

**Special Committee Q114  
(Biotechnology including Plant Breeders Rights)**

**Report by Committee for the Paris Congress of AIPPI 2010**

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**Introduction**

The last report from Special Committee Q114 was presented to the Boston Congress in 2008. In that report the Committee commented on the ECJ Referral C-428/08 in the case of *Monsanto v Cefetra*, regarding the interpretation of EU Directive 98/44EC, EPO Enlarged Board Referral G02/06 concerning patentability of human embryonic stem cells, EPO Enlarged Board Referrals G02/07 and G01/08 concerning the breadth of the "essentially biological processes" exclusion from patentability and the case of *Eli Lilly v Human Genome Sciences* in the English High Court. In the case of referrals G02/07 and G01/08, the only subsequent development has been the holding of an oral hearing before the Enlarged Board in July 2010 but as yet a decision has not been handed down. There have, however, been significant developments in each of the other three matters and these are reported below. In addition the Committee reports on a more recent referral to the ECJ (C-34/10) concerning rather wider questions on the patentability of human embryonic stem cells. Also reported are recent developments concerning biotechnology patents in US, Japan, Australia and France as well as recent UPOV work.

**1) ECJ Referral C-428/08 - Monsanto v Cefetra - (Claire Baldock)**

On 6 July 2010 the European Court of Justice (ECJ) handed down their judgement in the case of *Monsanto Technology LLC v Cefetra BV and Others*, a referral to the European Court of Justice (ECJ) from the Rechtbank's-Gravenhage of the Netherlands. This case is of particular significance for patent holders in the biotech industry since it has provided one of the first opportunities for the ECJ to address the scope of gene patents in Europe in light of Directive 98/44/EC (the Biotech Directive).

By way of background, the case concerned European patent EP0546090 to Monsanto, protecting an enzyme conferring resistance to the herbicide marketed by Monsanto as ROUNDUP®. The patent included claims to both isolated DNA sequences and specific DNA sequences encoding the enzyme, as well as the enzyme itself and plants expressing the enzyme and which were resistant to ROUNDUP®. In 2005 and 2006, Monsanto seized cargoes of soy meal imported into Amsterdam from Argentina and found their patented DNA sequences to be present in the meal, thereby establishing that the meal was derived from crops grown in Argentina containing the patented gene. Monsanto subsequently brought an action in the District Court of the Hague against the Dutch importer, Cefetra, for infringement of the European patent.

In their defence, Cefetra cited the provisions of the Biotech Directive and in particular, Article 9 which states:

*"The protection conferred by a patent on a product containing or consisting of genetic information shall extend to all material, save as provided in Article 5(1), in which the product is incorporated and in which the genetic information is contained and performs its function."***(emphasis added)**

On the basis of this wording, Cefetra argued that patent protection did not extend to the imported soy meal derived from the soy beans because the DNA sequence was not 'performing its function' in the dead meal material. Although Monsanto did not agree that this was the correct interpretation of Article 9, they argued in addition, that there was infringement of their patent by virtue of the absolute protection afforded to product claims under Dutch national law.

Given the legal uncertainty surrounding the interpretation of the Biotech Directive and its relationship with national law, the Dutch court referred a number of questions to the ECJ for a preliminary ruling. In particular, question 1 sought clarification on the interpretation of Article 9, question 2 addressed whether the Directive stands in the way of national law permitting absolute protection for product claims to DNA sequences as such, question 3 concerned the date from which the provisions of the Biotech Directive are deemed to be effective and question 4 related to whether it was necessary to take into consideration Articles 27 and 30 of the TRIPS Agreement relating to patentable subject matter and the exceptions to patent holders rights.

In its preliminary ruling of 6<sup>th</sup> July 2010, the ECJ answered these four questions as follows:

1. *Article 9 of Directive 98/44/EC of the European Parliament and the Council of 6<sup>th</sup> July 1998 on the legal protection of biotechnological inventions is to be interpreted as not conferring patent right protection in circumstances such as those in the case of the main proceedings, in which the patented product is contained in the soy meal, where it does not perform the function for which it was patented, but did perform that function previously in the soy plant, of which the meal is a processed product, or would possibly again be able to perform that function after it had been extracted from the soy meal and inserted into the cell of a living organism.*

2. *Article 9 of the Directive effects an exhaustive harmonisation of the protection it confers, with the result that it precludes the national patent legislation from offering absolute protection to the patented product as such, regardless of whether it performs its function in the material containing it.*

3. *Article 9 of the Directive precludes the holder of the patent issued prior to the adoption of that Directive from relying on the absolute protection for the patented product accorded to it under the national legislation then applicable.*

4. *Articles 27 and 30 of the Agreement on Trade-related Aspects of Intellectual Property Rights, do not affect the interpretation given to Article 9 of the Directive.*

This finding of the ECJ will now be binding on all EU member states. However, it is far from clear what the actual implications of this will be for holders of patents covering DNA, particularly when this is claimed as "isolated" as is commonly the case for EP patents drafted in the United States. The USPTO requires such language to be present when products from nature are claimed, to distinguish it from the product in its natural environment. However, of course, the completely isolated molecule would not perform any function and such a claim might be held unenforceable. Relevant to such a consideration may be how the term "isolated" is defined in the patent itself.

The formal answer to question 1 is that Directive 98/44 EC is to be interpreted as not conferring patent right protection *in circumstances such as those of the case*. This seems to be an acknowledgement of its rather unusual facts and a hint that its principles may not need to be extended to other more conventional DNA claim infringements. However, in the body of the judgement at paragraph 38 the Court states:

*"...the protection provided for in Article 9 of the Directive is not available when the genetic information has ceased to perform the function it performed in the initial material from which the material in question is derived".*

Such a general exclusion as this has much wider implications. For example, use of the DNA as a diagnostic probe to find a defective gene might not be held an infringement since the DNA is not performing its biological function in such a test.

On balance then, this decision does not give us a definitive answer on the scope of DNA claims in Europe and it remains to be seen how the National Courts will apply it in the future. The Committee will continue to monitor its effect.

