

Standing Committee on  
**Pharma and Biotechnology**

2016



Date: 5th August 2016

## REPORT Standing Committee on Pharma and Biotechnology

Chair: John C. TODARO  
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

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An annual Committee meeting was held at the Rio AIPPI conference on October 11, 2015. This was the initial meeting of the Committee, as the Pharma Committee was formed in the spring of 2015. There were over 20 members present (including members of the Biotech Subcommittee). The Committee discussed possible projects for the 2015-2016 term, including study proposals on the use of post-filing data in patent prosecution, patent term extension and patent linkage, the overlap of antitrust and patent law, and second medical use patents.

The Committee held two telephone conferences on January 21, 2016 (to accommodate different time zones). A total of 18 members participated (including members of the Biotech Subcommittee). Discussion topics included the Committee's survey on post-filing data, ideas for workshops at the 2016 conference, proposed work with the UPC committee, and a discussion of future study topics.

The Committee held two telephone conferences on May 26, 2016, in which 19 members participated (including members of the Biotech Subcommittee). Discussion topics included a report on the survey of post-filing data, which had been completed earlier in 2016. Other discussion topics included possible workshops for the 2016 conference, proposed work with the UPC committee, a possible experimental use study, and plans for the committee meeting at the Milan conference.

A joint teleconference between 4 members of the Pharma Committee and members of the TRIPS committee was held on July 1, 2016. Collaboration projects between the TRIPS and Pharma committees were discussed.

In addition to the formal meetings, there was frequent email communication among the Committee members during the reporting period.

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

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None of the Committee members have done any external representation of AIPPI during the reporting period.

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

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None of the Committee members have taken part in any external consultations for AIPPI during the reporting period.

- d) any studies or analyses undertaken or position papers prepared by your Standing Committee, with a brief summary of the outcome(s)
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The Committee has undertaken various studies or projects during the reporting period, as outlined below:

Survey of Post-Filing Data

The largest project that the committee has undertaken this term is a survey of the rules for using post-filing data in patent prosecution around the world. This issue is important to the pharmaceutical industry, because patent applicants often seek to rely on post-filing data created after the application filing date to establish the inventive step of the inventions in the pharmaceutical field during patent prosecution. Patent Offices around the world have established different standards for the admissibility of post-filing data to show inventive step, which sometimes accounts for different results in patent prosecution.

To better understand how each country approaches the issue, we developed a questionnaire based on some hypothetical scenarios that could be answered by the committee members. Committee members in many countries volunteered to complete the survey, and we received survey answers for 27 countries or regions.

The Committee plans to discuss the survey topic with its Reporter General at the AIPPI conference in Milan. We will discuss whether this topic is suitable for a position paper, workshop, study question and/or AIPPI resolution.

In addition, the Committee has engaged on several collaborative projects with other Standing Committees, as summarized below:

Collaboration with TRIPS Committee (Q94): We are collaborating with the TRIPS Committee to write a summary of the recent decision of the Spanish Supreme Court on the losartan case, which concerned the different roles of European national courts and European Union institutions in interpreting TRIPS provisions. The Committee has also started a collaboration with the TRIPS Committee on TRIPS issues of particular concern to the pharma industry. The current focus is on the provisions of Article 39.3 on unfair commercial use of clinical data and the scope of TRIPS protection for confidential clinical data.

Collaboration with Unitary Patent / Unified Patent Court (Q243): We are working with the UP/UPC Committee on a project to identify the issues that may arise when SPCs are litigated in the UPC. We are aiming to produce a short position paper dealing with these issues. Substantive work has yet to commence on this project, although a structure for the paper has been proposed and each Committee has formed a small working group. It may be that work on this project is delayed until the future of the UPC becomes clearer following the UK's vote to leave the EU.

Collaboration with Standards and Patents (Q222): We met with the Standards Committee in Rio to explore areas where there might be scope for collaboration. One area where there was mutual interest in working together was to explore the IP/antitrust interface and in particular how developments in the pharma industry affected the ICT industry and vice versa. A joint proposal was made for this topic to be explored at a workshop in Milan, but unfortunately the proposal was not taken up.

