Annual Report
of
Special Committee Q114

Biotechnology and Plant Variety Rights
September 2013

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
	Andrew N. Blattman	Australia
	Takashi Fujita	Japan
	Arpad Peto	Hungary
	Juergen Meier	Germany
	Edgar Krieger (Plant Varieties)	Germany
	Gesheng Huang	China
	Hari Subranamian	India
Reporter Responsible	Sarah Matheson	Australia

Summary

Current and Future Issues
Herein Committee Q114 provides an update on IP Developments in the Biotechnology Sector in Europe, USA, China, Japan, Australia and Brazil in the last year. The live issues for the Committee going forward into the next year include:

- The current uncertain position with patenting of stem cell technologies in Europe in light of the Decision of the Bundesgerichtschof in the case of Brustle v Greenpeace eV and now referral C-364/13 to the CJEU from the high court of England and Wales (see section 1B)

- The patenting of products *i.e.* plants and animals, of processes found to be excluded as essentially biological in the light of the new Enlarged Board of Appeal Referral G02/13 at the EPO. The window for filing an Amicus brief in the case by AIPPI is still open (see section 1A)

- The patenting of isolated nucleic acid molecules in Australia following the Appeal lodged by Cancer Voices Australia against the Decision of the Federal Court of Australia in February 2013 concerning the patentability of isolated gene sequences.

Deadline for any action
A deadline of 30 November 2013 has been set for third parties to file Amicus briefs to the Enlarged Board in the G02/13 referral.

Action Recommended
A recommendation regarding any action to be taken by the AIPPI regarding G02/13 will follow after a meeting of Q114 to take place in Helsinki on 7 September 2013.

Report of the Committee Activities during the reporting period
Following on from a meeting of the Committee at the Congress in Seoul in 2012, Q114 has continued to monitor developments relating to all the matters set forth in our 2012 report. The Committee held an interim meeting (by teleconference) in March this year. Updates provided by the members at that time have been included in the current report.

Matters debated by the Committee in the last year include:

- The possible filing of an Amicus brief to the EPO in Enlarged Board referral G02/12 concerning products of essentially biological processes. The option was rejected at the time because procedurally it appeared likely the whole proceedings would be terminated. However, a further opportunity to file a brief on the matter has now arisen and will be discussed in Helsinki.
- The possible filing of an Amicus brief at the Supreme Court in the Myriad gene patenting case in the US, and the filing of third party observations in the Brustle Stem Cell matter before the Opposition Division of the EPO. After deliberations however, it was agreed it was not appropriate for AIPPI to act in either of these matters directly at that time.

However, in the case of the stem cell issue it is expected a further opportunity will arise in due course and the matter will be revisited.

In addition our Committee has been greatly strengthened in the past year by four additional new members including a plant varieties expert and members from China and India. Overall therefore this Committee is well positioned to report and act on matters internationally.

Priorities for the following years' work of the Special Committee

The Committee will continue to monitor and report on all live issues identified in the report and to consider where any action or intervention by AIPPI might be appropriate. A particular short-term priority will be to decide on the filing of an Amicus brief in the G02/13 Enlarged Board referral and the preparation of such a brief if appropriate

1. Europe (Claire Baldock)

A. Products of Essentially Biological Processes

New Enlarged Board of Appeal Referral **G02/13**

In the Committee's Report for the Seoul Congress 2012, referral G02/12 to the Enlarged Board of Appeal of the EPO was discussed. That case concerned a patent with claims to methods of producing tomato plants and the tomato plants so produced. The Enlarged Board had previously held that the process claims were directed to an unpatentable essentially biological process (see G01/08) and the G02/12 referral is concerned with whether products of such an excluded process may be patented.

There has now been a further referral to the Enlarged Board on the same issue under G02/13. In this case the subject matter of the European Patent is broccoli rather than tomatoes and again it had already been decided in an earlier referral (G07/07) that the claimed process for producing the broccoli was an excluded essentially biological process. The status of the product claims is now the subject of the new referral.

Specifically, the questions referred are as follows:

i. *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?*

ii. *In particular:*

a) *Is a product-by-process claim directed to plants or plant parts 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 application?*

iii. *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.*

iv. *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 renounce on the protection for such generation by "disclaiming" the excluded process?*

The Enlarged Board has set a period expiring on 30th November 2013 for the filing of observations by third parties. The Committee will consider in Helsinki the position which might be taken by AIPPI in this matter and whether the filing of an Amicus brief is to be recommended.

Pertinent to these considerations may be that the European Parliament has already issued a statement urging the EPO to exclude from patentability products derived from conventional breeding and all conventional breeding methods including "precision breeding" and breeding material used for conventional breeding. (See previous Report of October 2012).