## **2) Eli Lilly v Human Genome Sciences, Inc - (Claire Baldock)**

As mentioned in the previous report, on 31st July 2008 a decision of the English High Court was handed down by Mr Justice Kitchin in the case of Eli Lilly v Human Genome Sciences Inc (HGS). Lilly had applied for revocation of HGS Euro (UK) patent EP-B 0939804 which related to a nucleic acid sequence and the protein it encoded which was identified as a novel member of the TNF ligand

superfamily of molecules. This new molecule was given the name Neutrokine-a. The nucleic acid and protein were claimed as well as antibodies specifically binding to the protein and pharmaceutical and diagnostic compositions containing the protein or antibodies. HGS had found the new molecule, not by any wet lab technique but purely using bioinformatic tools. The patent attributed to the molecule all the functional properties of other known TNF family members and provided a considerable list of possible pharmaceutical and diagnostic uses on that basis. However, these were mere predictions not supported by any experimental data obtained from *in vitro* or *in vivo* studies. Lilly contended that these predictions were wholly speculative and that HGS did not know the biological activity or function of Neutokine-a, the identity of any diseases with which it might be associated and hence the diseases it might be able to treat, at the time it filed the patent application. No utility existed for the invention claimed at the filing date and hence all the claims were invalid for failing to be capable of an industrial application. This was really the first time the Court had had to consider what is required for an industrial application to be recognised.

In a very detailed judgement Mr Justice Kitchin agreed with Lilly and found all the claims invalid for lack of industrial applicability. In reaching his decision, great weight was placed on the decisions of the EPO on this point, such as T0898/05, as well as the application of the Utility Requirement in the US. Specifically, the Judge held that the application did not provide any sound or concrete basis for recognising that Neutrokine-a could lead to a practical application in industry. Rather, it provided sound and concrete basis only for a research project to find out what the molecule actually did and what it could be used for. Its use as a tool to investigate its own activities did not constitute a relevant industrial application.

HGS lodged an Appeal. The judgement of the Appeal Court was handed down on 9<sup>th</sup> February 2010. It upheld the first instance decision of Kitchin J and dismissed the Appeal. However, in an interesting twist, in parallel proceedings at the EPO in which Lilly had opposed the HGS Patent centrally, the Technical Board of Appeal upheld the patent, finding an inventive step and an industrial application to be present (see T0018/09). In earlier decisions, in particular T0898/05 mentioned above, the Board had established that for a new biological molecule to be industrially applicable there must be an "immediate concrete benefit" which is derivable from the patent application without the need for a research programme. The application must lead immediately to a practical application in industry without extensive further research, if this is not already obvious from the nature of the invention or the background art. There had been a casualty of this approach in T0870/04 where industrial applicability for a protein called BDP1 could not be recognised since it was considered that a research programme would be required to characterise it, notwithstanding its relationship to other family members

However, in T0018/09 the Board acknowledged two extreme positions:

- 1) All family members share well-characterised and understood function so that the immediate concrete benefit is apparent and industrial applicability can be recognised without further data or

- 2) Family members have different pleiotropic effects which are not completely understood in which case experimental functional data would always be required in the application for finding of an industrial application.

Neutrokin-a was deemed to fall between these two extremes and detailed examination of the facts was required. Upon analysis the Board concluded that industrial application could be recognised on the basis of the common functions that neutrokin-a shared with the other family members. In particular it was held that the skilled person would expect neutrokin-a to be expressed on activated T-cells and to co-stimulate T-cells. This is a common functional feature of the family. This expectation was supported by statements in the specification, even though not directly by data. The skilled reader would be able to distinguish this positive technical information from the other allegedly contradictory broad statements because:

*".....skilled person realises that the description of the structure of Neutrokin-a, its structural assignment to the family of TNF ligands, and the reports about its tissue distribution and activity on leukocytes, are the first essential steps at the onset of research work on the newly found TNF ligand superfamily member".*

The Technical Board found an industrial application to be present on this basis, even though the need for a research programme was required and this apparently contradicts their earlier decisions. This EPO decision was issued before Judgment from the UK Court of Appeal and thus in reaching the opposite conclusion and upholding the earlier decision the Appeal Judges tried to set forth the reasons why this was so. In essence this was because the finding of fact by the EPO had been different to that of the UK court based upon the evidence before it and in the UK the appellate court should not disturb a first instance finding of fact. However, in its view the evidence suggested that the skilled person would not have been able to distinguish positive technical information (i.e T-cell co-stimulation) from all the other proposed functions and uses given in the application. Common general knowledge at filing date was that the only family member found to have any use at all was TNF-a and that use not proved to be directly linked to T-cell proliferation or T-cell mediated immune responses (considered the common linking feature for the family by the TBA). A paper published by HGS some years later still was not able to show T-cell activity for neutrokin-a. Therefore, a research programme was needed and the required "immediate concrete benefit" was not shown. Industrial application had to be denied and the Appeal dismissed. Obviously, it is disturbing when the Court of an EPC member state cannot agree with an EPO Technical Board of Appeal over the same patent but it seems this is partly because the first instance UK decision relied on the EPO case law as it stood at the time. The EPO changed its position in the interim but there was no basis for saying Kitchin J. had been wrong based upon the evidence before him and the precedent he had been relying on.

In any event this saga is not at an end because HGS have leave to Appeal to the Supreme Court. The committee will continue to monitor the situation.

### 3) **Enlarged Board of Appeal Decision G0002/06 - Human Embryonic Stem Cells (Claire Baldock)**

In the previous report of the Committee we commented on this referral to the Enlarged Board of the EPO. It relates to a patent application by Wisconsin Alumni Research Foundation (WARF), EP-A 0770125, concerning embryonic stem cells including human embryonic stem cells. At the 2005 Berlin ExCo meeting of AIPPI, a Resolution was adopted that patents should be available without any discrimination for all kinds of inventions including biotechnology. Furthermore, it was resolved that inventions based on isolated human embryonic pluripotent stem cells should be treated like any other invention and should be patentable if the general patentability criteria are met. Finally, it was resolved that exclusions to patentability due to the principles of order public and morality may be applicable but should be as limited as possible and should be defined very precisely. The attention of the Enlarged Board was drawn to this Resolution by the AIPPI in an Amicus brief prepared by this Committee.

The WARF application had claims to a cell culture comprising primate embryonic stem cells which can be prevented from becoming differentiated by being cultured on a fibroblast feeder layer. The application was refused by Examining Division at Oral Proceedings on 17 June 2004 citing rule 28(c) EPC) which had been introduced into the EPC based on the Biotech Directive and prohibits the patenting of industrial and commercial uses of embryos. The reason given was that the provisions of Art. 53(a) and R. 28(c) are not directed exclusively at the claimed subject-matter but rather concern "inventions" thus including all aspects that make the claimed subject matter available to the public. The application did not provide any alternative starting material except a pre-implantation embryo, thus the claimed cells are inseparable from the method used to make them and from use of the embryo.