- e) involvement of your Standing Committee in any other activities of AIPPI, eg Panel Sessions, contribution to Study Guidelines, etc
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Hugo Caro of the Committee served as a panelist at the 2015 Rio conference on "Personalized Medicine." Carlos Olarte and John Todaro of the Committee served as panelists at the 2015 Rio

conference on “Double Jeopardy: Policy-Based Examination of Patent Validity.”

Malathi Lakshmi Kumaran of the Committee and two of her law firm colleagues published an article in the March 2016 AIPPI e-news on the increasing public access to clinical data of pharmaceutical substances, and its implications for Article 39.3 of the TRIPs Agreement.

Duncan Ribbons of the Committee and one of his law firm colleagues published an article in the November 2015 AIPPI e-news on the interpretation and infringement of Swiss form second medical use claims in the UK.

- f) any other relevant activities

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*not responded*

- 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

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Committee members have reported on the following developments in 2015-2016 that are relevant to the Committee's terms of reference.

**Secondary Pharmaceutical Inventions in Latin America**

**Martin Bensadon, Argentina):**

Latin America has been no stranger to the policy of taking a restrictive approach towards secondary inventions in the pharmaceutical area. Although so far this trend has not seen statutory approval, it has been incorporated into regulatory provisions issued by the national PTOs and particularly in the day-t-day practice, as well in some draft bills. This has resulted in stricter requirements related to patentable subject matter, inventive activity and support.

The grounds for this policy were stated in the 17<sup>th</sup> Meeting of Health Ministers of the Mercosur (Argentina, Brazil, Paraguay, Uruguay and Venezuela), in Montevideo, Uruguay, on December 4, 2009, which declared the concern of the member countries about “the proliferation of patent application for subject matter which is not strictly inventive or involves only marginal developments”, and where the Health Ministers agreed “to promote in the Mercosur region guidelines for patentability to protect public health”.

As indicated, so far this trend has not brought about major changes in the national laws, but rather new regulations which invoke TRIPs “flexibilities” to support the new approach. Nonetheless new draft bills are being submitted to the various Legislatures which, if passed into law, may affect the legal situation of pharmaceutical inventions in Latin America.

The first approach –new administrative regulations which profess to implement the existing legislation (i.e., national laws and international treaties)– has been followed in Argentina and Paraguay. In May 2012 the Argentine Patent Office (National Institute of Industrial Property) and the Ministries of Industry and of Health issued a Joint Regulation with new guidelines for the examination of patent applications which severely restricted the patentability of several categories in the pharmaceutical field (polymorphs, hydrates, solvates, enantiomers, salts, esters, ethers, metabolites, prodrugs, formulations, combinations, Markush structures, selection inventions and processes). Shortly before, Paraguay had issued similar guidelines, albeit not as restrictive. In October 2015, the Argentine Patent Office issued Regulation No. 283/2015, which incorporates the current restrictive practice related to biotech inventions (especially those related to the agro industry).

The second approach –draft bills to change the national patent laws– has been pursued in Argentina, Brazil and Mexico. In Argentina, a bill was filed in Congress with the aim of turning the Pharmaceutical Guidelines into a formal law. In Brazil, a draft bill was submitted on April 18, 2013 with the aim of

restricting the patentability of new forms of known substances and to repeal the minimum 10-year term assured to all patents by the current law, regardless of the duration of their prosecution. Shortly thereafter, in July 2013 a draft bill was submitted to the Mexican Congress, seeking to exclude from patentability enantiomers, salts, ester, ethers or polymorphs of existing entities, new routes of administration or new dosage forms, changes in formulations and other similar pharmaceutical inventions.

A third approach has been followed in Ecuador, where in September 2012 the official fees were raised astronomically by the Patent Office, to the point that the most basic filing fees are in the vicinity of \$4,400 and the accumulated annuities for the full lifetime of a patent amount to \$140,000. The same approach has been recently taken by the Venezuelan Patent Office.