B. Human Embryonic Stem Cells

i. Oliver Brustle v Greenpeace eV – Bundesgerichtshof (BGH)

In our previous report of October 2012 we reported fully on the decision of the Court of Justice of the European Union (CJEU) in referral C-34/10 from the Bundesgerichtshof. The patent relates to the isolation and purification of neural precursor cells used for the treatment of neural defects, which precursor cells are derived from embryos. The questions referred to the CJEU related to the scope of Article 6(2) of Biotechnology Directive 98/44EC which expressly excludes from patenting "*uses of human embryos for industrial or commercial purposes".* On the scope of the exclusion the Court concluded:

"Article 6(2) of the Directive excludes an invention from patentability where the technical teaching which is the subject matter of the patent application requires the prior destruction of human embryos or their use as a base material, whatever the stage at which that takes place and even if the description of the technical teaching claimed does not refer to the use of human embryos."

Following this decision, the Bundesgerichtshof had to interpret and apply the CUEJ's finding in the Brustle case. The German Court handed down its decision on 27th November 2012. On the basis of the CJEU's conclusion on the scope of Article 6(2), the Patentee's main request to uphold the patent as granted was refused. The subject matter of the claims required the prior destruction of human embryos. However, the Patentee had filed an auxiliary request in which the relevant claims included a disclaimer stating:

"…no isolated purified precursor cells from human embryonic stem cells are encompassed during the generation of which embryos have been destroyed."

The BGH considered that a patent could be maintained with these claims without contravention of Article 6(2) of the Biotechnology Directive or its equivalent under National German Law. It interpreted the CJEU Decision as meaning that a use for industrial or commercial purposes was only excluded if such use entailed the destruction of the embryo. This more liberal interpretation of the Directive could mean that, in principle, use of human embryos could be patented if it does not destroy the embryo in the process. Techniques are now available such as "single blastomere biopsy (SBB)" for removing a single cell from a blastocyst without destroying it. Of course it remains to be seen whether the liberal interpretation applied by the BGH would be applied by other National Courts across the EU. The Committee will continue to monitor the situation. One relevant factor is that amendment of a claim to restrict solely to allowable subject matter may not be permitted (see below).

ii. European Patent Office

In proceedings parallel to those in the German Court, the European Patent of Dr Brustle was opposed by Geron Corporation, a commercial entity. Objections were raised under Article 53(a) and Rule 28(c) EPC which recites the equivalent exclusion to Article 6(2) of the Biotech Directive concerning the industrial and commercial uses of embryos. In addition to the opposition which also raised objections under other grounds, observations were also filed by other parties, including Greenpeace.

The claims of the patent were in a product-by-process format. Thus, the Patentee, in order to overcome the Rule 28(c) exclusion and avoid the adverse effects of the CJEU decision, filed amended claims which included the disclaimer language:

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

thereby creating a similar situation to that which had been the subject of a favourable decision by the German Court.

The EPO Opposition Division, however, rejected these amended claims on formal grounds because the introduction of the disclaimer language was regarded as "adding matter" i.e. extending the content of the application beyond that which was filed. In reaching this conclusion the Opposition Division followed the Enlarged Board of Appeal Decision G02/10 on allowable disclaimers. This decision makes it clear that a disclaimer can be permitted, in principle, but not in a situation where the subject matter of the amended claim, once the disclaimer has been inserted, is not clearly and unambiguously derivable from the application as filed. In the case under consideration the application was not deemed to disclose any process for producing neural precursor cells which did **not** involve destruction of an embryo. Therefore, the disclaimer added matter.

This decision is unfortunate in that, rejection of the claims on formal grounds has meant that the issue of patentability of the subject matter in general, in the light of the CJEU Decision was not considered by the Opposition Division, leaving uncertainly as to the EPO's actual position. This uncertainty is likely to last for some time. The Committee will be monitoring the situation and consider whether third party observations on behalf of AIPPI might be appropriate if an appeal is lodged in due course.

iii. <u>New referral to CJEU concerning human embryonic stem cells – C-364/13</u>

In Oliver Brustle v Greenpeace the CJEU was asked what is meant by human embryos in Article 6(2) of the Biotech Directive. The court found an embryo to be, amongst other things:

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

This finding has been criticised 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 new referral 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 definition of an embryo and 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 stated as his preliminary view that if, as in the case of parthenogenesis, the process of development is incapable of leading to a human being, then it should not be excluded from patentability. However, he considered it unclear from the CJEU Decision whether *“capable of commencing the process of development of a human being* “, had meant merely commencement of a process regardless for potential of completion of the process or whether only processes which could lead to the birth of a viable human being were excluded. Thus, he 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?”*

The exclusion of “parthenotes” from patentability would seem to go much wider than the Biotech Directive intended when drafted. Amicus briefs from the public at large are not permitted at the CJEU and only comments on behalf of national governments may be made. However, the Committee will, of course, continue to monitor the situation.