This decision was appealed (T1374/04) and the Appeal Board then referred the following questions to the Enlarged Board:

- 1) *Does Rule 28(c) EPC forbid the patenting of claims directed to products which, as described in the application at the filing date, could be prepared exclusively by a method necessarily involving the destruction of human embryos from which the said products are derived, even if the method itself does not form part of the claims?*
- 2) *Does Article 53(a) EPC forbid patenting such claims as being contrary to morality?*
- 3) *Is it of relevance that after the filing date the same products could be obtained without having to recur to a method necessarily involving the destruction of human embryos?*

The Enlarged Board handed down its Decision in November 2008 and it was not favourable concerning patentability of human embryonic stem cells. Rather the Enlarged Board decided that "it was the intention of the legislators (of the Directive)" to forbid patenting of inventions which necessitate destruction of an embryo, on moral grounds. Therefore R.28(c) EPC, equivalent to Art. 6(2)(c) of the Biotech Directive, DOES prevent patenting of WARF's invention, even though the *claim* does not refer to destruction of an embryo. It was irrelevant that the claimed cell culture could have been made

without destruction of an embryo after the patent filing date. The last paragraph of the Decision read, however:

*"In view of the questions referred, this decision is not concerned with the patentability in general of inventions relating to human stem cells or human stem cell cultures. It holds unpatentable inventions concerning products (here: human stem cell cultures) which can only be obtained by the use involving the destruction of human embryos"*

This has generally been regarded as an indication that human stem cell-related inventions could still be patented providing a source of the cells was available without using an embryo. Indeed EPO practice post G0002/06 would seem to confirm this is the case. Claims are being allowed for those applications filed after the date when deposited human ES cell lines were available.

Finally, one interesting aspect about this Enlarged Board referral was a request by the Applicant for the Enlarged Board to refer the matter to the ECJ. The Board declined to do this. It considered that neither the EPC nor its Implementing Regulations make provision for any such referral. The powers of the Boards are limited to those conferred by the EPC. Article 234 of EU Treaty requires referred questions to be raised in proceedings before a national court of an EU member state and the EPO Boards of Appeal are not such courts but rather tribunals of an International organisation whose contracting states are not all members of the EU. Accordingly, the Enlarged Board had no power to refer the matter. However, as reported in the next section, a national court has now referred much more far reaching questions concerning patentability of human embryonic stem cells to the ECJ as referral C-34/10 and the outcome could have implications for national practice in EU Member states and by implication, for the EPO.

**4) Referral of the German Federal Court of Justice to the ECJ on the interpretation of the Directive 98/44/EC - ECJ Case C-34/10 (Ralf D. Kirsch)**

**A) ECJ Case C-34/10 - Referral of the German Federal Court of Justice**

On December 17th, 2009 the German Federal Court of Justice (BGH, "Bundesgerichtshof") issued a decision, which concerns the interpretation of Article 6 of the Directive 98/44/EC on the legal protection of biotechnological inventions with regard to the term "human embryo" (BGH, decision Xa ZR 58/07, "*Neurale Vorläuferzellen /Neural precursor cells*").

The decision recites three questions that have been referred to the European Court of Justice (ECJ) under Art. 267 of the Treaty on the Functioning of the European Union for preliminary ruling (currently pending at the ECJ as Case **C-34/10**). The language of the proceedings is German - an English translation has been published in the Official Journal of the European Union on April 17, 2010:

"1. What is meant by the term 'human embryos' in Article 6(2)(c) of Directive 98/44/EC?"

- a) Does it include all stages of the development of human life, beginning with the fertilisation of the ovum, or must further requirements, such as the attainment of a certain stage of development, be satisfied?
- b) Are the following organisms also included:
  - (1) unfertilised human ova, into which a cell nucleus from a mature human cell has been transplanted;
  - (2) unfertilised human ova whose division and further development have been stimulated by parthenogenesis?
- c) Are stem cells obtained from human embryos at the blastocyst stage also included?

2. What is meant by the expression 'uses of human embryos for industrial or commercial purposes'?

Does it include any commercial exploitation within the meaning of Article 6(1) of the Directive, especially use for the purposes of scientific research?

3. Is a technical teaching to be considered unpatentable pursuant to Article 6(2)(c) of the Directive even if the use of human embryos does not form part of the technical teaching claimed with the patent, but is a necessary precondition for the application of that teaching,

- a) because the patent concerns a product, whose production necessitates the prior destruction of human embryos,
- b) or because the patent concerns a process for which such a product is needed as base material?"

## **B) The history of the C-34/10 referral**

The run up to the BGH decision was as follows: On April 29, 1999 the German Patent Office granted a national, German patent to the stem cell researcher Oliver Bruestle on isolated and purified neural precursor cells and on a method for making such cells from embryonic stem cells.

Subsequently, Greenpeace filed a nullity suit against this patent at the Federal Patent Court (BPatG, first instance) in Munich based on an alleged violation of ordre public and morality and requested to declare nullity of the patent in as far as the claims cover neural precursor cells that have been made from human embryonic stem cells. The Federal Patent Court declared nullity of the patent insofar.

The patentee filed an appeal against said decision at the Federal Court of Justice (BGH), which stayed the proceedings and referred the above three legal questions to the ECJ.



**C) German Patent Act §2 (2) No.3: No patents for use of human embryos for industrial or commercial purposes - relevant point in time for assessing "ordre public"**

According to the BGH, the most relevant legal norm in this is § 2(2) No.3 of the German Patent Act (PatG), which excludes patents for "the use of human embryos for industrial or commercial purposes" (§ 2 (2) first sentence No.3 PatG) - which is the same wording as recited in Art. 6 No.2 (c) of the Directive, which was implemented into the German Patent Act.

According to the BGH this legal norm needs to be applied, even if it has entered into force only after the filing date of patent in suit, since the question of whether or not a violation of ordre public and morality has taken place would need to be answered at the time of making the decision (as opposed to the priority and filing date, respectively).

**D) The first question: Ambiguity of Article 6 of the Directive**

According to the BGH, Article 6 of the Directive is unclear and ambiguous with regard to several aspects - what are "human embryos"? Is a stem cell that has been derived from a blastocyst an "embryo" even if it is not capable of developing into a human individual?

**E) The second question: What is meant by the term "uses of human embryos for industrial or commercial purposes"?**

Using embryos or stem cells for science is not prohibited in Germany if the relevant regulations are properly taken care of. But the question is whether this scientific use does also fall under the expression "industrial or commercial purposes" as used in Article 6 of the Directive and therefore under the patentability exclusion of the Directive.

**F) The third question: Use of human embryos as a necessary precondition**

The question of whether or not a "blastocyst" is an "embryo" according to Article 6 of the Directive will be relevant if the exclusion of "use of human embryos" in the Directive already would apply when the claimed human stem cells (which are not embryos themselves) would require destroying blastocysts for making them.

If the ECJ would say that the requirement of using blastocysts/human embryos first in order to get embryonic stem cells is against Article 6(2)(c) of the Directive then this would correspond to the decision G 02/06 ("Use of Embryos"/WARF) of the Enlarged Board of Appeal of the EPO, as discussed above, which said that EP patents cannot be granted for products that require the destruction of human embryos at the time of filing, even if the method as such is not part of the claims.