On the other hand, Chile has introduced patentability guidelines of its own, but they are directed mainly to procedural matters. In turn, the Peruvian Patent Office is gradually gaining a reputation for speed and responsiveness, and has lately granted patents for polymorphs. The free trade agreements signed by various Latin American countries (Chile, Peru, Colombia, CAFTA, NAFTA) are another limitation to the restrictive approach towards secondary inventions, as is the Trans-Pacific Partnership (TPP) agreed on in October 2015.

As indicated, this trend affects the patentability of compounds, compositions, formulations, dosages, intermediaries, salts, esters, ethers, solvates, enantiomers, metabolites, prodrugs, polymorphs, Markush structures, selection inventions, analog processes and uses.

**(Gabriel Di Blasi, Brazil):**

With regard to inventions related to uses, although ANVISA may oppose this protection, the BPO does not state any restriction for the patentability of this kind of invention. Therefore, in principle, in accordance with the new BPO's Guidelines, uses can be protected in Brazil.

The Bill No 139/99 has not moved forward since the National House of Representative has been in cessation of business since December 2015. It seems that this Bill will not be voted soon, because there are other political issues that have more priority than it.

**U.N. Development Program: Guidelines for The Examination of Patent Applications Relating to Pharmaceuticals (Carlos-Fernandez Davila, Peru):**

The United Nations Development Program (hereinafter "the UNDP") has published its Guidelines for the Examination of Patent Applications relating to Pharmaceuticals, also named Guidelines for Pharmaceutical Patent Examination: Examining Pharmaceutical Patents from a Public Health Perspective (hereinafter "the Guidelines") in June 09, 2016. The author is the Argentinean generic advocate Dr. Carlos Correa. This document represents a follow-up to the Guidelines for the Examination of Pharmaceutical Patents: Developing a Public Health Perspective, which was published in 2007.

The document emphasizes the fact that the TRIPS Agreement leaves WTO member countries many "flexibilities" for defining own policies and standards on the protection of intellectual property rights. For instance, there are flexibilities regarding the concept of invention, definition of the patentability standards and the sufficiency of disclosure. The guidelines suggest that the WTO members should use these flexibilities to apply rigorous patentability criteria for avoiding "low-quality" patents as well as to determine the rules applicable to the disclosure of the invention, in order to ensure its reproducibility and to avoid broad, generic claims.

The Guidelines recommend WTO members to limit the grant of secondary patents by adopting the following criteria, for instance:

- Novelty should be assessed considering what has been expressly, implicitly or inherently disclosed in the prior art, and not only in an express X document.
- Inventive step can be objected without citing a specific prior art document, to prove that a claimed

- invention falls within the common knowledge, or is obvious for an expert in the field.
- Markush formulae claims should be limited to the claimed embodiments that are actually enabled by the disclosure in the specification.
  - Selection patents should be rejected on the grounds of lack of novelty.
  - Polymorphs are obtained through routine pharmaceutical methods and their patent applications should be denied on the grounds of absence of patentable invention or inventive step.
  - Claims over the dose of a drug or the new use of a known drug can be rejected since they do not comply with the industrial applicability requirement.

#### **Developments in the UK/EU (Duncan Ribbons):**

##### SPCs:

In *Seattle Genetics* (C-471/14) the Court of Justice of the European Union held that the relevant date for calculating the term of an SPC is the date on which the holder of a marketing authorisation is notified of the decision to grant the authorisation rather than on the date of the decision itself. This decision has extended by a few days the term of many SPCs granted in countries which had previously used the date of the decision to calculate the term.

##### *Proposal for manufacturing waiver*

On 28 October 2015 the European Commission proposed introducing an SPC waiver to allow generic companies to manufacture products for export to countries where there are no patent rights and to stockpile products allowing launch immediately upon expiry of the SPC. This project is thought to be a priority for the Commission and might be implemented through an amendment to the SPC Regulation. The next step is likely to be a consultation on the proposal. No timetable has been fixed for this.

##### *Review of SPC regime*

Also, the European Commission is commissioning a study to investigate whether the existing SPC regime needs revision to meet the objectives of the system and the needs of industry. Depending upon the findings of the study, a proposal from the Commission to revise the current regime could follow.