2. United States (Peter Ludwig)

A) Association for Molecular Pathology v. United States Patent and Trademark Office

On June 13, 2013 the US Supreme Court delivered its long awaited opinion in Association for Molecular Pathology v. Myriad Genetics, Inc.569 U.S. ____ (2013). A unanimous Court found that genomic DNA does not become patent eligible under Section 101 of US law (which sets out the scope of patent eligible subject matter) merely by virtue of being “isolated.” In an opinion authored by Justice Thomas, the Court held that "a naturally occurring DNA segment is a product of nature and not patent eligible merely because it has been isolated, but that cDNA is patent eligible because it is not naturally occurring." The decision has far reaching implications but fails to address several important issues for the biotechnology industry.

On May 12, 2009, the American Civil Liberties Union and the Public Patent Foundation brought suit against the US Patent and Trademark Office, Myriad Genetics, and the University of Utah Research Foundation., which hold the patents on the *BRCA1* and *BRCA2* genes. The suit

contended that patents for human genes were a violation of the First Amendment and US patent law on the grounds that genes are "products of nature," and therefore cannot be patented. The District Court decided in favor of the plaintiffs and found the Myriad claims were patent ineligible as products of nature.

Thereafter in 2011 the Court of Appeals for the Federal Circuit reversed the holding by the District Court Judge that Myriad's claims to isolated DNA were not patent eligible because they covered products of nature (*Association for Molecular Pathology* v. *United States Patent and Trademark Office*, 653 F. 3d 1329 (2011)). The plaintiffs petitioned for review by the Supreme Court.

On remand from the Supreme Court for reconsideration in view of the Supreme Court's prior decision in the Mayo v. Prometheus case, , the Federal Circuit again found that Myriad's claims to isolated DNA sequences were patent eligible. The court held that the act of isolation created a new product sufficiently different, both structurally and functionally, from that which existed in the genome and that the isolated DNA was no longer a natural product. As a consequence, the Federal Circuit majority deemed isolated DNA patent eligible. All of the Federal Circuit judges on the panel that decided the case were in agreement that claims relating to cDNA met the patent eligibility requirements of §101 because they did not have introns, could not be isolated from nature and had to be created in the laboratory.

In a footnote to their June 2013 decision the Supreme Court rejected Myriad's arguments regarding the plaintiff's lack of standing. The Court also rejected any deference to the USPTO on the issue before the Court, noting, among other things, that the United States had argued before the Federal Circuit and the Supreme Court that isolated DNA (but not cDNA) was patent ineligible under §101. The Court characterized Myriad's principal contribution as "uncovering the precise location and genetic sequence of the BRCA1 and BRCA2 genes within chromosomes 17 and 13." and recognized the extensive effort required to accomplish this. Nonetheless the court found that was "insufficient to satisfy the demands of §101." In addition, the fact that isolation breaks chemical bonds did not save the claims. In a comment that may have implications for claim drafting, the court said that "Myriad's claims are simply not expressed in terms of chemical composition, nor do they rely in any way on the chemical changes that result from the isolation of a particular section of DNA. Instead, the claims understandably focus on the genetic information in the BRCA1 and BRCA2 genes." The Court then went on to distinguish cDNA, stating that it "does not present the same obstacles to patentability as naturally occurring, isolated DNA segments." The Court reasoned that "creation of a cDNA sequence from mRNA results in an exons-only molecule that is not naturally occurring" and as such was patent eligible. However, Justice Thomas cautioned about a "very short series of DNA [that] may have no intervening introns to remove when creating cDNA. In that situation, a short strand of cDNA may be indistinguishable from natural DNA."

Finally, the opinion identified several issues that were not addressed by the Court. Thus, the decision does not concern method claims. Thus innovative methods for manipulating genes may be patentable. In addition, the opinion did not address "the patentability of DNA in which the order of the naturally occurring nucleotides has been altered." Summarizing, Justice Thomas stated, "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 Myriad decision has important implications for existing in-force US patents with claims directed to isolated genomic DNA., The Supreme Court's opinion raises questions about patenting of cDNA from any sources in which the polypeptide-coding sequences are not interrupted by introns (e.g., certain bacterial and plant species). The opinion also raises questions about the patenting of primers and probes if the sequences of such molecules can be found embedded in the corresponding natural sequences. What is clear is that any claimed DNA with altered sequence or with other chemical structures not found in nature, such as detectable markers, likely will qualify as patent eligible subject matter. The extent to which this Supreme Court decision implicates other "naturally occurring" chemicals, such as antibodies, hormones, therapeutic RNA, and other biological molecules, remains to be determined. However, provided such molecules can be claimed with modifications not found in nature, the claims are likely to be found patent eligible.

B) Bowman v Monsanto Company

On 13th May 2013, the Supreme Court delivered its judgment in the case of *Bowman v Monsanto* concerning whether farmers who buy patented seeds can continue to replant and harvest subsequent generations without the patent holder's permission.

