AIPPI

Standing Committee on

Subcommittee Biotechnology

2016

International Association for the Protection of Intellectual Property
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REPORT
Standing Committee on

Subcommittee Biotechnology

Chair: Claire BALDOCK
Responsible Reporter: Ralph Nack

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

Please provide a general overview of the activities of your Standing Committee over the last 12 months, but please include at least:

a) meetings of the Standing Committee during the reporting period

Our first meeting as a sub-committee took place at the Rio Congress on 11 October 2015 and was well-attended. The Australian member reported on the very recent ruling of the Australian High Court in the case of *D'Arcy v Myriad Genetics Inc.* ([2015] HCA35) which held that isolated DNA is not patentable by virtue of not defining a "manner of manufacture". Given a similar outcome for the Myriad patents in the United States and clear lack of International harmonisation which has developed in the patenting of genetic material, it was agreed that the Committee would conduct a study with a view to producing a position paper on the topic (see (d) below). Telephone conferences with committee members took place on 21 and 22 January 2016 to progress the gene patent study.

At the Rio meeting workshop proposals for Milan and working questions for Sydney were discussed.

b) any external representation on behalf of AIPPI by any member of your Standing Committee

There has not been any external representation of AIPPI by any member of the sub-committee in the reporting period.

c) any contribution by your Standing Committee to any external consultations

There has not been any contribution to any external consultations by any member of the committee so far within the reporting period but one is in progress (see (f) below).

d) any studies or analyses undertaken or position papers prepared by your Standing Committee, with a brief summary of the outcome(s)

Following the committee meeting at the Rio congress, reports on the situation with regard to gene patenting were gathered from each of the committee members for their own territory and collated into a position paper calling for International harmonization. A final draft approved by the committee has been provided to the responsible reporter on 29 June 2016 for further consideration and input.

e) involvement of your Standing Committee in any other activities of AIPPI, eg Panel Sessions, contribution

to Study Guidelines, etc

Following a request from the General Secretariat, the US, Australian, Chinese and German members of the sub-committee were put forward as speakers for panel sessions at the Milan congress. We are pleased to report that our Chinese member, Gesheng Huang, has been selected as speaker in the Pharma I session entitled “In(gene)ious but not patentable? Patentable eligible subject-matter”.

f) any other relevant activities

The Indian Government has issued a Draft Notification of “Licensing Guidelines and Formats for GM Technology Agreements” which is out for consultation and for which comments from interested parties are invited by **24 August 2016**. The Notification seeks to put limits on the price and on IP licensing royalties for GM cotton seeds.

The Biotechnology Sub-Committee has been asked to prepare comments in support of IP rights holders, to be filed on behalf of AIPPI in response to the consultation invitation from the Indian Government. At the time of preparing the report the preparation of these comments is in hand.

2) Key issues/developments relevant to the Terms of Reference of your Standing Committee during the reporting period

Please include a short summary of any significant case law, legislative or regulatory developments, or policy initiatives, including their relevance and/or any implications for the work of your Standing Committee or for AIPPI more generally

(A) Europe

1) UK

a)Two disputes have been before the High Court of England and Wales during the reporting period, both concerning the issue of sufficiency of disclosure in relation to patents and prior art.

In *Regeneron v Kymab Ltd and Novo Nordisk a*/s two patents were at issue relating to Regeneron’s Velocimmune® transgenic mice suitable for therapeutic antibody discovery. Regeneron initially brought a claim for infringement of their Patents, and it was decided by the High Court that Kymab’s transgenic mice were within the scope of the claims of both Patents. The defendants were however, successful in challenging the validity of the Patents for lack of sufficiency. This case is of significant interest for its consideration of fundamental platform technology in the therapeutic antibody field.

The Patents at issue in this case describe methods for generating transgenic mice capable of producing “reverse chimeric” antibodies having human variable regions and mouse constant regions. The methods involve replacing gene segments of the variable regions (the V,D,J segments) in the murine immunoglobulin loci with the human counterparts, instead of the full-length loci. The transgenic mice having the reverse chimeric loci exhibit improved antibody production as compared with the fully-human transgenic mice, and the hybrid antibodies may be subsequently humanised by the addition of a human constant region for testing as therapeutic candidates.

