim as limitations, area specified by the features of a medicament on which the instant disposal is disposed has already been made workable by the previous disposal. Accordingly, it is NOT considered necessary to obtain the instant disposition to work the patented invention, hence, the application falls under section 67 ter item(1) and the patent term extension cannot be registered.

(ii)

There have been two interrelated case decisions relating a PTE application and correction trial where an amino acid sequence approved for marketing is different in a few positions from a patented claim:

- H24Gyoke10268 (IP High Court) decided on September 30, 2013; An appeal against a Board of Appeals' Decision to reject a request for corrections to a granted patent;
- H25Gyoke10309 decided on September 30, 2013 ; After Approval of the Omalizumab by PMDA, the patentee filed an application for registration of Patent Term Extension. The application was rejected by the examiner. The patentee then appealed to the Board of Appeals, and further appealed to the IP High Court; The court found the insertion of Lys-Gly- at positions 125-126 was a clear error, thus revoked the decision, and remitted to the case back to the BoA. Grounds are similar to those of the interrelated case of. H24Gyoke10268.

8. Brazil – Gabriel Di Blasi

In December of 2012, the BPTO released a draft of a proposed guideline for only the biotechnology fields, for public comments, and a final text must be available until the end of 2015.

In a brief comparison between the current guidelines for examination of patent applications in the areas of Biotechnology and Pharmaceuticals and the new guidelines proposed by the BPTO, it is to be noted that the last one is more detailed, points out topics which are not discussed in the current guidelines, and is full of examples for each topic. On the other hand, it seems like a simple formalization of this is already applied by the BPTO.

The new proposed guidelines state that reach-through claims are not eligible for protection; detail what would be "biological materials found in nature", including extracts of living beings, not considered to be invention; define the generic term "microorganism", including unicellular algae; explain how to protect biological sequences worded as Markush; clarify the differences among homology, identity and similarity; mention how to protect SNPs (single nucleotide polymorphism), promoters, vectors, cDNAs, ESTs (expressed sequence tags), fusion proteins, chimeric / humanized antibodies and antibody fragments; make clear that oligonucleotides (primers) are not considered to be invention; clarify that ORFs (open reading frames) are not entitled to protection; differentiate paralogs and orthologs; state that hybridomas are eligible for protection if deposited in an institution authorized by BPTO; explain how to proceed in case of patent applications involving components of genetic heritage.

In sum, the proposed guidelines seem to be improved in comparison with the guidelines in force. However, biotechnology guidelines should be reviewed more frequently since the developments in the biotechnology area are constantly evolving. The Committee is monitoring the situation

9. India – Hari Subramaniam

The law relating to Biotechnological inventions has not undergone any change in the last year. Normally, the feeling amongst stake holders has been that it is rather difficult to obtain patents in India for inventions relating to biotechnology and even if patents are granted it is not easy to defend them or enforce them. Such impression is not without basis since Indian Patents Act, 1970 has a specific “negative list” which enumerates ‘inventions’ which are not patentable. From biotechnology perspective, the ‘negative list’ includes (i) essentially biological processes; (ii) living organisms except micro-organisms; (iii) any part of living organisms; (iv) seeds; and (v) simple admixtures resulting only in a mere aggregation of the properties of its individual ingredients. Therefore, it was rather refreshing when the Indian Patent Office granted a patent for an invention for a composition where the only active ingredient was a known bacterium and the Intellectual Property Appellate Board (IPAB) affirmed its validity in November last year. This case is summarised below:

La Renon Healthcare Pvt. Ltd. vs. Kibow Biotech Inc. & Controller of Patents (ORA/29/2011/PT/MUM, IPAB, 13 November 2013)

Patent No. 224100 was granted to a US corporation Kibow Biotech Inc. for “A composition for augmenting kidney function in a subject comprising at least one probiotic bacterium wherein said probiotic bacterium is selected from *Streptococcus thermophilus* at about 5 billion to about 20 billion colony forming units of said at least one probiotic bacterium other ingredient being selected from vitamin, mineral, carbohydrate, protein and fats”.

The product is marketed commercially by the Patentee under the name Renadyl™.

An Indian company, La Renon Healthcare Pvt. Ltd. filed a revocation (cancellation) petition against said Indian Patent No. 224100 on grounds *inter alia* that (i) the patent was obtained on

false suggestion; (ii) the alleged invention was obvious and lacked in inventive step and (iii) what was claimed was a simple admixture as opposed to a synergistic composition as there can be no synergy between an active and additives.