The particular dispute concerned Monsanto's patent for ROUNDUP READY (RUR) soy beans which are resistant to the herbicide glyphosate. These are sold by Monsanto to farmers pursuant to a licensing agreement that authorizes the production and sale of beans from a single crop but prohibits the purchaser from saving such beans for replanting.

The defendant, Vernon Bowman, has purchased seeds from a grain elevator and, on the basis that the seed batch would inevitably contain some RUR seed, sprayed with glyphosate. He was able to successfully harvest some RUR beans and save seed for future growing seasons.

When sued for patent infringement by Monsanto, Bowman's defense was that Monsanto's patent rights were exhausted since the sale of seed to the grain elevator had been authorized. The Supreme Court, while agreeing that Monsanto's rights in the seed actually sold to the grain elevator had been exhausted, nevertheless held that the doctrine restricts the patentee's rights only as to the "particular article" sold but leaves the patentee's ability to prevent the purchaser from making new copies of the patented item untouched. The court reasoned that applying the doctrine in this manner would allow farmers to benefit from RUR technology, yet continue to reward Monsanto for its innovation.

The Decision confirms for the US what is established by the Biotech Directive in Europe, that a claim to a transgenic plant or animal should be construed to cover all subsequent generations.

3. China (Gesheng Huang)

A. Update regarding China: Biotechnology-

Judgment of the court on biotechnological invention

The Supreme People's Court of China issues various reports on IP judicial protection annually, such as the Annual Report on IP Judicial Protection and Annual Report on IP Cases, etc. These reports are important materials for understanding and studying attitude of the Supreme People's Court, although China pursues to the statutory law, but judgments of Supreme People's Court does have a great influence on the practical trial activity of people's courts of local levels.

In the Annual Report of Supreme People's Court on IP Cases (2012), the most important IP cases trialed by the Supreme People's Court and their corresponding judgments are selected and issued to the public. By making judgments on these IP cases involving hot or complex IP issues, the Supreme People's Court has explained its attitude and tries to unify the standard for application of law.

Among the cases in the annual report, we have selected two cases involving biotechnological invention, which represent attitude of Supreme People's Court on the relevant issues.

i. Case 1: An administrative case on pharmaceutical composition for the treatment of diabetes

Case Number: [(2012) the Supreme People's Court Administrative Judgment No. 41]

Upon the trial of this case, the Supreme People's Court holdss that, while determining the inventiveness of an invention, if the applicant supplements experimental data of comparison after the filing date (priority date) in order to show that the technical solution brings unexpected technical effect, premise or condition for accepting such data is that such technical effect has been clearly disclosed in the original application documents.

ii. Case 2: An infringement case on a patent named "adenosine disodium triphosphate and magnesium chloride for injection"

Case Number: [(2012) the Supreme People's Court Retrial Judgment No. 10]

This case relates to a patent named "adenosine disodium triphosphate and magnesium chloride for injection", with its patent number ZL200410024515.1.

In this case, the Patentee sued two companies for infringing his patent. The court of the first instance believed that the excipient "sodium bicarbonate and arginine" in the accused infringing product are not the essential components and thus the accused infringing product is the same as the patented product. The court of the second instance refuted the judgment of the first instance and believed that since the patent is invalidated, the patentee had lost the right basis to accuse others of infringement. The patentee filed a petition for retrial and proved that the invalidation decision made by the Patent Reexamination Board of SIPO had been refuted by the Higher People's Court of Beijing.

Upon the retrial of this case, the Supreme People's Court holds that, for the close-ended claims, it shall be explained that structural components or steps and

procedures which are not defined in the claims are excluded from the scope of protection; for the close-ended claim of a composition, it shall be explained that the composition only comprises the defined components other than all other components, however, impurities in appropriate amount can be included in, and the excipients do not belong to the impurities.

Besides the explanation of the claims, the Supreme People's Court has also made some comments about application of *Doctrine of Equivalents* in infringement case involving close-ended claims. The Supreme People's Court indicates that, if the patentee chooses the close-ended claim to show that other undefined structural components or steps and procedures are excluded from the scope of protection, it is not proper to reincorporate such structural components or steps and procedures into the scope of protection by applying the *Doctrine of Equivalents*.

Relative laws, regulations and department rules

In order to adapt to the rapid development of biotechnology, laws, especially administrative regulations and department rules are amended or drafted in recent years in China.

First, the *Regulations on the Administration of Human Genetic Resources (Draft)* (hereinafter referred as *Regulations*) have been disclosed to the public for advice, recently.

The draft *Regulations* is directed to the protection and use of the human genetic resources in China, and applies to the activities for the purpose of scientific study on the human genetic resources, such as collection, deposition, study and development and the import-export. The term "human genetic resources" refers to resource materials comprising the human genome, gene and the product thereof, such as the organ, tissue, cell, nucleic acid, and the nucleic acid product, and the information materials generated there from.