#### 4) US Update - (Peter Ludwig)

##### Recent Developments in US Law

###### **Introduction**

In the past year the US courts have been active in developing case law in the biopharma space and on the subject of what constitutes patentable subject matter. Examples of cases falling into this category are the US Supreme Court decision in *In Bilski v Kappos* 561 US \_\_\_, 2010 (the machine or transformation test is a "useful and important clue ,an investigative tool, for determining whether some claimed inventions are processes under §101," but "not the sole test for deciding whether an invention is a patent -eligible process." and the US district court decision in *Association for Molecular Pathology, et al v. United States Patent and Trademark Office, et al*, No. 09-Civ-4515 (S.D.N.Y.)No. 09-Civ-4515 that patents owned by Myriad Genetics claiming "isolated DNA containing sequences found in nature are unsustainable as a matter of law and are deemed unpatentable under 35 U. S. C. § 101." (Now on appeal to the United States Court of Appeal for the Federal Circuit). However, more important developments of more legal and commercial significance are the enactment of a Biosimilars law and new Guidelines from the USPTO OF from the commercial standpoint to, the more significant developments are likely the adoption of a Biogenerics Law (the Biologics Price Competition and Innovation Law (the Biogenerics Law) which is included as Title VII of the Patient Protection and Affordable Care Act) and publication by the USPTO of updated Examination Guidelines for Determining Obviousness under 35 U.S.C. § 103 in view of the Supreme Court Decision in *KSR International Co. v. Teleflex Inc.* Federal Register/Vol. 75, No. 169 ; 53643 September 1, 2010.

###### **The Biogenerics Law**

For some time generic pharmaceutical companies and healthcare advocates have sought passage of a law that would be the biologics counterpart of the by now well known Hatch Waxman law which permits approval of generic versions of authorized innovator drugs without the need for the extensive and expensive clinical and pharmaceutical testing required by the US Food and Drug Administration (FDA)for initial registration. Under US law, biologics are generally defined to include virus,, therapeutic serum, toxins and other therapeutic protein products such as monoclonal antibodies. Biologics are usually larger molecules than chemical drugs, are more difficult to manufacture and characterize, and are not eligible for the abbreviated registration procedures available for chemical drugs under the Hatch Waxman Act.

The Biogenerics law establishes a mechanism for approval of generic biologic products as either a "biosimilar" to a reference (innovator) biologic product or as "interchangeable"(if it can be substituted for the innovator (reference biologic product) without the intervention of the healthcare provider that prescribed the reference product. A company seeking approval to market a generic version of an innovator reference product must file an application with the FDA which establishes inter alia that the

proposed biogeneric product and the reference biologic product "utilize the same mechanism or mechanisms of action for the conditions or conditions of use prescribed" (to the extent the mechanism of action is known) and that the "route of administration", dosage form and strength of the proposed biogeneric product are the same as that of the reference (innovator) biologic product. Under some circumstances products approved as "biosimilar" may also be approved as "interchangeable" if it is established that the "Biosimilar" product "can be expected to produce the same clinical result as the reference product in any given patient".

Under the law there is a four year period of "data exclusivity" during which the FDA cannot accept an application to register a biosimilar product and a twelve year period during which the FDA may not approve an application to register such a product.

The Biologics Law contains extensive and complicated patent provisions that are said to be designed to balance the rights of innovator (branded) companies and those seeking approval of generic substitutes for the branded reference biologic product. Under the law, the party seeking to register a biogeneric version of a registered reference biologic product must disclose the contents of its application to the sponsor of the reference product within twenty days after the FDA accepts the application for registration of the biogeneric . This is true even if the party seeking approval for the biogeneric does not intend to bring its product to market until after the innovator's patents have expired. Thereafter each party must disclose to the other the patents that believes to be relevant to the biosimilar and reference biologic products. Unlike the Hatch Waxman law, the Biologics law does not require the FDA to publish a listing of approved biologic products and the patents that the owner of the reference biologic product believes cover such product. Thus there is no equivalent to the so called "Orange Book" that lists registered chemical drugs and the patents claimed to cover them. The sponsor of the reference product has twenty days to provide a list of the patents it believes cover the biologic product. The party seeking registration of the biosimilar then has sixty days to respond to the reference sponsor's listing and to give reasons why the referenced patents are either invalid, not infringed or unenforceable. The reference sponsor is then given sixty days to provide a counter-statement indicating why each patent mentioned by the reference sponsor would be infringed and is not invalid or unenforceable. The reference sponsor and the applicant for registration of the biogeneric product must then engage in "good faith negotiations to agree on which, if any, patents" previously identified should be the subject of patent litigation. If the parties agree, the sponsor of the reference biologic product must then initiate an action for patent infringement for each of the agreed upon patents within 30 days. If no agreement is reached the parties simultaneously exchange additional lists of patents. Following this exchange the the reference sponsor of the biologic product must bring an action for infringement of all patents on both parties lists. While there is no automatic regulatory stay of approval of the generic product (as with the Hatch Waxman law) , there is an opportunity for the reference sponsor of the biologic product to seek a preliminary injunction barring manufacture or sale of the biogeneric product, by asserting one or more patents that was not asserted during the initial litigation but was identified by either party on the lists of patents that were previously exchanged.

Both the regulatory and patent provisions of the new law are somewhat vague and appear to raise many questions that will likely be resolved through litigation.

### **2010 KSR Guidelines Update issued by USPTO for**

On September 1, 2010 the USPTO issues updated guidelines for use by office personnel in applying the law of obviousness under 35 USC 103. The 2010 Guidelines Update highlights case law developments since the US Supreme Court's 2007 decision in *KSR v Teleflex*. In *KSR* the Supreme Court rejected the so-called "Teaching-suggestion-motivation" test as the sole approach for making a determination of obviousness under section 103 of the US Patent Law. Subsequent cases have applied the *KSR* rationale and a group of these cases are discussed and a "teaching point" is provided for each case, the "teaching point" is meant to show the relevance of each case. Interestingly, more than half of the cases discussed in detail involve pharma , biotech or chemical patents. The new Guidelines are intended as a supplement to the 2007 Guidelines issued by the USPTO and not as a replacement for them.

In general, the Guidelines emphasize the factual inquiries spelled out in the US Supreme Court's earlier decision in *Graham v. John Deere* 383 U.S. 1 (1966) as the starting point for making a determination of obviousness,(i.e. determining the scope and content of the prior art, the differences between the claimed invention and the prior art, the level of ordinary skill in the art and secondary indicia of obviousness such as commercial success and long felt need). They also identify the 7 rationales for assessing obviousness under the *KSR* decision.

