



Standing Committee on **Pharma and Biotechnology**

2017



Date: 15th October 2017

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, including at least:

- a) Internal meetings of the Standing Committee during the reporting period (whether by telephone, video conference or in person);

An annual Committee meeting was held at the Milan AIPPI Congress on September 18, 2016. There were over 20 members present (including members of the Biotech Subcommittee). The Committee discussed possible projects for the 2016-2017 term, including study proposals on the use of post-filing data in patent prosecution.

The Committee held two telephone conferences on February 2, 2017 (to accommodate different time zones). A total of 18 members participated. Discussion topics included the Committee's ongoing work, including the survey on post-filing data and the resulting AIPPI position paper, ideas for workshops at the 2017 Congress, proposed work with the UPC committee, and future study topics.

The Committee held two telephone conferences on June 7, 2017, in which a total of 19 members participated. Discussion topics included a report on the AIPPI position paper on use of post-filing data, which had been completed earlier in 2017. Other discussion topics included the ongoing work with the TRIPS Committee on the response to the UN Report on Access to Medicines, workshops for the 2017 Congress and plans for the committee meeting at the 2017 Congress.

A joint teleconference between 4 members of the Pharma Committee and members of the TRIPS committee was held on May 18, 2017. The collaboration project between the TRIPS and Pharma committees was discussed.

The Committee held two telephone conferences on September 5, 2017, in which a total of 20 members participated. Discussion topics included the annual committee report, and continuing work on the response to the UN Report on Access to Medicines. Other discussion topics included two new committee projects: 1) a collaboration with the Biotech Subcommittee on antibody patenting, and 2) a survey of restrictions on patenting secondary inventions in the pharmaceutical field (such as pharmaceutical formulations, salt forms, polymorphs, etc), and a possible AIPPI position paper.

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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Committee Member Martin Klok (Netherlands) was contacted as a member of the AIPPI Pharma & Biotech Committee by a representative of Alfred Radauer of Technopolis Group, an agency doing research for the Dutch government. The research topic was the effects on society of pharma legislation, in particular various forms of supplementary protection. Mr. Klok held a personal meeting in his office with Mr. Radauer.

The discussion centered on ways to provide patients with better access to innovative new drugs, at an acceptable cost for society. With this aim, various forms of supplementary protection were selected for review. Technopolis sought the opinion of experts in various fields as to the effects of supplementary protection certificates (SPC's), data-exclusivity and market exclusivity (for orphan drugs) on innovation on the one hand, and on drug prices on the other.

Mr. Klok and a colleague discussed their personal experience with these systems, and their insights into how pharmaceutical companies make use of the various forms of protection available. The overall view expressed was one of support of the present system.

- c) any contribution by your Standing Committee to any external consultations; and
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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:

AIPPI Position Paper on Post-Filing Data

The Committee drafted and approved an AIPPI Position Paper advocating that all patent offices permit the use of post-filing data to support inventive step, and drafted a Position Paper for consideration by the AIPPI Bureau. The AIPPI Bureau approved the Paper in April 2017. In the position paper, AIPPI called for jurisdictions around the world to allow consideration of post-filing data in the assessment of inventive step, in particular if the post-filing data elaborate on effects that are already apparent from the application or patent. The Paper supports this practice both during prosecution and during post-grant challenges to validity.

Committee members who contributed to the drafting of the position paper include Martin Klok of the Netherlands, Carolyn Harris of Australia, Amy Feng of China, Hector Chagoya of Mexico and John Todaro of the United States.

Collaboration with TRIPS Committee (Q94)

The Committee has an ongoing collaboration with the TRIPS Committee, with the goal of drafting an AIPPI position paper responding to the September 2016 report of the United Nations Secretary General's High-Level Panel on Access to Medicines. The draft position paper submits that the UN Report inappropriately targets intellectual property rights as a barrier to access to medicine, and ignores the many other factors that impact access to medicine. The Committees hoped to host a panel discussion on this topic at the Sydney Congress, but the proposal was rejected. Nevertheless, the Committees hope to make progress on the position paper at the Sydney Congress.

Committee members who have contributed to the drafting of the position paper include Martin Bensadon of Argentina, Carlos Fernandez-Davila of Peru, Amy Feng of China, Hector Chagoya of Mexico, Malathi Lakshikumaran of India, Beat Rabuber of Switzerland, Claire Baldock of the United Kingdom and John Todaro of the United States.

In addition to the ongoing studies, at the Milan Congress Committee secretary Duncan Ribbons moderated the panel “Antitrust and Pharma – Seeking a Balance,” as part of the pharma day sessions.