The claims of the ‘287 Patent included process claims reciting methods of modifying an endogenous immunoglobulin heavy chain variable region gene locus in an isolated mouse embryonic stem cell, and also two product-by-process claims covering genetically modified eukaryotic cells, ES cells or mice containing a genetically modified immunoglobulin heavy chain variable region locus *obtainable by* the process of the preceding claims. Claim 1 of the ‘163 Patent was a product claim reciting a transgenic mouse having replacements in both the murine heavy and light chain loci such that hybrid antibodies are produced containing human variable regions and mouse constant regions.

It was concluded by the judge that the process defined in the claim was not capable of being performed at the priority date without undue burden. This conclusion was based primarily on the fact that that the evidence from the experts suggested there was no means available (either described in the Patent or

presented as an alternative by the Patentee) by which the skilled person could have made the insertions and deletions at the murine immunoglobulin loci of the size required by the claimed process without making a further invention. The '163 Patent was invalidated on the same grounds on the basis that the product claims were broader in scope than the process claim of the parent Patent.

Interestingly, the claims of '287 Patent considered by the English High Court in these proceedings were the amended claims approved by the EPO Board of Appeal at the Oral Proceedings held on 27, 28, 29 October and 9 November 2015. The Board of Appeal's conclusions on sufficiency were that if one skilled in the art had found the large size replacement failed he would have tried smaller ones falling with the claim to achieve the same result. There was relevant guidance for this in the specification and hence the claim was sufficient. Thus, as is so often the case, a diverging decision between the EPO and the English Courts has arisen because of a difference evidential basis.

In *GlaxoSmithKline v Wyeth Holdings* the High Court had an opportunity to review what constitutes an "enabling disclosure" in the context of assessing novelty. In these proceedings, GSK had lodged a claim for revocation of Wyeth's patent relating to a Meningitis B vaccine. Wyeth counterclaimed for infringement by GSK's Bexsero vaccine. The novelty of Wyeth's patent was questioned based on the prior use and prior description of vaccines that contained the same active ingredients. However, the High Court decided that neither the use nor the description constituted "enabling disclosures". Ultimately, Wyeth's patent was held to be valid, and GSK's Bexsero vaccine was found to infringe.

Wyeth's patent EP(UK)2,343,308 claims a composition comprising a 2086 protein, and additionally at least one PorA protein. This composition is effective as a vaccine to prevent meningitis caused by *N. meningitides* serogroup B, and claims 18-20 are directed to this use. It was known, prior to Wyeth's filing, that vaccines containing PorA proteins did not provide broad protection against a sufficient variety of bacterial strains to be particularly effective. In contrast, Wyeth had found that inclusion of 2086 protein (also known as fHbp) provides compositions that elicit bactericidal antibodies to multiple strains.

In GSK's claim for revocation, invalidity was asserted on the basis that certain claims of the patent lacked novelty. GSK relied upon prior use of a vaccine developed at the Finlay Institute in Havana, Cuba, which was being administered to patients before Wyeth's first priority document. GSK also argued lack of novelty based on an abstract describing the antibody response of a vaccine developed from a Norwegian strain of Men B.

Both the Cuban and Norwegian vaccines included bacterial OMVs (outer membrane vesicles). These OMVs are released from the bacterium and thus contain associated proteins and lipids, some of which are strongly immunogenic. It was well known at the priority date that a major immunogenic component of OMVs was the PorA protein. However, the precise identity of other proteins of the OMVs was not known. It was later discovered that both the Cuban and the Norwegian vaccines did in fact include 2086 protein.

GSK submitted that there was evidence the Cuban vaccine contained 2086 protein in 2009, and alleged that the vaccine would have had an equivalent composition before Wyeth's priority date in 2001.

Wyeth submitted that in order for the Cuban vaccine to anticipate as prior use, the skilled person must have been able to analyse it and identify the presence of 2086 protein at the priority date. The Judge relied on principles set out previously in both *Merrell Dow Pharmaceuticals Inc. v HN Norton & Co Ltd* [1996] RPC 76 and in *Synthon BV v SmithKline Beecham plc* [2006] RPC 10 whereby anticipation requires clear communication of information to the public. It was expressly stated that *"Acts done secretly or without knowledge of the relevant facts, which would amount to infringements after the grant of the patent, will not count as anticipations before"*. The judge thus agreed that it was necessary for the skilled person to be able to identify the presence of the 2086 protein at the priority date, and since the techniques were not available to allow this, the prior use was not novelty-destroying.