##### Antitrust:

##### *Pay for delay*

##### Paroxetine

In February 2016, several companies including GSK were fined a total of almost £50M by the UK competition authority for conduct in relation to settlement of patent litigation concerning paroxetine, which involved cash payments and profit margin transfers from GSK to generics manufacturers. This is the first pay for delay case pursued by the UK competition authority to a decision, and is notable because it also includes findings of abuse of dominance in addition to findings of anticompetitive agreements. GSK and the generic companies have all appealed the findings and the appeal is due to be heard in the first quarter of 2017.

##### Citalopram

In October 2015, Lundbeck's appeal against the € 94M fine imposed on it by the European Commission in respect of patent settlement agreements relating to citalopram was heard by the General Court. The decision is now awaited and will be the first chance the General Court has had to review to the European Commission's approach to pay for delay cases.

##### *Royalty obligations in respect of invalid or not infringed patents*

On 7 July 2016, the Court of Justice of the European Union handed down its decision in *Genentech v Hoechst and Sanofi-Aventis* holding that, where a licensee has the right to terminate a licence on reasonable notice, it is not contrary to competition law to require him to pay royalties during the term of

the licence agreement in respect of either (a) an invalid patent or (b) a patent which (even without a licence) would not be infringed by the royalty bearing product.

Second medical use:

*Pregabalin*

In its decision of 10 September 2015, the English Patents Court (1<sup>st</sup> instance) held that Actavis did not infringe Warner-Lambert's Swiss form claims by selling a generic version of pregabalin under a skinny label, even though Actavis knew that some of its product would be used to treat patients suffering from the patented indication. Warner-Lambert's appeal of this decision was heard by the Court of Appeal in May 2016 and judgment is awaited.

**Developments in Mexico (Hector Chagoya):**

The Mexican Patent Office (IMPI) seems to have become more strict with regard to experimental evidence related mainly to claiming intervals in compositions and Markush claims.

**Polymorphs.** For polymorphs it seems that the Mexican patent office does not have a clear criteria related to omnibus claims directed to the figure showing the X ray diffraction pattern of the claimed form. Mexican rules for claim drafting in general prohibit omnibus claims "unless strictly necessary". Whereas it seems that most examiners will promote them and even request the applicant to claim specifically the pattern as shown in the description, some consider it not allowable and request to claim specifically the peaks. Furthermore, some examiners have been requesting to provide in the claim details related to the actual apparatus and/or the source of radiation used for obtaining the patterns. Despite the lack of consensus among examiners, it seems that for enforcement purposes including details at least in the description related to the actual method used to obtain the pattern, including equipment and radiation source, seems a reasonable recommendation for comparing an infringing product in case the method used for the infringing product is different.

**Second use claims.** In drafting this kind of claim in practice examiners are accepting generally both Swiss style and EPC style. However, particularly for EPC style claims that have large Markush descriptions and/or alternatives for the formulation, some examiners have started requesting to make it clear somehow before starting the formulae or large descriptions that it is a second use claim.

**Developments in Turkey (Ezgi Beklaci):**

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 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 to 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 a patent within 6 months following the publishing 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.

Please note that the Draft IP Law still has not become a law yet, meaning it is still open to amendments.

We would like to underline a recent development on an invalidity action regarding the second medical use patents. An EP patent granted prior to EPC 2000 was found null and void by 1<sup>st</sup> Intellectual and Industrial Rights Civil Court of Istanbul. In the dispute, the plaintiff filed an infringement action based on its patent, which was granted in 2005 (before EPC 2000 was in force in Turkey) and disclosed a new dosage regime. The defendant filed a counteraction and requested invalidation of the plaintiff's patent on the basis that it does not meet the patentability criteria. The first instance court ruled that the subject of the patent was a "treatment method" and therefore should not have been registered in the first place, without examining the novelty or inventive step. The court also noted that EPO Board of Appeal decisions were not binding on Turkish Courts. Therefore, the understanding of the EPO Board of Appeal decision numbered G5/83 of the Swiss-type claims, was not adopted by the Turkish court. The decision was appealed, and the Court of Appeal reversed the first instance court's decision. It noted that the general patentability criteria should be applied considering the lack of any provisions in Turkish Law allowing or prohibiting the second medical use claims. However, the first instance court insisted on its previous judgment repeating its previous claims. As a next step, the file was sent to the General Civil Assembly of Court of Appeal.