Regarding to the collection and deposition of the human genetic resources, it is specified in the *Regulations* that without approval, no entity or individual could collect and deposit the human genetic resource material. The *Regulations* also specifies in detail the conditions and the procedure to get the approval and some limitations upon the collection and deposition activities.

As to the study and development of the human genetic resources, it is specified in the *Regulations* that the oversea institutes and its branches that do not enjoy the status of a juridical person, should co-operate with the juridical person within the territory in China, to study and develop the human genetic resources. The *Regulations* also specifies in detail the conditions to carry out the international co-operation activity, the procedure to get the approval of the activity, and some provisions relating to the intellectual protection of the research productions. Particularly, it is stipulated in the *Regulations* that as to the international co-operation in China, it would not be approved if the ownership of the intellectual property rights in the co-operation is not clear or the assignment of the rights is not reasonless. The *Regulations* also encourages the Chinese partners of the co-operation to protect the research production by acquiring intellectual rights or by other effective measures.

Regarding to the export and import of the human genetic resources, it is specified in the *Regulations* that the export of the Chinese human genetic resources need to be approved, while the import of the resources should be recorded. The *Regulations* also specifies in detail the condition to export the resources, the procedure to get the approval, and some limitations upon the export of the resources.
In addition, several penalty provisions were also specified in the *Regulations* regarding to the activities on the human genetic resources.

4. Japan (Takashi Fujita)

Court cases relating to Biotechnological inventions

i. Inventive Step/Evaluation of unexpected effects where an enzyme similar to that claimed is disclosed in the prior art but the alleged unexpected effects are not disclosed. (RNase HII Case, 2012 Gyo-ke 10252 decided on March 18, 2013)

a) Claim
Amended Claim is directed to an RNase HII from Thermococcus litoralis.

b) Facts
D3 discloses RNase HIIpk (RNase HII from Pyrococcus kodakaraensis KOD1). The RNase HII from Pyrococcus kodakaraensis KOD1 has an identity of 70% or less with claimed RNase HII.

Later published document Exhibit 2 indicates RNase HIIpk can cleave on the 5' side of an RNA even if the number of RNA was one.

Instant specification mentions that Pfu RNase HII (RNase HII derived from Pyrococcus furiosus), and Pho RNase HII (RNase HII from Pyrococcus horikoshii) can cleave on the 5' side of an RNA even if the number of RNA was one, and there was no report on an RNase H that cleaves even if the number of RNA is one as of filing.

c) Board of Appeals
The Board found that the claim lacks inventive step over D3.
Board judged that RNase HIIpk disclosed in D3 should have the same ability of cleaving a DNA strand containing an RNA among duplex DNA strand, because Pyrococcus kodakaraensis in D3 belongs to the same genus of Pyrococcus furiosus, and Pyrococcus horikoshii, and the specification mentions that Pfu RNase HII and Pho RNase HII can cleave on the 5' side of an RNA even if the number of RNA was one.

d) IP High Court

The Court mentioned in dicta that it is NOT permissible to find prior arts based on the description of the instant patent application.

Thus it is wrong to presume that RNase HIIpk disclosed in D3 should have the same ability of cleaving a DNA strand containing an RNA among duplex DNA strand and to judge that instant RNase HII is not so different from RNase HIIpk disclosed in D3 in view of the later published Exhibit 2.

The Court maintained the decision of the Board of Appeals in its conclusion, as the instant specification lacks concrete description that RNase HII from Thermococcus litoralis can cleave on the 5' side of an RNA even if the number of RNA is one.

ii. Inventive Step/Late submitted Data
Gene Therapy case, reported last year (H22 Gyo-ke 10203), in which the IP High Court vacated the decision to reject appeal by the Board of Appeals of JPO and remitted the case back to the Board of Appeals, was considered by the JPO. The JPO this time decided to grant a patent.

iii. Pharmaceutical Cases/ Enablement and Support requirements
Some IP High Court decisions revisited the issue of enablement or support requirements of pharmacological inventions. In one case (corresponding to WO2000/06174), the court decided that enablement was not met when claims are directed to combination of (a) and (b), where only some data relating to (a) was described in the specification and no data concerning the combination and no data concerning (b) was described in the specification.

5. Australia (Andrew Blattman)

On 15th February 2013 the Federal Court of Australia handed down its decision in the case of Cancer Voices Australia & Yvonne D'arcy v Myriad Genetics Inc & Ors. The presiding judge, Justice Nicholas, identified the issue in the case as one "of considerable importance", framing the question to be decided as whether a "valid patent may be granted for a claim that covers naturally occurring nucleic acid that has been isolated".

Justice Nicholas answered that question in the affirmative.