With regard to the Norwegian vaccine described in the abstract, GSK alleged that this composition was within the scope of claim 1 of Wyeth's patent, and that the skilled team could have determined the components of the OMVs using standard techniques. However, both GSK's and Wyeth's technical experts indicated that this task would have been "extremely laborious" and "very unlikely to work". Furthermore, no specific method or growth conditions were disclosed in the abstract. Thus, it was not considered

inevitable that OMVs produced by the skilled person would contain 2086 protein. On this basis, it was concluded that the abstract did not amount to an enabling disclosure.

In finding in Wyeth's favour, this decision has reinforced the idea that for a prior disclosure to anticipate there must be sufficient transfer of information to the public. What is critical is what would have been known or achievable by the skilled person at the time of disclosure, regardless of what is learnt subsequently. Disclosure by prior use may be of particular interest in the field of biologics, where significant investment may be required to determine the active ingredients of a mixed composition. For those in this field, the decision is a positive one, since it confirms that even if the same composition was in use before, if the relevant information was unknown, a patent may still be granted on the basis of discovering the active ingredients and demonstrating their therapeutic effect.

b) Brexit

On 23 June 2016, the people of the UK voted in a referendum for the UK to leave the European Union. At present the UK Government has not triggered Article 50 of the Lisbon Treaty which will initiate the leaving process but the Prime Minister is currently indicating this will happen in early 2017. Thereafter the UK is expected to remain a member of the EU for at least another two years. Brexit throws up formidable challenges for Intellectual Property, especially where pan-EU rights have been available, such as trademarks, Designs and Community Plant Variety Rights. The European Patent Convention, however, is not an EU Treaty and the UK will remain a member post-Brexit. Euro(UK) patents granted through the European Patent Office will remain in force in the UK and such patents will still be able to be obtained through applications to the European Patent Office. UK European Patent Attorneys will continue to be able to represent applicants before the European Patent Office.

EU Directive 98/44 on the Legal Protection of Biotechnological Inventions forms part of the UK Patents Act 1977 by virtue of Section 76A of the Act and Schedule A2, introduced with effect from 28 July 2000. Therefore, this will remain in the Act on Brexit and is very unlikely to be changed. However, we do not know at present whether the UKIPO or the UK Courts will follow interpretations put on the Directive by the CJEU in future.

1. European Patent Office

There has been very little case law of significance to the Biotech sector at the European Patent Office during the reporting period. However, of interest is an apparent change of practice regarding patentability of inventions involving human embryonic stem cells (hESC). Following the Decision of the Enlarged Board of Appeal in G2/06 (WARF) and the Decision of the CJEU in C-34/10 *(Brüstle V Greenpeace*), inventions relating to or involving hESC which necessarily involved destruction of a human embryo could not be patented. However, the prohibition did not apply to applications filed after February 2008 when it was deemed that technology allowing recovery of hESC without embryo destruction was available.

In December 2014 the CJEU in C-364/13 held that the product of an ovum stimulated to divide by parthenogenesis was not an "embryo" if, in the light of current scientific knowledge, it does not have the inherent capacity of developing into a human being. A method for recovering hESC from parthenotes was first published on 5 June 2003. Consequently, in more recent examinations of stem cell related inventions at the EPO, this 2003 date is being used as the cut-off before which hESC and applications thereof are prohibited from being patented. This more permissive regime is clearly beneficial to those working in the field over a number of years. This development is the reason why the stem cell position paper which the Committee agreed to produce following its meeting at the Toronto Congress in 2014, has not so far been advanced. The improved position deems the contribution it might make less useful. The usefulness of such a paper needs to be re-evaluated.