*" It remains true that "[t]he determination of obviousness is dependent on the facts of each case."Sanofi-Synthelabo v. Apotex, Inc., 550 F.3d 1075, 1089 (Fed. Cir. 2008) (citing Graham, 383 U.S. at 17-18 (1966)). As for the reasoning required to support an obviousness determination, the 2007 KSR Guidelines noted that the teaching-suggestion-motivation (TSM) test was but one possible approach. The 2007 KSR Guidelines identified six other rationales gleaned from the KSR decision as examples of appropriate lines of reasoning that could also be used. The six other rationales identified in the 2007 KSR Guidelines are: (1) Combining prior art elements according to known methods to yield predictable results; (2) simple substitution of one known element for another to obtain predictable results; (3) use of a known technique to improve similar devices, methods, or products in the same way; (4) applying a known technique to a known device, method, or product ready for improvement to yield predictable results; (5) obvious to try—choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success; and (6) known work in one field of endeavor may prompt variations of it for use in either the same field or a different one based on design incentives or other market forces if the variations are predictable to one of ordinary skill in the art. " 75 FR*

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The Guidelines discuss each of the above rationales and offer some examples of how Examiners may use them in rejecting claims for obviousness under US law.

While the Guidelines do not constitute rule-making by the PTO and do not constitute a law or regulation, they do offer some insight into the approaches that US patent examiners may take in evaluating inventions for obviousness under the Patent Law and should offer guidance to patent practitioners on dealing with this issue in the USPTO as well as in court contests.

## **6) Japanese Update - (Takashi Fujita)**

### **Recent JP High Court Decisions dealing with the Written Description/Support requirements or Enablement relating to Medicinal Invention**

Early this year, the IP High Court clarified the difference between the Support requirement (Section 36(6)1) and Enablement (Section 36 (4)1). The JPO had applied the Support requirement in almost the same way as it applied the Enablement requirement when assessing the data requirement for pharmacological use inventions. The court rejected the JPO practice in this regard, and differentiated the two requirements.

Furthermore, the Court cautioned the JPO that it is not adequate to adopt simple per se test of whether or not pharmacological data is disclosed in the detailed description, but the conclusion should be drawn after considering all facts.

#### **Pharmacological Test**

#### **Support Requirements vs Enablement**

##### **I. Examination Guideline Medicinal Inventions**

1. Section 36, paragraph 6, item 1 (Current version) Typical examples of violation of Article 36(6)(i) are as follows:

(1) While an antiemetic drug having an ingredient A as an active ingredient is claimed, neither a description about a pharmacological test method nor pharmacological data are described in the detailed explanation of the invention. Furthermore, it would not be possible to presume that ingredient A was effective as an antiemetic drug in light of the common general technical knowledge as of the filing.

2. Regarding examination under Section 36 (4) Enablement, the same guideline lists the following example as one of the (2) Examples of Cases where Reasons for Refusal are Notified.

(a) A case in which the result of the pharmacological test is not described Generally, since it is difficult to predict whether a compound, etc. can actually be used for a specific medicinal use from only the structure and name of the compound, etc., it remains difficult for a person skilled in the art to predict whether the compound etc. can actually be used for the specific medicinal use even where an effective dose, a mode of administration, and formulation method are described in the description as filed, but the results of a pharmacological test are not described. Accordingly, in such a case, in principle, reasons for refusal are notified. It should be noted that even if results of a pharmacological test are submitted afterward, the reasons for refusal will not be overcome. (Tokyo High Court Judgment Hei

10.10.30 (Heisei 8 (Gyo Ke) 201) "Judgment on Antiemetic Drug": Examination Guidelines Part I, Chapter 1 5. Examples 5.3, Example 3-5: Tokyo High Court  
Judgment Hei 14.10.1 (Heisei 13 (Gyo Ke) 345: Tokyo High Court Judgment Hei 15.12.22 (Heisei 13 (Gyo Ke) 99)

## **II. IP High Court Case No. Heisei 21 (Gyoke) 10033 decided on Jan 28, 2010 Brief**

### **History of the case**

Board of Appeal rejected the Appeal against the examiner's decision that the patent application does not meet requirements of Section 36 (6) 1.

### **Summary of the Decision**

#### 1. Relationship between Section 36(6)1 and Section 36(4)1

Section 36, paragraph 4 stipulates requirements for description/specification, and paragraph 6 item 1 stipulates requirements for claims.

1-1. Section 36 (4) requires that the description shall be clear and sufficient for a person in the art to carry out the invention, and the description includes items such as problems to be solved by the invention, their solution and the like, that are necessary for a person in the art to understand the technical meaning of the invention.

#### Purpose of Section 36 (4)

If a person seeking a patent were able to obtain an exclusive right without (a) disclosing items necessary for a person in the art to understand the technical meaning of the invention such as problem to be solved by the invention, their solution, and like, or (b) disclosing items in a manner clear and sufficient to enable a person in the art to carry out the invention, the patent system would lose its meaning. Thus, the section requires a patent applicant to describe these items.

(ii) Section 36 (6) 1 requires that a claimed invention be described in the description. Purpose of

#### Section 36(6)1

If claims are broader than the technical matters disclosed in the "description" and exclusive rights are granted to the broad technical scope, this would violate the purpose of Patent System of granting exclusive rights as a reward for the disclosure of technical matters to the extent that the technical matters are disclosed.

For example, if only limited technical matters are disclosed in the examples and description, but the claims go beyond the disclosed technical matters, then the requirements of section 36(6) 1 are not met.

## 2. Assessment on compliance with the Section 36 (6) 1

In order to assess whether claimed inventions are described in the description, it is necessary to grasp what technical matters are disclosed in the description. Since Section 36(6) 1 stipulates requirements for claims, and was established to preclude the grant of exclusive right that is too broad relative to the technical matters disclosed in the description, the grasp of the disclosure of the description for purpose of the assessing compliance with the requirements should be made using a method necessary and reasonable to judge the above points.

On the other hand, as Section 36(4) independently stipulates requirements "that the description shall be clear and sufficient for a person in the art to carry out the invention" and "that the description includes the items such as problems to be solved by the invention, their solution and the like, that are necessary for a person in the art to understand the technical meaning of the invention", failure to meet the above requirements means the application contains grounds for rejection, or a patent contains independent grounds for invalidation. Thus, if the assessment of compliance with Section 36(6)1, diverging from the purpose of the Section 36(6)1 to preclude the grant of exclusive right that is too broad relative to the technical matters disclosed in the description, is made using the same method that is used for assessing compliance with Section 36(4) 1 (Enablement), this would lead to a duplication of judgments on the same matters. If it is permissible to interpret that failure to meet the requirements of Section 36(4) 1 (enablement) means failure to meet the requirements of Section 36(6) 1 (support requirement), then the very importance of the existence of the Section 36(6)1 would be lost.