Although the patent includes 30 claims, it was only claims 1 to 3 that were in dispute. Claim 1 of the patent is: [an] isolated nucleic acid coding for a mutant or polymorphic BRCA1 polypeptide, said nucleic acid containing in comparison to the BRCA1 polypeptide encoding sequence set forth in SEQ.ID No:1 one or more mutations or polymorphisms selected from the mutations set forth in Tables 12, 12A and 14 and the polymorphisms set forth in Tables 18 and 19. Claims 2 and 3 are dependent claims extending only to DNA. The challenge to the claims was solely on the basis that they include non-patentable subject matter. In particular, the applicants contended that each claim

comprises “isolated” nucleic acid that is not materially different to the nucleic acid that occurs in nature.

Under Australian law, other than specific exclusions of certain subject matter, the question as to what constitutes patentable subject matter is answered by reference to section 18(1)(a) which asks whether the invention “is a manner of manufacture within the meaning of section 6 of the Statute of Monopolies”. The leading case on that point is the decision of the High Court of Australia known as NRDC. Following that decision, Justice Nicholas observed that “a composition of matter may constitute patentable subject matter if it consists of an artificial state of affairs, that has some discernible effect, and that is of utility in a field of economic endeavor”.

Justice Nicholas’ decision identifies three considerations influential in leading to his conclusion that isolated nucleic acids are patentable. First, that the High Court in NRDC was “deliberate in its use of very expansive language” to emphasise the “broad sweep" of patentability. Secondly, the importance of “isolated” in that the claim is to a nucleic acid that is the product of human intervention. Third, that it would “lead to very odd results if a person whose skill and effort culminated in the isolation of.. an isolated DNA sequence could not be rewarded by grant of a patent because the [subject matter]… was held to be inherently unpatentable”.

Importantly, the decision emphasises that patentability of isolated nucleic acids “does not turn upon what changes have been made to the chemical composition of such substances as a result of them having been isolated”, thereby making it clear that there is no requirement for changes in chemical composition of the claimed nucleic acid.

The patentability of gene sequences has received close attention in Australia over recent years, with several government-appointed inquiries having been held. Justice Nicholas’ decision makes reference to the Australian Government Response of November 2011 to the Reports of three of those inquiries, that response specifically accepting the recommendation of the Australian Law Reform Commission that the Patents Act not be amended to exclude genetic materials from patentable subject matter. The decision also makes reference to the Senate Committee Report into a parliamentary Bill introduced in 2010 which sought to exclude from patentability biological materials, defined in that Bill as including DNA and RNA, Justice Nicholas noting that the Report recommended the Senate not pass the Bill (which has now lapsed).

The decision identifies that one of the “main arguments” raised against the patentability of isolated DNA sequences is the impact that such patents may have on future research, for example in diagnostic and therapeutic technologies. In making this observation, Justice Nicholas noted the “significance” of a recent amendment to the Patents Act, which introduced an explicit statutory exemption from infringement for research and experimental activities. Thus, under new section 119C of the Act “[a] person may, without infringing a patent for an invention, do an act that would infringe the patent apart from this subsection, if the act is done for experimental purposes relating to the subject matter of the invention”. Inclusive provisions in the Amended Act illustrate the scope of

"experimental purposes" and include "improving or modifying the invention". Section 119C applies in relation to acts done on or after 16 April 2012 in relation to patents granted before, on or after that date. Whilst the decision may again lead to calls for legislative change it does make clear that isolated nucleic acids sequences are currently patentable in Australia.

This decision of the Federal Court is now under Appeal to Australia's Full Federal Court and the case was recently heard. A judgment is expected in a few months. The committee will continue to monitor the situation.

6) Brazil (Gabriel Di Blasi)

The Ordinance No. 005/2012 published by the BPTO, establishing the rejection of patent applications that may violate the Brazilian Biosafety Law (Law No. 11,105/05) and the Law on Genetically Modified Soybean (Law No. 10,814/03).

Basically, according to the Biosafety Law, the patenting and licensing of genetic technology of restrict use and derived products, as well as the ones applicable to the soybean culture, namely, any process of human intervention to the generation or multiplication of genetically modified plants to produce sterile reproductive structures and any form of genetic manipulation aimed at the activation or deactivation of genes related to fertility of the plants by external chemical inducer are forbidden.

The law itself defines as crime the patenting or licensing of this kind of technology, foreseeing from 2 up to 5 years of imprisonment.

Therefore, the BPTO will reject patent applications containing the referred scope, on the grounds of Article 6, item VII, of Law No. 11,105/05 and Article 12, of Law No. 10,814/03.

7) India (Hari Subranamian)

Monsanto Technology LLC v. The Controller of Patents & Designs

The Intellectual Property Appellate Board (IPAB) of India on 05 July 2013 dismissed US based Monsanto Technology's appeal relating to an invention for climate resistant traits in plants. This is the first decision of the IPAB wherein IPAB has interpreted S. 3(d) in connection with plants. The invention was directed to method for producing a transgenic plant that renders the plants tolerant to extreme environmental condition such as excess heat, salt and draught.