#### **Developments in Colombia (Carlos Olarte):**

Compulsory License procedure against Novartis imatinib beta polymorph patent

A compulsory license (CL) against the patent covering the beta polymorph of imatinib mesylate (covering Novartis' GLIVEC product) was requested by several NGOs in 2015. The NGOs based their CL request on grounds of "public interest" as contemplated under Art. 65 of Andean Decision 486. Art. 65 and domestic implementing regulations establish a two step process in order for a CL to proceed. The first and pivotal step requires a Declaration of Public Interest (DPI) from the Minister of Health (in the case of a pharmaceutical patent). Should a DPI issue, the Minister can transfer the case to the Patent Office for further processing of a CL (including, establishing general terms of the license, including royalties, as well as opening an invitation for potential licensees). Alternatively, local regulations allow the Minister to adopt other mechanisms, different from a CL, to attempt to solve the circumstances leading to the DPI.

In essence, the principal argument proffered by the NGOs was that the price of imatinib was excessively high, and that a CL would permit competition and therefore reduce the price. This in turn would allegedly allow greater patient access to imatinib. However, no evidence of lack of access was proffered. To the contrary, the Colombian health system guarantees coverage for all patients, obviating any need for patients to have to pay for pharmaceutical products from their pockets. Moreover, the patent under discussion only covers a specific polymorph, meaning non-infringing products could be on the market (indeed, a number of generic imatinib products are on the market). Finally, imatinib is subject to price control, whereby the government establishes the maximum price at which the product can be sold, thereby meaning any price below this maximum price is *per se* reasonable.

By means of Resolution 2475 dated 14 June 2016, the Minister of Health issued a Declaration of Public Interest, but did not opt to pursue a CL. Instead, the Minister requested the National Pharmaceutical Price Commission (NPPC) to develop and adopt a new methodology to reduce the price of GLIVEC. Specifically, it proposed using international generic imatinib prices as references to establish a maximum price, effectively preventing Novartis from seeking any sort of pricing premium. The Minister argued that it issued a DPI and associated pricing request in an effort to preserve the sustainability of the Colombian Health System, stating that even though Glivec is subject to price control, he was obligated to pursue all tools at his disposal in an effort to achieve this legally mandated goal.

All parties filed a Reconsideration Action against the DPI, which automatically suspends the effects of the decision. Novartis is seeking revocation of the DPI; the NGOs insist on a CL. A decision from the Minister



is expected by late August. Said decision is subject to judicial review before the Council of State.

### **Developments in Japan (Makoto Ono):**

The Doctrine of Equivalents (DOE)

In Japan, the Doctrine of Equivalents (DOE) is a defense. The Grand Panel of the Intellectual Property High Court has recognized broad coverage under the Doctrine of Equivalents.

On March 25, 2016, the IP High Court in *Chugai Pharmaceutical v. generic companies* found patent infringement under the DOE and opined that, even though an allegedly equivalent element was well known before the filing date of the patent application, a mere fact that the element is not recited in the patent claims does not prevent the Court from finding patent infringement under the DOE except where the patent applicant is considered to have been well aware of the allegedly equivalent element e.g., the applicant expressly described such an element in the patent specification or had disclosed the element elsewhere such as scientific articles.

Specifically, the patent in suit was directed to a process for preparing a pharmaceutically active compound. The defendants prepared the compound by using a slightly different starting material from the claimed starting material, and asserted that the plaintiff is estopped from asserting infringement even under the DOE because the plaintiff did not claim the defendant's starting material even though the plaintiff should have been aware of such a well known material, which should be construed that the defendant's starting material is expressly excluded from the scope of the patent protection by the plaintiff. However, the Court found infringement as in the above.