IPAB rejected all grounds of revocation and upheld the validity of the patent. It held that the claimed composition aided in carrying out the kidney functions *viz*., the removal of waste and toxins thereby augmenting the kidney function and the same was evident from the disclosure in the specification. The IPAB further held that the claimed composition was inventive and non-obvious over the cited art and finally held that there was a clear evidence of synergy between the pro-biotic bacteria of a specific type along with other additives.

While, the Indian Patent Office has generally allowed claims for synergistic compositions comprising two or more, but at least two actives, it is rather rare for a patent to be granted where only one active is envisaged, that too a known micro-organism.

10. Plant breeders rights – Thomas Bouvet

10.1 *a. Africa*

The African Intellectual Property Organization (OAPI) became the second intergovernmental organization and the seventy-second member to join the International Union for the Protection of New Varieties of Plants (UPOV 1991) from 10 June 2014.

OAPI operates a plant variety protection system which covers the territory of its 17 member States: Benin, Burkina Faso, Cameroon, Central African Republic, Chad, Comoros, Congo, Côte d'Ivoire, Equatorial Guinea, Gabon, Guinea, Guinea Bissau, Mali, Mauritania, Niger, Senegal and Togo. The headquarters of OAPI are in Yaoundé, Cameroon (see http://www.oapi.int/).

b. France

Decree N° 2014-731 of 27 June 2014 amends the French intellectual property code to allow the new Plant Breeders Rights Office (*Instance nationale des obtentions végétales)* created by the Act of 8 December 2011 to actually start operating (it replaces the previous office *Comité pour la protection des obtentions végétales*).

10.2. European Union

ORDER OF THE GENERAL COURT (Third Chamber), 21 October 2013, T-367/11, Lyder Enterprises c. OCVV

This decision relates to the entitlement to file Community Plant Variety Right and the possibility for CPVO to control entitlement:

*32. Article 11(1) of Regulation No 2100/94 provides : "*The person who bred, or discovered and developed the variety, or his successor in title, both – the person and his successor – referred to hereinafter as "the breeder", shall be entitled to the Community plant variety right.*"*

33. Under Article 50 of Regulation No 2100/94, one of the conditions to be satisfied by an application for a Community plant variety right is that it contains the name of the breeder and an assurance that, to the best of the applicant's knowledge, no other persons have been involved in the breeding, or discovery and development, of the variety. That article also provides that if the applicant is not the breeder, or not the only breeder, he is to provide the relevant documentary evidence as to how the entitlement to the Community plant variety right came into his possession.

34 Moreover, Article 53 of Regulation No 2100/94 provides, in relation to the formal examination of the application, that the CPVO is to examine whether the application complies with the conditions laid down in Article 50 of that regulation.

(…)

37. It follows, therefore, from the provisions referred to in paragraphs 32 to 36 above that, where the applicant is not the breeder, Regulation No 2100/94 requires him to provide the CPVO with the relevant documentary evidence indicating how the entitlement to the Community plant variety right came into his possession, including, where appropriate, information establishing the content of the relevant national legislation. In such a case, it is, first, for the competent CPVO bodies to assess the authority and scope of the information submitted by the applicant in that respect and, secondly, for the General Court, in the event of an action brought before it, to conduct a full review of the lawfulness of the CPVO's assessment of the information in question (see, by analogy, Case C-263/09 P Edwin v OHIM [2011] ECR I-5853, paragraphs 50 to 52).

38. Accordingly, contrary to the applicant's submissions, the CPVO was competent to decide on questions of fact concerning the determination of the status of the party applying for the Community plant variety right, including, inter alia, the interpretation of a contract transferring ownership between two New Zealand companies such as the deed of assignment. That was the case a fortiori since that deed had been submitted to the CPVO by the applicant itself and the intervener had contended, in accordance with Article 59 of Regulation No 2100/94, that the conditions laid down in Article 11 of that regulation had not been complied with, submitting other evidence to that effect.

39 It follows that the CPVO and, in particular, the Board of Appeal were competent to determine whether the applicant was the breeder of the plant variety SOUTHERN SPLENDOUR and, in that respect, to interpret the deed of assignment. The plea must therefore be rejected as manifestly lacking any foundation in law.

10.3. Brazil

(i) Regarding the plant variety rights, the number of lawsuits on infringement of such rights at the Brazilian Courts has been increased every year. The reasons which have motivated this scenario are the growth of production of crops in the Brazilian market, as well as the growth of the protection for varieties before the National Plant Variety Protection Service (SNPC), mainly eucalyptus for production of cellulose.