Monsanto Technology LLC filed Indian Patent Application No. 2407/DELNP/2006 on 01 May 2006 with the priority date of 29 September 2003. The original claims of the patent application were drawn to recombinant DNA, plant cell progene, plant, crop plant, propagule, seed etc. However, during prosecution the claims were amended and the claims on record at the time the appeal was filed at the IPAB were directed to method of

producing a transgenic plant comprising the steps of inserting a recombinant DNA molecule into the genome of plant cell.

IPAB in its decision of 05 July 2013 upheld the Controller's decision to refuse the application under the ground of lack of inventive step, 3(j) and S. 3(d). Although, Monsanto submitted post-filing data that demonstrated an increased tolerance of the transgenic plant to heat and draught as compared to the non-transgenic controls, the IPAB was of the view that due to the disclosure in the cited prior art the use of proteins employed in the patent application was known for expressing cold shock protein in *E. coli*, yeast cells and the like. Thus, in accordance with S. 3(d) IPAB upheld the Controller's decision that the invention related to use of cold shock proteins in production of plant which are heat, salt and draught tolerance. The cold tolerant property of cold shock protein was already known in the prior art. Hence, heat, salt and draught tolerant was nothing but new use of known substance and was therefore not permissible u/S 3(d) of the Indian Patents Act, 1970. Thus, the method involved a mere application of already known cold shock proteins in producing stress tolerant plant which were also tolerant in heat, salt and draught condition. However, both the Indian Patent Office and the IPAB failed to appreciate that the invention related to a process/method which employed cold shock proteins and resulted in the production of a transgenic plant with increased heat, salt and draught tolerance, viz. the claimed method involved use of a process which resulted in a new product.

In connection with S. 3(j) the IPAB was of the view that the claimed method employs a series of generic steps modified by plant cell such as transformation, regeneration and solution of transgenic heat, salt and draught tolerance. Thus, claimed method entailed many generic method steps that were essentially biological employed in a specific sequence which did not involve inventive step and the mere fact of human intervention did not change the composition. Hence, the claims fell u/S 3(i) of the Indian Patents Act.

<u>Avesthagen v. Dept. of Industrial Policy & Promotion (DIPP), Govt. of India</u>

Using Traditional Knowledge Digital Library (TKDL) Indian Patent related to the beneficial effects to the *Eugenia* (Jamun) in curing diabetes has been revoked in India using a Section 66 of the Indian Patents Act, 1970 viz. "*Revocation of patent in public interest of the Central Government*". Avesthagen filed Indian Application No. 1076/CHE/2007 on 23 May 2007 related to a synergistic Aurvedic/functional food bioactive composition comprising extracts of plants selected from *Eugenia*/ *Cinnamomum*/ *Salacia* for the management of diabetes. The Indian Application 1076/CHE/2007 was granted on 27 April 2012. Employing the provision of Section 66 of the Indian Patents Act, the Central Government quashed the grant of this application and vide an official notification in the Gazette of the IPO on 18 October 2012 this patent was revoked. It was held that as the plants are known to act against a particular disease, their extracts are bound to perform the same function.

This is the second time since the inception of the Indian Patents Act, 1970 a patent had been revoked under Setion 66. The only other time that the provision of this Section was

used to quash a patent was when a patent was granted to a US firm for developing cotton cells by tissue culture.
In view of revocation of this patent a list of patent applications involving traditional knowledge has been put on Patent Office website. Following this, the Controller General has laid draft guidelines for processing of applications related to traditional knowledge and National Biodiversity.

8) Plant Variety Rights

A. Brazil

Law No. 9.456, of April ,1997 establishes the protection of intellectual property rights regarding plant varieties

The protection of intellectual property rights regarding plant varieties is performed through the granting of a Plant Variety Protection Certificate before the SNPC (National Plant Variety Protection Service).

The application for protection, which may only refer to a single plant variety, should include:

i. the botanical species;
ii. the name of the plant variety (varietal denomination);
iii. the genetic origin;
iv. a specification duly completed including all required descriptors;
v. name and address of the applicant and of the breeders;
vi. evidence of the DHS characteristics (Distinctness, Homogeneity and Stability) for national and foreign plant varieties.
vii. report of other descriptors indicative of the distinctness, homogeneity and stability thereof, or evidence of performance, by the applicant, of tests concerning the plant variety together with specific controls or those indicated by the competent agency;
viii. a statement as to the existence, in another country, of protection, or an application for protection, or of any request concerning the right of priority, relative to a plant variety which protection is being requested (if occurred) ;
ix. an abstract allowing the identification of the object of the application; and
x. Photographs.