Except under special circumstances where such an interpretation is needed to avoid conflict with the purpose of the patent system, it is impermissible to interpret and judge the requirements of Section 36 (6)1 in the same way as judging compatibility with the requirement of Section 36(4) 1.

## 3. Reasons of rejection by the Board of Appeals

3.1. In a use invention concerning a pharmaceutical, generally, since it is difficult to predict its efficacy from only the name of the substance and the chemical formula, even where the effective amount, method of administration and formulation thereof has been described to some extent in the specification, it is not possible for a skilled person with only this information to know whether or not the pharmaceutical has efficacy in respect of this use. Consequently, there is a need to provide support for the efficacy of this use by description in the specification of pharmacological data or the equivalent thereof. If the detailed description of the invention does not contain such a description, then the claims do not meet requirements set forth in Section 36(1).

3.2. The Board found that the instant specification does not contain any pharmacological data supporting the efficacy of flibanserin as a medicament for treatment of disorders of sexual desire. Furthermore, the board found that the descriptions in the detailed description do not amount to a description that can be deemed equivalent to pharmacological data. Therefore, the detailed description of the invention does not include any pharmacological data or description that can be deemed equivalent to pharmacological data, thus it fails to meet the requirement set forth in section 36(6)1.

4. The Court finds as follows:

The Board's reasoning mentioned in (3-1) above may apply to the judgment of compliance with Section 36(4)1(Enablement).

Generally, under Japan Patent Law where a use invention for a medicament is acknowledged, it is common that a process of objectively validating the efficacy of the use is disclosed in the detailed description of the invention, and in many cases this would be interpreted as proper. As it is most effective, adequate and reasonable to use data showing the relationship between a medicament and its use in order to disclose the validation process, it could be said that it is often the case that failure to describe such data would be judged as a failure to disclose the invention to a manner clear and sufficient to carry out the invention.

However, regarding compliance with the requirements of section 36(6)1, the Board stated:

"Consequently, there is a need to provide support for the efficacy of this use by description in the specification of pharmacological data or the equivalent thereof."

In the interpretation of "the detailed description" for the assessment of support requirements in order to compare the breadth of claims with detailed description, it would be sufficient to understand formally the technical matters described and disclosed through examples and like in the detailed description, which is the same as the method to understand the described content of the detailed description of the invention. It may not be said, except under extraordinary circumstances, that it is indispensable to describe pharmacological data or its equivalent thereof.

The Board of Appeal considered compliance with Section 36 (6) 1 only through an investigation of whether pharmacological data or equivalent thereof is disclosed in the detailed description, without considering the breadth of the technical matters from detailed description understood by a person in the art in comparison with the claims. Thus, the Court found that the Board of Appeals had erred in its judgment.

In response to the argument submitted by the JPO that it is indispensable to describe pharmacological data or equivalent thereof in the description in view of IP High Court Enlarged Division's decision H17(Gyoke)10042, the Court mentioned that the Enlarged Division's decision dealt with a case where (1) interpretation of a claim defined by plural number of parameters was at issue, and (2) whether the claims were broader than the description was contested. The instant case differs in respect of both points (1) and (2) above. Thus, the Court did not agree with the JPO's argument.

5. Section 36(4)1 (in dicta)

The court found that instant application does not disclose in the detailed description a process for validating that "flibanserin has a property of intensifying sexual desire." However, as already mentioned above, with regard to the lack of a validation process indicating that technical matters described in the detailed description are certain, it would be sufficient to judge whether the requirement



under Section 36 (4) 1 is met. (In addition, in a case where a disclosure lacks a concrete validation process regarding whether or not the technical matters described in the detailed description are certain, a conclusion concerning compliance with the requirements of Section 36 (4)1 should be drawn after considering all facts regarding whether a person may understand the technical meaning of the invention through problems to be solved by the invention, their solution, and the like, and may carry out the invention, even in the absence of a concrete description.)

III. There are other recent decisions revoking Board of Appeals decisions relating to lack of support regarding pharmaceutical products. For example, in Case No. H21 Gyoke 10134, decided Jan 13, 2010, the IP high court also revoked a decision by the Board of Appeals, JPO to reject an Appeal against the examiner's rejection of JP A 2004-238453. The case relates to whether or not a claimed invention directed to "an agent for eliminating hydroxyl radicals wherein the agent is effective for adult disease induced by active oxygen-----" meets the support requirements.

## **7) Australian Update - (Dr Andrew Blattman) I**

### **Inquiry into Gene Patents**

On 11 November 2008 the Australian Senate referred matters relating to the patenting of human genes and genetic materials to the Senate Community Affairs Committee ("the Committee") for inquiry and report. The terms of reference for the inquiry directed the Committee to look into:

The impact of the granting of patents in Australia over human and microbial genes and non-coding sequences, proteins, and their derivatives, including those materials in an isolated form, with particular reference to:

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

On 23 November 2009, the Senate granted an extension of time until 17 June 2010. A further extension of time was granted on 16 June 2010 until 2 September 2010. Finally in July this year, Parliament was dissolved in advance of a Federal election. The Committee determined that it was unable to provide a comprehensive report at this time despite the numerous extensions obtained. The Committee will reconsider the issues of the inquiry in the event that it is referred to the Committee in a new Parliament.

## **II BRCA1 Gene Patent**

### **Revocation Action in the Australian Federal Court against the BRCA1 Patent.**

The action has been bought by Cancer Voices Australia, an advocacy group for individuals with cancer, and a Brisbane woman, Yvonne D'Arcy, who has breast cancer. The grounds of revocation include a patentability argument relating to genes reflecting discoveries as opposed to invention.

## **III Reviews of the Australian Patent System**

The Australian Patent Office ("IP Australia") released a series of consultation papers directed at improving the function of the Australian patent system. Amongst a number of issues, the proposed reforms include reviews of full description, fair basis and inventive step.

### **III.1 Full Description and Fair Basis**

In Australia a complete specification must describe the invention fully including the best method of performance known to the applicant for performing the invention. Recent Australian court decisions have clarified the first part of this requirement such that:

"It is not necessary for inventiveness to disclose all the alternative means, it is enough that there is disclosure in the sense of enabling the addressee of a specification to produce something within each claim." (*Kimberly-Clark Australia Pty Ltd v Arico Trading International Pty Ltd (2001) 207 CLR 1.*)

Australian law also requires that the claims defining the invention be "fairly based" on the matter described in the specification. This fair basis requirement has come to be understood as almost one of consistency between the specification and the claims. It is not necessarily a test whether the description of the invention and technical detail in the body of the specification is sufficient to support the scope of the invention that is claimed.