B) Turkey

1. A new draft law on Intellectual Property ("**Draft IP Law**") has passed through the Turkish Grand National Assembly, and examined by the Industry, Commerce, Energy, Natural Resources, Information and Technology Commission. This draft sets forth many amendments, including the following which

might have an effect on pharma patents:

- The new draft IP law brings new provisions regarding the non-patentable inventions. Accordingly, excluding microbiological process or products obtained by means of such a process, biological processes regarding plant or animal varieties or production thereof is considered as non-patentable.
- Moreover, the simple discovery of human body of its elements, at the various stages of its formation and development, including the sequence or partial sequence of a gene, cannot constitute patentable inventions.
- Processes for cloning human beings, processes for modifying the germ-line genetic identity of human beings and the use of human embryos for industrial or commercial purposes, processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and animals resulting from such processes are also clearly excluded from patentable inventions.
- The article regarding the patentability criteria does not set forth corresponding provisions to Articles 54/4 and 5 of EPC 2000. Therefore, second (or further) medical use are still not explicitly allowed or prohibited in Turkish law.
- As to the registration process of patents with substantive examination, there is a minor change. In order to compare, Decree Law on the Protection of Patent numbered 551 sets forth that if the Turkish Patent Institute ("**TPI**") concludes that the application does not meet the patentability criteria, the applicant is allowed six months to either amend its claims or object to the TPI's report. The TPI will consider the applicant's objections or amendments and if the TPI stands by its previous decision, the applicant is allowed three months to make a second round of objections or amendments. The TPI's next decision on the matter is final. However, according to the Draft IP Law, the applicant is entitled for a third round of amendment and objections.
- The Draft IP Law also introduces a post grant opposition system. According to this system, third parties are entitled to oppose to a patent within 6 months following the publish of the grant decision. The opposition grounds may be that the patent does not meet the patentability criteria, the invention is not disclosed in a sufficient manner or the patent exceeds the scope of the application. The applicant is entitled to respond to the claims of the opponent or amend its claims within three months. The decisions of the TPI are final, and cannot be appealed before TPI or first instance courts.

The Draft IP Law still has not become a law yet, meaning it is still open to amendments and not finalized.

C) Australia

1. A first for the Raising the Bar Act in Australia – November 2015

CSR Building Products Limited v United States Gypsum Company [2015] APO 72 is the first decision by the Australian Patent Office to consider the new requirements for support and disclosure under the *Raising the Bar Act.* The new requirements are similar to s 14(3) of the UK Patents Legislation and Article 83 of the European Patent Convention and UK court decisions such as *Generics (UK) Ltd v H Lundbeck A/S* [2009] RPC 13. An Australian court is yet to consider the new requirements.

Subsection 40(2)a and 40(2)aa of the *Raising the Bar Act* states that the specification must:

a. Disclose the invention in a manner which is clear enough and complete enough for the invention to be performed by a person skilled in the relevant art; and

aa. Disclose the best method known to the applicant of performing the invention

The Australian Government's Explanatory Memorandum stated that these sections were modified to require enablement across the full width of the claims. It was indicated that a specification that provides a single example of the invention may satisfy the requirements, but only where the skilled person can extend the teaching of the specification to produce the invention across the full width of the claims, without undue burden, or the need for further invention.

Subsection 40(3) states:

The claim or claims must be clear and succinct and supported by matter disclosed in the specification.

In CSR the test required to meet the disclosure required by section 40(2) was:

i. Construe the claims to determine the scope of invention as claimed,

ii. Construe the description to determine what it discloses to the person skilled in the art, and

iii. Decide whether the specification provides an enabling disclosure of all the things that fall within the scope of the claims.

The Hearing Officer noted that a reasonable amount of trial and error is permissible when it comes to assessing sufficiency of disclosure. However, there must be adequate instructions in the specification leading the skilled person necessarily and directly towards success.

However, if the work involved amounts to an undue burden, then the specification has not provided an adequate disclosure. It was found that financial costs of the trials and experimentation can be an undue burden.

The test to determine whether the claims are supported by the description is:

i. Construe the claims to determine the scope of the invention as claimed,

ii. Construe the description to determine the technical contribution to the art, and

iii. Decide whether the claims are supported by the technical contribution to the art.

It is therefore clear that under the new support and disclosure requirements a fuller description will be required to allow a person skilled in the art to perform the invention across the full width of the claims without undue burden.

2. IP Australia releases Myriad Examination Guidelines – December 2015

In October 2015 the High Court of Australia handed down its decision in *D'Arcy v Myriad,* deciding once and for all that isolated nucleic acids do not define patent-eligible subject matter in Australia. The decision brought Australia's position on isolated DNA and RNA in line with that of the United States, while representing a marked deviation from major trading partners such as Europe and the US on the issue of patentability of cDNA

In December 2015, IP Australia released new Examination Guidelines for applications which may be affected by the Australian High Court's decision in *D'Arcy v Myriad Genetics* ("*Myriad*"). The full Examination Guidelines were incorporated into the Examiner's Manual of Practice and Procedure on 11 January 2016.