### **Developments in India (Archana Shanker)**

1. **Herceptin case****Background:** Roche sued Biocon over its manufacture of biosimilar version of Herceptin. Justice Manmohan Singh passed an order with regard to this restraining Biocon and Mylan (its partner) from using the name Herceptin or its associated trademark. However, both companies were permitted to use the INN Trastuzumab. **Update:** In the appeal against the earlier Manmohan Singh order, the division bench, confusingly, held that the position before the Manmohan Singh order would regulate the parties. Subsequently, Roche took issue with Biocon's mention of Herceptin at an international scientific conference on the ground that the latter was restrained from making such references as per the Delhi High Court order. In addition, they also filed contempt proceedings for the same. In response, Biocon also filed contempt proceedings alleging that Roche had made disparaging statements about the former. Both the contempt proceedings are scheduled to be heard in November.
2. **New Patent Rules** The Patent (Amendment) Rules 2016 entered into force in May 2016.

#### Expedited Examination - Rule 24C

An expedited request for examination of application can be made in form 18A (within 48 months from the priority date of the application) on the following grounds:

- That India is designated as the international searching authority or elected as the international preliminary examining authority in the corresponding international application; or
- That the applicant is a startup (definition in rule 2(fa))

A request for examination filed u/r 24B can be converted to a request for expedited examination by paying the relevant fees and submitting the relevant documents.

Except in cases where the application has already been published or the request for publication has already been filed a request for expedited examination shall be accompanied by a request for publication under rule 24A.

Where the request for expedited examination does not comply with the requirements of the rules, the request shall be processed as a request u/r 24B with intimation to the applicant and shall be deemed to have been filed on the date of which the expedited examination was filed.

The application shall be referred by the Controller to the Examiner in order in which the request is filed.

The examiner shall make the report within one month but not exceeding two months from the date of reference of the application by the Controller.

The Controller shall dispose of the examination report within one month from the date of receipt of the report.

A first statement of objections shall be issued by the Controller within fifteen days from the disposal of the report of the examiner by the Controller.

Time for filing the reply to the examination report shall be six months from the date of the first statement of objections. Said time can be extended by three months on a request in form 4 made before the expiry of the six months' period.

The reply to the examination report shall be processed in order of receipt of the reply.

The Controller shall dispose the application within three months from the date of receipt of the last reply to the first statement of objections or within a period of three months from the last date to put the application in order for grant u/s 21, whichever is earlier.

The Controller can by notification limit the number of requests for expedited examination to be received during the year.

The Patent (Amendment) Rules 2016 entered into force in May 2016.

**National IPR Policy-** The government on 13<sup>th</sup> May 2016 announced the long-pending, "all-encompassing" National Intellectual Property Rights (IPR) Policy. The Policy, to be reviewed every five years, aims to push IPRs as a marketable financial asset, promote innovation and entrepreneurship, while protecting public interest including ensuring the availability of essential and life-saving drugs at affordable prices.

**Draft Biosimilar Guidelines-** On July 5 2016, India passed its draft of biosimilar approval guidelines and narrowed the scope to issue waivers required to run Phase III trials and rely on clinical references to biologic drugs not marketed yet in the country. The new guidelines widened pharmacokinetic and pharmacodynamics criteria and noted confirmatory safety and efficacy studies are mandatory for mAb products.

### **Developments in Australia (Carolyn Harris):**

#### Legislation

There have been no significant changes in legislation in Australia that affect pharmaceuticals.

#### Case Law

*Commonwealth of Australia v Sanofi (formerly Sanofi-Aventis)* [2015] FCAFC 172

The Full Court of the Federal Court of Australia found that the usual undertaking for damages in pharmaceutical patent infringement cases is not limited by the Therapeutic Goods Act 1989. On this basis, the Commonwealth is able to recover compensation both by way of the TG Act and also pursuant to usual undertakings as to damages which is a pre-requisite for an interlocutory injunction.

The question arose in relation to two separate patent litigation proceedings - in both cases the patentees'

infringement proceedings were unsuccessful, the relevant claims were invalid and the injunctions dissolved. The Commonwealth claimed that it had paid (under the Pharmaceutical Benefits Scheme) more than it would have had the interlocutory injunctions not been in place and the generic products allowed to enter the market.