(ii) Fibria v. Eldorado Brasil: Mato Grosso do Sul Court (TJ-MS) (Pending procedure)

The Brazilian corporation Fibria Celulose S.A. (Fibria), acquired information that Eldorado do Brasil S.A. (Eldorado), a direct competitor, may have been using eucalyptus cultivars protected by Fibria in its commercial plantations. In this sense, Fibria set out to collect evidences and after concluding the DNA tests the report released by the laboratory confirmed that there is a likelihood of 99.999% that the sample taken to the lab matches Fibria´s genetically protected plant. Based on the result, Fibria filed a lawsuit with the Mato Grosso do Sul Justice Tribunal (TJ-MS). Ultimately, Fibria secured a court action to disclosure evidence and some procedural aspects of the lawsuit are being discussed at the Superior Court of Justice – STJ, making this a test of the law and a benchmark case. Fubria maintains that its efforts in this action are to preserve technological knowledge and safeguard the intellectual property rights of the cultivar sought to be protected.

c. Marketing authorisations for plant varieties and GMO

a. 2013/0137(COD) - 06/05/2013 Legislative proposal on Plant reproductive material: production and making available on the market

The majority of Council Directives for making available on the market of plant reproductive material have first been adopted between 1966 and 1971 and some Directives are more recent. The complexity and fragmentation of the existing legislation is likely to perpetuate existing uncertainties and discrepancies in its implementation between the Member States. This creates an uneven playing field for professional operators on the single market.

Developments in the areas of agriculture, horticulture, forestry, plant breeding and making available on the market of plant reproductive material have shown that the legislation needs to be simplified and further adapted to the developments of the sector by replacing the existing Directives by a single Regulation.

The objectives of the proposal are announced as follow: *« the proposal seeks to: (i) ensure a level playing field across the EU through simplified, clarified and harmonised rules; (ii) reduce unnecessary costs and administrative burden and to increase flexibility; (iii) align PRM legislation with other recent Union strategies; and (iv) foster innovation in plant breeding. The scope of the proposed Regulation covers all forms of PRM. »*

The varieties, in order to be made available on the market throughout the Union, shall be included in a national register or in the Union register via direct application procedure to the Community Plant Variety Office (CPVO). CPVO will keep the updated information on all plant varieties that can be made available on the market in the Union, including the varieties registered in national registers (Union plant variety database).

Specific provisions will apply to forest reproductive material.

b. Marketing authorisations for Genetically modified organisms

Reminder

In the territory of the European Union, genetically modified organisms (GMOs) may be released into the environment or placed on the market only if consent has been given, subject to specific conditions and granted with a view to specified uses, after a scientific assessment of the risks. The authorisation system consists of two different procedures which are applied depending on the intended use of the GMOs:

- Directive 2001/18/EC relates to authorise GMOs with a view to their deliberate release into the environment; it is in principle for the Member State with which an undertaking has lodged an application for this purpose to issue consent, however, the other Member States, and also the Commission, may raise objections vis-à-vis the intended consent decision;
- Regulation 1829/2003, concerns genetically modified food and feed; in that case, the application for consent is assessed at EU level.

Where, in the context of the first procedure, an objection has been raised or, in the context of the second procedure, an application for consent has been submitted, the final decision on the authorisation is taken by the Commission or by the Council on the basis of the scientific opinions of the European Food Safety Authority (EFSA).

c. Court of the European Union, 13 December 2013, T-240/10, Hungary V. Commission

BASF Plant Science GmbH has made two requests regarding GMO potato:

- It asked the Swedish authorities to authorise the placing on the market of the genetically modified potato Amflora with a view to its cultivation and use for industrial purposes; several Member States having made observations regarding that application, the taking of the final decision was entrusted to the EU authorities.
- It directly initiated an authorisation procedure before the EU authorities with a view to the production of animal feed based on that potato; That latter application also covered the situation of the adventitious presence of GMO traces in food for human or animal consumption.

The Commission granted the two authorisations applied for by decisions of 2 March 20104.

Hungary brought an action for annulment of the Commission's authorisation decisions; France, Luxembourg, Austria and Poland intervened in the proceedings in support of Hungary.

In its judgment of 13 December 2013, the General Court has annulled the Commission's decisions concerning authorisation to place on the market the genetically modified potato Amflora on the ground that the Commission did not comply with the procedure provided in the Regulations by not submitting the amended drafts of those decisions, together with the EFSA's consolidated opinion of 2009 and the minority opinions, to the competent committees. By having decided to request a consolidated opinion from the EFSA, and by basing the contested decisions on, inter alia, that opinion without allowing the competent committees to comment on the opinion or on the amended draft decisions, the Commission departed from the rules of the authorisation procedures.

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