IP Australia received and considered a broad range of submissions on the issue of patentability of nucleic acids, and ultimately maintained a fairly narrow interpretation of the High Court's decision.

Blanket exclusions from patentability apply to isolated *naturally occurring* DNA and RNA, whether human, non-human, coding or non-coding.

Synthetic nucleic acids (including cDNA), probes, primers and isolated interfering/inhibitory nucleic acids are only excluded where they "merely replicate the genetic information of a naturally occurring organism".

In circumstances where subject matter which *may* be affected by the decision is not expressly excluded from patentability, the new Guidelines call for a case by case consideration of the following factors:

1. What is the substance of the claim (not merely its form)?
2. Has the substance of the claim been "made" or changed by man, or is "artificial"?
3. Does the invention have economic utility?

4. Does the invention as claimed represent a new class of claim?

The Guidelines elaborate on the application of these factors, but ultimately, in the absence of legislative changes, it will be up to the courts to determine the breadth of the ramifications of the *Myriad* decision.

In the meantime, the Guidelines have indicated that the following remain patentable subject matter:

- Recombinant or isolated proteins;
- Pharmaceuticals and other chemical substances;
- Methods of treatment;
- Methods of applying herbicides; and
- Applications of computer technology.

D) China

Draft Regulation on Administration of Human Genetic Resources

On February 4, 2016, the State Council issued the Draft for public opinion.

As drafting body of the Regulations, Ministry of Science and Technology of China pointed out in the legislative specification on the regulations that, with competition relating to human genetic resources and relevant intellectual property rights thereof becomes fiercer than ever before, illegal collection and obtaining of Chinese human genetic resources by foreign institutions occur frequently. And these illegal activities becomes more stealthy and various, which brings great challenges to current administration of human genetic resources in China. Under such circumstance, the original *Interim Measures on Administration of Human Genetic Resources* which was issued in 1988 cannot well respond to the challenges faced by current administrator of human genetic resources.

According to the draft Regulations, the sovereignty of China shall be respected during any activities relating to human genetic resources. Collection, gathering, international cooperation and exportation of human genetic resources shall bring no harm and potential hazard to safety of the society and the state. And also in accordance with the draft Regulations, where an entity which collects, gathers human genetic resources in China or carries out international cooperation relating to Chinese human genetic resources without permission of competent administration has power to impose administrative liability on such entity, such as issuing a cease and desist order, imposing a fine ranging from 20,000 RMB to 100, 000RMB or even requiring competent authority to prosecute the criminal liability.

Besides this, human genetic resources collection and utilization activities relating to clinical diagnosis and treatment, blood collection, criminal investigation, doping detection and funerals are not regulated by this Regulations but other laws and regulations.

E) Japan

Patentability of Functional Foods

Until April 1, 2016, the JPO had continually decided that an invention directed to a new use of a known food lacks novelty. For example, a food composition for use in preventing a hangover containing an ingredient A as an active ingredient lacks novelty, because “use in preventing a hangover” is not limiting the food.

A new law for labeling foods allowing a manufacturer to label a food with a functional indication under certain conditions became in force last year, and food industry expressed their view that they would increase R&D in this field. In response, the JPO has revised examination guideline in this respect. The JPO now treats “for use in preventing a hangover ” as limiting food for particular use if following (i) and (ii) are met:

(i) "The use in preventing a hangover" is derived from discovering of an unknown attribute that promotes alcohol metabolism by an ingredient A.

(ii) The use application which is derived from the attribute is different from any known uses and novel.

F) Philippines

On 26 July 2016, the Philippine Supreme Court overturned its 08 December 2015 decision which nullified the rules and regulations for the importation and release into the environment of plants and plant products derived from the use of modern biotechnology. The December 2015 decision also temporarily restrained the conduct of field trials, and the propagation and importation of genetically modified organisms (“GMOS”) in the Philippines.