As a consequence, if an innovator is unsuccessful in stopping a generic company, not only will it need to pay damages to the generic company, but the Commonwealth may also seek damages.

### Reviews

Most recently, in May 2016 the Australian Productivity Commission released a draft report in relation to Intellectual Property. The Commission is charged with providing quality, independent advice and information to the government on key policy or regulatory issues which influence Australia's economic performance and community wellbeing.

In relation to pharmaceuticals the report made the following recommendations:

1. The Commission recommends that extension of term provisions be better aligned to actual 'unreasonable regulatory delay'. That is, that the calculation of extended term be altered from one based on the delay between patent filing and regulatory approval, to one solely dependent on the speed of the Australian regulatory regime. It is argued that extension of term periods would be shorter, and that the consequent cost of innovative drugs to the Australian public would be lower because patent term would be shorter.  
It is also suggested that the scope of subject matter susceptible of an extended term be tightened so as to avoid the subject matter creep latterly observed toward medical devices.
2. The Commission recommends that 'manufacture for export' of drugs be an exemption from patent infringement. This recommendation is underpinned by The Commission's perception that, because the rights are held by an Australian patentee, Australian manufacturers miss out on selling drugs into off shore markets where corresponding patents do not, or no longer exist.
3. The Trans Pacific Partnership discussions were almost derailed by the Australian Government's insistence that it would not provide a term of data protection beyond the present 5 years. The Commission steadfastly supports this policy position in respect of both pharmaceuticals and biologics. The interesting twist here is that since this report was commissioned, the High Court has handed down its decision in Myriad [[http://www.hcourt.gov.au/cases/case\\_s28-2015](http://www.hcourt.gov.au/cases/case_s28-2015)] from which has arisen practice guidelines from the Patent Office which make the patentability of biologically-based drugs considerably more difficult than was previously the case. In this context, data protection becomes an even more important tool through which an innovator can obtain a return on investment.
4. Lifecycle management is a strategic consideration for all originators of medicines so as to be able to maximise financial returns on research and development investment which can run to more than a billion dollars [<http://www.scientificamerican.com/article/cost-to-develop-new-pharmaceutical-drug-now-exceeds-2-5b/>]. However, strategic options founded on intellectual property management are often characterised by the broader market as 'gouging'. The Commission has considered the practices of (patent) evergreening and 'pay-for-delay' (an ostensibly US-based practice). It has concluded that raising the bar on inventive step (again) to remove the requirement that a skilled person 'be led as a matter of course' to the invention, and to include 'social' factors such as the value of the invention to the community, might address what it perceives as an imbalance between the level of protection provided to pharmaceutical innovators and the cost of drugs to the market. The Commission had also suggested a US-style system whereby generic companies are incentivised to challenge innovator patents albeit it found no evidence that 'pay-for-delay' strategies were utilised in the Australian market.

The final report is due to be released in September 2016.

### **Developments in the United States (John Todaro)**

#### Inter-Partes Review

The use of US PTO Inter-Partes Review (IPR) procedures to challenge granted pharmaceutical patents has

continued to grow in importance. The IPR process was established in 2011, with passage of the America Invents Act. IPR's have emerged as a mechanism for generic manufacturers and other competitors to challenge pharmaceutical innovator patents on the basis of prior art. According to USPTO statistics, the rate of IPR filings has decreased from the numbers filed during 2015. There were 1,737 IPR's filed in fiscal year 2015 (October 2014 to September 2015), and 710 filed in the first two quarters of fiscal year 2016 (to the period ending March 2016).

The cost of pursuing an IPR patent challenge is significantly less expensive than challenging patent validity in federal court. Also, IPR's are usually decided within 18 months from the filing date (whereas most federal court patent litigations will not be decided until more than two years from filing). See W. Egbert and S. Kamholz, "Good, Fast and Cheap Certainty: The Case for Patent Office Litigation" *New York Law Journal* (Sept. 18, 2015).