There is a notable difference between the full description and fair basis requirements in Australia and requirements in the US, Europe and Japan. A number of these jurisdictions require that the patent specification provide sufficient details of the invention to enable the reader to produce anything across the full scope of the invention claimed. This contrasts with the Australian situation where the requirement is simply that there is sufficient detail to produce something, potentially only one thing, within the scope of the claim.

Requiring that the specification provide sufficient detail to make the invention across the full scope of the claims is IP Australia's suggestion to ensure that the *quid pro quo* is met.

Essentially, the IP Australia proposal involves amending the Act to introduce descriptive support requirements, including that the whole scope of the claimed invention be enabled (across the width of the claim).

### **III.2 Inventive Step - Common General Knowledge**

In Australia inventive step is assessed:

- against a prior art base that includes information in a document, or information made publicly available by doing an act, anywhere in the world; and
- against common general knowledge in the relevant art in Australia.

This restricts common general knowledge in a way that is not the case with Australia's major trading partners and is inconsistent with the global concept of prior art, on the basis that information that invalidates a patent in one jurisdiction should invalidate a patent in another.

#### **Proposed Change**

Amend s7(2) of the Patents Act to:

- remove the limitation that common general knowledge be confined to that existing in Australia.

### **111.3 Prior Art**

Currently, Australian law places limitations on how prior art information can be considered that do not exist elsewhere. The prior art base is defined in Schedule 1 of the Act as:

- information in a document that is publicly available, whether in or out of the patent area; and
- information made publicly available through doing an act, whether in or out of the patent area.

In Australia prior art information must be such that a skilled person in the art could be reasonably expected to have ascertained, understood and regarded as relevant. This approach has led to circumstances where the Federal Court has found that information in US patents, although highly relevant and readily understood, would not have been ascertained in certain circumstances. The Federal Court also noted that when the ability of the skilled person to ascertain relevant prior art is in doubt, it is necessary to have evidence to resolve the dispute. This has the potential to introduce significant additional costs to litigating patent disputes.

In contrast, in other jurisdictions, although prior art must pass the test of being considered relevant, and therefore understood by the skilled person, there is not the requirement that the skilled person would have been expected to have looked for and found the prior art.

#### **Proposed Change**

Amend s7(3) of the Patents Act to:

- remove the requirement that prior art information for the purpose of inventive step must be such that a person skilled in the art could be reasonably expected to have been ascertained, while retaining the requirements that prior art be understood and regarded as relevant.

The definition of the prior art base for inventive step will not change.

#### **111.4 Test for Inventive Step**

A further difference arises in relation to the threshold test set for inventive step. This test was most recently considered by the High Court in *Lockwood v Doric*, where the Court affirmed that the test for lack of inventive step, or obviousness, was whether or not the skilled person would be led directly as a matter of course to try a particular approach with a reasonable expectation of success.

In contrast, in jurisdictions such as the EPC, the question that is asked is: "Would the invention have been obvious to try with a reasonable expectation of success?" This approach takes account of situations where it is routine in the art to conduct testing or combine particular approaches in order to solve a particular problem or in order to find a better way of doing things. As such, it sets a lower requirement for establishing a lack of inventive step than the Australian requirement, in that it accepts that in certain circumstances some degree of routine experimentation would be standard practice for a skilled worker in the art.

Of course it can be argued that differences between inventive step standards internationally make it difficult to identify an appropriate standard to set for Australian inventive step. However, while acknowledging that there are differences between the threshold levels set for EPC, Japanese and US inventive step, IP Australia's position is that there is closer alignment between these three jurisdictions than between Australia and any one of these three. In particular, all three jurisdictions accept a worldwide concept of common general knowledge and apply a test that, in contrast to the Australian test, does not necessarily require that it be established that a skilled person would have found a citation and would have been directly led to try a particular approach.

#### **Proposed Change**

The proposed change seeks to:

- revise the inventive step test to a test where the claimed invention is obvious if it was "obvious for the skilled person to try a suggested approach, alternative or method with a reasonable expectation of success".

## **8 Update on plant variety rights (Thomas Bouvet)**

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### **8.1 Draft French Act to comply with UPOV 1991 treaty**

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France signed the UPOV 1991 act, but still has not adhered to this treaty; France only adhered to the 1978 act.

French law still does not comply with UPOV 1991 act.

A draft Act No. 2676 has been filed on 24 June 2010, to amend French plant variety rights, to make it comply with the UPOV 1991 act and in particular:

- ▶ to extend protection to essentially derived varieties;
- ▶ to introduce the farmer's exemption, under conditions similar to those provided in European regulation No. 2100/94 of 27 July 1994.

### **8.2 Case law on plant variety rights**

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I circulated, on 6 January 2010, the summary of an interesting decision issued by the court of appeal in The Hague, on 29 December 2009, in the matter *Astée Flowers vs. Danziger*.

This is one of the few decisions issued regarding essentially derived varieties (EDV): it stresses that in order to qualify as an EDV, the number of phenotypic differences with the initial variety should be one or very few (see paragraphs 20 and 21 of the judgment).

I copy hereunder the summary of this decision, made in my e-mail of January 2010:

*“ On 29 December, 2009, the Court of Appeal in The Hague rendered its long awaited decision in the appeal on the *Blancanieves* matter (*Astée Flowers / Danziger*). The Court of Appeal confirmed the first instance judgment given in 2005. The Court of Appeal expressed substantial reservations with respect to the AFLP fingerprinting technology which formed the basis of DNA tests produced by Danziger in support of its claims. In the opinion of the Court of Appeal the AFLP technology is not well suited for obtaining a sufficiently reliable representative sampling within the relevant genome. Also, the Court of Appeal held that the assessment of genetic similarity requires the use of multi-allelic markers (see paragraphs 16 thru 18 of the judgment). Furthermore, the Court of Appeal rejects the view of CIOPORA with respect to the level of phenotypic similarity that is required for the assessment of dependency. In this context the Court of Appeal makes reference to UPOV explanatory documents and the ISF Regulation for the Arbitration of Disputes concerning Essential Derivation. According to the Court of Appeal these documents make clear that in order to qualify as an EDV the number of phenotypic differences with the original variety should be one or very few (see paragraphs 20 and 21 of the judgment).”*

I think the decision issued by the court of appeal of The Hague should be approved.

Decisions dealing with EDV are rare enough to be highlighted.

AIPPI should monitor case law on EDV.

No decision of importance has been issued by French courts in relation to plant variety rights, since the last report made in relation to Q114.