A media brief issued for the press on 26 July 2016 stated that the justices of the Philippine Supreme Court unanimously agree with the nine (9) motions for reconsideration filed by the proponents of the Bt eggplant project (the University of the Philippines Los Baños Foundation Inc., University of the Philippines and International Service for the Acquisition of Agri-Biotech Applications Inc.), the Environmental Management Bureau, and petitioner-intervenors Crop Life Philippines Inc., Biotechnology Coalition of the Philippines and several other intervenors. The high court said that it should have junked the writ of kalikasan (writ for the protection of the environment) filed by Greenpeace and other alleged environmentalist groups in April 2012 seeking to stop the field trials of Bt eggplant, because the aforementioned field trials have been completed and terminated and the biosafety permits for such field trials expired in 2012.

Thus, the Philippine Supreme Court pronounced that the aforementioned cases were mooted by the expiration of the biosafety permits issued by the Philippine Bureau of Plant Industry and the termination of Bt talong field trials subject of the permits. These effectively negated the need for the reliefs sought by Greenpeace, et. al as there was no longer any field test to stop.

G) United States

The issue of eligibility for patenting continues to dominate the patent landscape in the United States.

In May of 2016 the USPTO issued updated Subject Matter Eligibility Guidelines directed to natural products. These guidelines supplement the previous (2014) Interim Guidance on Subject Matter Eligibility. The 2014 Guidance included examples for use in determining whether various subject matter was patent eligible.

The current (May 2016) Guidance has additional examples of subject matter spanning a wide spectrum of life science technologies. One example (number 29 -directed to method of diagnosis claims) has received considerable attention. According to the Guidance the diagnostic claims in example 29 are patent eligible because the steps called for in the claims "...are not themselves natural laws". Although the Guidance and the examples in the Guidance do not have the force of law, they offer some indication that the USPTO considers that some diagnostic methods are eligible for patenting.

On July 5, 2016, hard on the heels of the May 2016 Supplemental Guidance on eligibility, the Court of Appeals for the Federal Circuit vacated and remanded a summary judgement by a district court that the patent in suit was not eligible for patenting and accordingly invalid under section 101 of the US patent law. In Rapid Litigation Management Ltd., v Cellzdirect Inc. and Invitrogen, the court found that the patent in suit was not directed to a law of nature, but applied the law of nature and claimed a process leading to a "new and useful" result.

The patent in suit claimed a method for preserving hepatocytes (liver cells). The Circuit court’s decision included an analysis of step one of the by now well-known Alice procedure for determining patent eligibility -is the claim directed to a law of nature. The Federal Circuit found that "The end result of the ‘929 patent claims is not simply an observation or detection of the ability of hepatocytes to survive multiple freeze-thaw cycles. Rather, the claims are directed to a new and useful method of preserving hepatocyte cells”. The decision is important as it indicates that biological processes are patent eligible subject matter under section 101 of US patent law. Many practitioners feel this decision may signal a shift by the court in favor of life science patentees.

H) Mexico

For technologies related to stem cells, Mexican examiners typically object to claims directed to human embryo origin cells. However, recently, even if not present in the claim, when the description or examples describe the use of human embryo origin cells the examiners object to also the patentability of the invention as attempting to patent life.

I) Canada

The Canadian Intellectual Property Office has recently implemented new examining guidelines for diagnostics (Practice Notice PN2015-02), which are now posing significant challenges during examination. The Practice Notice is remarkable for its lack of case law citations, and because there was no apparent public consultation prior to its release.

J) Brazil

Regarding the lasted event, Brazil created new rules to the Genetic Heritage Access Law. On May 11, 2016 the Federal Government published the Decree No. 8,772, which aims to regulate and clarify the provisions contained in Law No. 13,123/2015 – the Genetic Heritage Access Law- which entered into force last year and address access to genetic heritage, protection and access to the associated traditional knowledge, and the sharing of benefits for conservation and sustainable use of biodiversity in Brazil.

In sum, the main regulated points are:

- The establishment of the National Genetic Heritage Management and Associated Traditional Knowledge System (SISGEN) to carry out and control the access to the national genetic heritage and associated traditional knowledge;

- The definition of standards for the sharing of benefits arising from economic exploitation of a finished product or reproductive material that result from access to genetic heritage of Brazilian species;

- The regulation of the Benefit-Sharing National Fund (FNRB);

- The establishment of administrative sanctions; and

- The provision of rules for the adequacy / regularization of activities carried out under de previous legislation or activities in which there were access to national genetic resources without authorization.