IPR's raise the possibility that a patent that has been found valid and infringed by a court in a patent infringement case may separately be found invalid by the PTO's Patent Trial and Appeals Board. In the pharma context, a potential scenario is that a patent has been pharmaceutical Orange Book listed patent is found valid and infringed by a federal court, resulting in an injunction barring the generic from introducing its product in to the market. Thereafter, an IPR is instituted and the same patent found valid by the court is found invalid in the IPR proceeding by the PTAB.

In 2016, the United States Supreme Court issued a ruling which impacted IPR procedures. In *Cuozzo Speed Technologies LLC. v. Lee*, 136 S. Ct. 2131 (2016), the Court clarified the rules for patent claim interpretation used by the PTO in deciding IPR's. The PTO's original regulations stated that the PTAB would construe patent claims according to "its broadest reasonable construction in light of the specification of the patent in which it appears." This standard is identical to what is used by PTO Examiners on initial examination of a patent application. See USPTO Manual of Patent Examining Procedure § 2111. The claim construction standard is in contrast to the federal courts, which apply the "ordinary meaning" of the claims, taking into account the claim language, the specification, and the statements made during the prosecution of the patent. The Supreme Court upheld the PTO regulations as a reasonable exercise of the rulemaking authority that Congress delegated to the Patent Office." 136 S. Ct. at 2144. The Supreme Court ruling ensures that IPR's will continue to examine patent claims. Most commentators contend that the broadest reasonable construction standards leads to broader claims scope, thereby potentially increasing the risk that a patent will be invalidated in an IPR in comparison to in patent infringement litigation in a federal court.

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

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The Committee has no current recommendations for AIPPI involvement.

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

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The Committee is hoping to advance its post-filing data project, either as a position paper, study question for AIPPI or as the subject of a panel discussion or other investigation. The Committee will be discussing its plans with the Reporter General at the Milan conference.

In addition, the Committee continues work on other current projects (as outlined above), some of which may result in a recommendation for AIPPI involvement.

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

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The Committee intends to hold at least two teleconferences in 2017 - one in January and a second in May. Additional teleconferences will be scheduled as needed. Frequent email communication will continue.

The Committee intends to advance its post-filing data survey, as a position paper, possible study question or panel discussion for a future AIPPI conference.

The Committee also plans to start work on a review of experimental use/Bolar provisions around the world. This issue will be discussed at the Committee meeting in Milan.

As noted above, the Committee also intends to continue its work with other AIPPI committees on joint projects. The Committee will collaborate with the Unitary Patent Court Committee to produce a short paper outlining the potential problems that will be encountered when SPCs are litigated in the UPC. The Committee has also begun collaborating with the TRIPS Committee on TRIPS issues of particular concern to the pharma industry (including Article 39.3 on confidential data).

There are additional possible workstreams on secondary pharma patents, and the limitations on secondary patents presented by various countries.

The Committee will also continue to monitor IP developments around the world that are of particular importance to the pharma industry.

## Names and Functions of Committee Members

Chair	John C. TODARO	United States of America
Co Chair(s)	Amy FENG	China
Secretary	Duncan RIBBONS	United Kingdom
Members	Orly ALSTER	Israel
	Gusztáv BACHER	Hungary
	Ezgi BAKLACI	Turkey
	Martin BENSADON	Argentina
	Christina BIGGI	Italy
	Charles BOULAKIA	Canada
	Hugo CARO	Spain
	Hector CHAGOYA	Mexico
	Maria Sophia E. C. CRUZ - ABRENICA	Philippines
	Li FENG	United States
	David GILAT	Israel
	Sevgi GÖKCEK AYGÖREN	Turkey
	Rana GOSAIN	Brazil
	Carolyn HARRIS	Australia
	Simon HOLZER	Switzerland
	Martin KLOK	Netherlands
	Joanna KRAKOWIAK	Poland
	Andras KUPECZ	Netherlands
	Cyra NARGOLWALLA	France
	Makoto ONO	Japan
Beat RAUBER	Switzerland	
Christophe RONSE	Belgium	
Nicolas RUIZ	Spain	
Joseph SCHMITZ	Switzerland	
Ran VOGEL	Israel	