### **8.3 UPOV update**

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Two work conducted within UPOV could be of interest for AIPPI, namely regarding:

- ▶ matters arising after grants of plants breeder's rights;
- ▶ possible use of molecular markers in the examination of distinctness.

#### **8.3.1 Matters arising after grants of plants breeder's rights**

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The Administrative and Legal Committee (CAJ) is working on a document entitled "*Matters arising after grants of a plants breeder's rights*".

UPOV invited members of the Union to provide examples of matters that might be covered by these documents, e.g. nullity (circular letter E-1168).

At the 61<sup>st</sup> session of the CAJ of 25 March 2010, the CAJ decided to elaborate a document on matters arising after grants of plants breeder's rights, based on the contribution received in reply to circular letter E-1168.

AIPPI could suggest CAJ to discuss the possibility for third parties to challenge the validity of a community plant variety right.

As explained in my e-mail of 6 January 2010, I think that Regulation EC No. 2100/94 does not provide with a real nullity procedure.

#### **8.3.2 Possible use of molecular markers in the examination of distinctness**

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The Administrative and Legal Committee (CAJ) is working on molecular techniques, in particular on proposals for the use of biochemical and molecular techniques in the examination of distinctness, uniformity and stability.

Three possible application models are considered.

First, molecular techniques are considered to be used as a predictor of traditional characteristics, namely morphological and physiological characteristics.

Molecular markers which are directly linked to traditional characteristics might be useful for the examination of traditional characteristics that cannot be consistently or easily observed in the field, or require additional special arrangements (e.g. diseases resistance characteristics).

The Technical Committee agreed that work should continue on this issue and assumed that the use of a specific molecular marker of phenotypic characteristics could be acceptable within the terms of the UPOV convention and should not undermine the effectiveness of protection offered under the existing UPOV system.

Secondly, it is considered to combine phenotypic and molecular distances in the management of variety collections in order to identify the varieties against which distinctness should be assessed.

The Technical Committee considers that, provided molecular distance may be assessed in a reliable manner, its use could be acceptable within the terms of the UPOV convention and would not undermine the effectiveness of protection offered under the existing UPOV system.

Thirdly, the working group is considering the development of a new system in which clearly distinguishable differences in molecular characteristics would be considered as a threshold level for judging distinctness.

There is no consensus within the Working Group on the acceptability of proposals made (in relation to rose and wheat) within the term of the UPOV convention and no consensus was obtained on whether they would undermine the effectiveness of protection offered under the UPOV system.

Concerns were raised that, using this approach, it might be possible to use a limitless numbers of markers to find differences between varieties.

AIPPI should monitor the work on possible use of molecular markers in the examination of distinctness uniformity and stability.

I consider that the conclusion above is acceptable, provided that the use of molecular markers would be limited to:

- ▶ predict traditional characteristics;
- ▶ assess molecular distance in order to manage variety collections.

However, using molecular markers to develop a new model would radically change the UPOV system and should be examined very carefully.

AIPPI should monitor this issue closely.

## **9 French case law on biotechnology**

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Two matters must be reported:

- ▶ Institut Pasteur v. Siemens Healthcare Diagnostics;
- ▶ Collectis v. GenOway and Collectis v. Taconic Farms.

The second matter is of particular interest for AIPPI.

## **9.1 *Institut Pasteur v. Siemens Healthcare Diagnostics***

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I attach a copy of the decision issued on 28 May 2010 by the *tribunal de grande instance* of Paris, 3<sup>rd</sup> chamber, 2<sup>nd</sup> section, (in French and in English) in a matter between Institut Pasteur and Siemens Healthcare Diagnostics, for infringement of a patent regarding HIV detection kits.

Institut Pasteur alleged that Siemens Healthcare Diagnostics would have committed acts of contributory infringement of the French designation of its European patent No. 0 178 978 regarding “*cloned DNA sequences, hybridisable with genomic RNA of lymphadenopathy associated virus (LAV)*” by selling certain kits for the detection of HIV in blood samples.

The *tribunal de grande instance* dismissed Institut Pasteur’s claim on the ground that the detection kit of Siemens Healthcare did not fall within the scope of the patent and that their sale did not amount to contributory infringement.

This decision is the copycat of a decision issued by the court of appeal of Paris on 14 April 2009 in a matter between Institut Pasteur and Chiron, that I mentioned in my note for AIPPI Q114 of 31 August 2009.

From a legal standpoint, the decision is interesting for several reasons:

- ▶ it reminds that the extent of protection conferred by a patent shall be determined by the terms of the claims and that this rule applies even in relation to a pioneer patent; the *Cour d’appel* accepts that the claims of a pioneer patent be drafted in general terms but it specifies that, if the claims are drafted narrowly, the patent, even a pioneer one, has a limited scope;
- ▶ it indicates that the patent claims which have been amended during prosecution or opposition proceedings before the European patent office can not, under the pretext of interpretation, be given the extent of claims to which the patentee renounced, as this would prejudice to the security of third parties;
- ▶ it reminds the provisions regarding contributory infringement by indicating that:
  - a means must be considered as essential if it contributes to the result of the invention;
  - the means supplied must be suited for putting the invention into effect; in this specific matter, the *Cour d’appel* dismissed the action on the ground that the use of the accused detection kits was not suited to obtain the RNA subject matter of claim 11.

## **9.2 *Collectis v. GenOway and Collectis v. Taconic Farms***

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Two interesting decisions have been issued in two separate matters between Collectis and:

- ▶ GenOway: *tribunal de grande instance* of Paris, 12 November 2009, 3<sup>rd</sup> chamber, 4<sup>th</sup> section;
- ▶ Taconic Farms: *tribunal de grande instance* of Paris, 26 June 2010, 3<sup>rd</sup> chamber, 1<sup>st</sup> section.

In both matters, Collectis is the owner (or master licensee) of a family of patents resulting from WO 90/11354, notably EP 0 419 621 regarding a “*method for the specific replacement or insertion of a gene*”.

Collectis has granted two separate non exclusive licences of this patent to Taconic and GenOway.



Both licensees have been selling breeding pairs of transgenic mice to their customers and authorized said customers to have them reproduce.

Collectis alleged that such sale would breach the licence agreements which prohibits the grant of sublicenses and therefore requested the termination of the licence agreements and the payment of royalties.

In both decisions, the *tribunal de grande instance* of Paris considered that the sale of breeding pair of transgenic mice, with the authorisation of reproducing the mice, amounts to an authorisation of reproducing the product directly obtained by the patented process.

In both decisions, the *tribunal de grande instance* of Paris terminated the licence agreement.

In the first decision against GenOway (12 November 2009), the court also ordered the destruction of the “*product*” namely of the mice; in the other decision against Taconic (26 June 2010), the destruction of the mice was not ordered.

**30 September 2010**