The previous legislation required prior authorization to the access of national genetic resources or associated traditional knowledge. From now on, a simple registration will be enough. The registration must be done, for example, in case of sending material abroad, prior to requesting any intellectual property right, prior to publishing a scientific paper, among others.

The new Decree also sets out the basis for the sharing of benefits resulting from economic exploitation of a finished product or reproductive material those results from access to national genetic heritage or associated traditional knowledge. The sharing of such benefits may or may not be monetary, and micro and small companies and individual entrepreneurs will be free from benefits' sharing.

Finally, there will be a term of one (1) year, as from the availability of the system which allows the electronic registration (SISGEN), in order that activities carried out under the previous legislation can be adjusted to the new legislation (carrying out registration and sharing of benefits in case of economic exploitation). Moreover, activities in which there was access to genetic resources without authorization may be regularized within the same term. In order to regularize patent applications filed at the BPTO, applicants must submit proof of registration by SISGEN.

K) India

1.National GMO Policy

The agriculture ministry has come out with a draft policy for transgenic crops laying down rules for the

licensing of GM seed technology in future - a clear indication that the Centre is ready to expand the GM base beyond Bt Cotton and hence aims to have a clear-cut policy related to it. The policy was open to suggestion and comments from public in regard to the licensing issues. According to the May 18 draft licensing policy, the GM technology provider cannot deny a licence to any eligible Indian seed company nor can it charge a royalty that exceeds 10% of the maximum sale price of the seeds, which is to be fixed by the government every year. It specifies that the cap of 10% will apply for the first five years. The royalty will decrease by 10% a year from the sixth year onwards.

The Sub-Committee is preparing observations on the draft policy for submission on behalf of AIPPI (see 1(f) above).

2.Revocation of Monsanto's Patent

Mahyco Monsanto Biotech Limited (MMBL) was the patent holder over BT Cotton- a veriety infused with a certain bacterium that makes the seeds resistant to bollworms. Recently, in March 2016, the Department of Industrial Policy and Promotion sent a show cause notice to MMBL asking why the latter's patent should not be revoked in light of the failure of the patented product to deliver on its claimed functionality.

3.Sequential Listing

A per page fees shall be chargeable for every page of sequence listing with a cap amount of INR 24000 (for natural person), INR 60000 (for small entity/startup) and INR 120000 (for other than natural person and small entity/startup.

3) Any recommendation for AIPPI involvement/action for the next 12 months

This need not be limited to recommendations for your Standing Committee but can be recommendations for AIPPI more broadly. In each case, please explain why such involvement/action is recommended, by whom it should be undertaken and any relevant time frames. For example, please include:

a) any recommendation for involvement/action in relation to any upcoming or foreshadowed case law, legislative or regulatory developments, or policy initiatives

The Committee is involved in preparing comments for the Government's consultation in India on the draft licensing guidelines and formats for GM technology (see 1(f)) above.

It will also be important for AIPPI to review the IP position as the Brexit situation unfolds. Although the British group is naturally already very active, questions will undoubtedly arise where input at the more International level would be useful.

Please see above and Section 1(f).

b) any other recommendation(s) for AIPPI involvement/action

Recommendations for future actions will be considered at the meeting of the Committee in Milan on 18 September 2016.

4) Outline of the work programme of your Standing Committee for the next 12 months

Please set out specific activities and priorities having regard to the matters in 1) - 3) above, including any relevant time frames

This work program will be established at the meeting of the Committee in Milan on 18 September 2016.

Names and Functions of Committee Members

Chair	Claire BALDOCK	United Kingdom
Co Chair(s)	Thomas BOUVET	France
Secretary	Peter LUDWIG	United States of America
Members	Andrew BLATTMAN	Australia
	Graeme BOOCOCK	Canada
	Olga CAPASSO	Italy
	Magnus DAHLMAN	Sweden
	Garbiel DI BLASI JR.	Brazil
	Takashi FUJITA	Japan
	Gesheng HUANG	China
	Israel JIMENEZ HERNANDEZ	Mexico
	Edgar KRIEGER	Germany
	Maria del Pilar LOPEZ	Costa Rica
	Maria Carmela T. MARANAN	Philippines
	Jürgen MEIER	Germany
	Yoon S. SHIN	Republic of Korea
	Min SON	Republic of Korea
	Hariharan SUBRAMANIAM	India