The protection of the plant variety shall be effective from the date of granting of the Provisional certificate of Protection, for a period of fifteen years, except for vines, fruit trees, forest trees and ornamental trees, including, in each case, the mother graft thereof, for which the term shall amount to eighteen years.

B. China

i. *Regulations on the Protection of New Varieties of Plants* have been amended and reissued in 2013. To be specific, stipulations about the administrative penalty have been amended, which reflects that the administrative authorities will give the right owner a strong protection.

ii. Relative governmentaldepartments have issued or drafted department rules on protection of intellectual properties involving biotechnology. In 2012, the Ministry of Agriculture (MOA) drafted the *Views of Ministry of Agriculture on Further Strengthening the Agricultural IPR Management*, promulgated *Regulations on the Naming of Agricultural Plant Varieties*, and developed the draft directory of the 9th batch of plant varieties under protection.

iii. The State Forestry Administration (SFA) completed the collection and validation of 5th batch of new forestry varieties under protection and organized the formulation of *Measures for Acquisition and Benefit Sharing of Forestry Biological Genetic Resources (Draft)*.

C. India

Maharashtra Hybrid Seeds Co. Ltd. v. UOI Ors & Nuziveedu Seeds (P) Ltd. v. UOI & Ors

Petitioner filed an application under the Protection of Plant Varieties and Farmers' Rights Act, 2001 to register its variety of cotton. The application was published by the Protection of Plant Varieties and Farmers' Rights Authority in the Plant Variety Journal dated 01.09.2008. Once an application for registration of a variety is accepted, the same has to be advertised under Section 21(1) of the Act. Under Section 21(2), a notice of opposition can be made by any person within three months from the date of advertisement of the application. The provisions thereafter refer to the procedure as to how such an opposition application is to be dealt with while Section 22 of the Act requires the Registrar to consider the opposition and to pass order on the same.

It is in view of these provisions the Opponent (Respondent herein) filed an opposition to the application, but beyond the stipulated period of three months as prescribed. The delay was of 86 days in filing the notice of opposition. The opposition was considered by the Registrar and the delay in filing the notice of opposition was condoned *ex parte* vide the order dated 11.06.2009. The condonation of delay was assailed by the Petitioner before the Delhi High Court by filing writ petition. The Petitioner succeeded in the same and the impugned order was set aside by the High Court vide Order dated 03.11.2009 on the ground that the condonation of delay was granted without notice to the Petitioner. The matter was thus remanded back for re-consideration before Regisitrar which thereafter proceeded to hear both the petitioner and R-3 and vide order dated 09.03.2010 condoned the delay.

As per Section 21(2) of the Act: **Advertisement of application**: "*Any person may, within three months from the date of the advertisement of an application for registration on payment of the prescribed fee, give notice in writing in the prescribed manner, to the Registrar of his opposition to the registration.*"

As per Section 31of the Act: **Notice of opposition under sub-section (2) of section 21:** *"Any interested person, may within three months from the date of advertisement of an application for registration, may give a notice of opposition to the registration of a plant variety in Form PV-3 of the First Schedule.*" As per Section 32 of the Act: *32.* **Compliance with time schedule:**-"*The time schedule provided for advertisement, opposition, defense, hearing and amendment of specification under these rules shall not be extended and failure in compliance with these time schedules shall forfeit the opportunity granted.*"

As per Section 33(1 and 6) of the Act: **Manner of submitting evidence and time limit for filing notice of opposition, counter-statement or producing evidences under section 21**: Section 31(1) "*Any evidence upon which the applicant may rely shall be submitted in duplicate to the Registrar with a copy to the opponent within thirty days from the date of receipt of opponent's evidence*." Section 31(6) "*The time-limit for filing the evidence shall not ordinarily be extended except by a special order of the Registrar given on an application filed by the person seeking extension of time and on payment of the fee specified in the Second Schedule and such an application for extension shall be in Form PV-5 of the First Schedule*."

The question to be decided was: Whether the power under Rule 33(6) can be imported into Rule 32 to extend the time for filing of notice of opposition. The Court held that the word "shall" used in Rule 32 has to be read as "may". Their primary reason for arriving at such a conclusion was that there are no penal consequences provided under Section 21(2), which is the substantive provision, prescribing three months time period for a notice of opposition from the date of advertisement of the application. If such a provision is compared with Section 21(2) of the Trade Marks Act, 1999 the significance is obvious viz., prescribing that the party shall be deemed to have abandoned its application. It was held that such procedures fixing time limit are only to facilitate an early disposal and avoid unnecessary adjournments but such procedures should not be put in an absolute straightjacket. Thus, the intent of the legislature is directory and not mandatory in character.

The Court concluded that the mandate of Rule 32 should be read as one which is directory and not mandatory and, therefore power can be exercised in an appropriate case by the Registrar to extend the time period for filing the application for opposition.