Committee members have also submitted items to the AIPPI E-News. Committee Chair John Todaro reported in AIPPI E-News No. 52 (June 1, 2017) on the AIPPI’s April 2017 approval of the Committee’s position paper supporting the use of post-filing data to support inventive step. The AIPPI Position Paper originated from the work of the AIPPI Pharma & Biotech Committee. As noted in the E-News Article, between November 2015 and February 2016 the Committee surveyed its members about the use of post-filing data in member jurisdictions. The Committee found variable practices around the world. However, the Committee concluded that most jurisdictions allowed the use of post-filing data to support inventive step, particularly when the data related to properties of the invention that are disclosed in the specification of the application or patent. As noted in the position paper, the use of post-filing data is of particular importance in biotechnology and pharmaceuticals. In these fields, early patent filing is important to secure investment for expensive development work. Pharmaceutical and biotech inventions often have long development times, from 5 to 10 years, or longer. Important data about the invention, such as in vivo data or clinical results, do not become known until after the filing of the patent application.

Committee member David Gilat, along with his colleague Eran Bareket, reported in the AIPPI E-News No. 49 November 7, 2016, about the *Unipharm Ltd. v. Sanofi et al* (Tel Aviv Dist. Ct., 2015) decision in Israel. In this case, an Israeli court allowed Unipharm, an Israeli generic company, to disgorge a portion of Sanofi’s profits from Plavix® due to a finding of unlawful conduct before the Patent Office. The judgment created a private enforcement mechanism in cases of unlawful chilling effect caused by an innovative pharmaceutical company, due to misuse of the patent system. Such disgorgement of profits was deemed a punitive measure, without regard to actual damages to the competitor.

2) Key issues/developments during the reporting period

Please include 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.

Committee members have reported on the following developments in 2016-2017 that are relevant to the Committee’s terms of reference:

Developments in the US (John Todaro):

Doctrine of Equivalents in Chemical/Pharma Cases

In *Mylan Institutional LLC v. Aurobindo Pharma Ltd.*, 857 F.3d 858 (Fed. Cir. 2017), the U.S. Court of Appeals for the Federal Circuit reversed a trial court decision which had found infringement under the doctrine of equivalents of a patent claiming a chemical/pharmaceutical process. The claim covered a process of preparing a compound, comprising the step of “combining a suspension of isoleuco acid of the formula [X] in a polar solvent with silver oxide.” The infringing party’s process did not use the claimed silver oxide, but instead used magnesium oxide. The trial court found infringement under the doctrine of equivalents using the U.S. Supreme Court’s “function-way-result,” i.e. “whether the accused product performs substantially the same function in substantially the same way to obtain the same result.”

The CAFC reversed, and remanded the case back to the district court. The CAFC reviewed the district court’s analysis, and found that the court erred in its application of FWR to the claimed process (noting that the use of magnesium oxide was “substantially different” from the use of silver oxide in the claimed process). Additionally, the CAFC suggested that in chemical cases the proper standard for determining the doctrine of equivalents is the “insubstantial differences” test rather than the FWR test.

There are few cases in which the CAFC has commented on the interpretation of the doctrine of equivalents in chemical and pharmaceutical cases, and thus the *Mylan Institutional* case may be important to those enforcing chemical and pharmaceutical patents.

On Sale Bar to Patentability

The CAFC decided a case of potential importance to pharmaceutical developers in *Helsinn Healthcare S.A. v. Teva Pharmaceuticals, USA, Inc.*, 855 F.3d 1356 (Fed Cir. 2017). In this case, Helsinn patented a formulation of the drug palonosetron, and marketed the patented formulation in the United States. Teva sought entry into the market with a generic palonosetron product, and brought suit under the U.S. Hatch Waxman system alleging that Helsinn's patents were invalid. Teva argued that the patent was invalid under 35 U.S.C. §102(a)(1) provides that subject matter is not patentable if "the claimed invention was patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date." Teva noted that before the patent had been filed, and during the clinical study period, Helsinn entered into an exclusive license and supply and purchase agreement with MGI for the patented formulations of palonosetron. Teva argued that as a result the product was "on sale" before the patent filing date. The trial court found no on sale bar, on the grounds that the invention was not ready for patenting at the time of the agreement with MGI.

On appeal, the CAFC reversed, determining that the invention was in fact ready for patenting. Notably, the CAFC also found that 35 U.S.C. §102(a)(1) barred patenting even though the sale was secret in that the details of the invention were not publicly disclosed in the sale. The court stated that "an invention is made available to the public when there is a commercial offer or contract to sell a product embodying that invention and that sale is made public." 855 F.3d at 1370.

In view of the CAFC's interpretation of the on sale bar provision, pharmaceutical manufacturers need to be careful about entering into supply agreements prior to filing patents covering the drug.

Induced Infringement of Method of Treatment Claims

The CAFC decided a case relevant to the infringement of method of treatment claims, in *Eli Lilly & Co. v. Teva Parenteral Medicines, Inc.*, 845 F.3d 1357 (Fed. Cir. 2017). The claims covered a method for administering pemetrexed to a patient, in which first folic acid and vitamin B12 are administered to the patient, followed by the pemetrexed. The case arose under the Hatch Waxman patent linkage system, in which a generic manufacturer (Teva) sought to enter the market by first certifying no infringement of the Orange Book patents owned by the innovator (Eli Lilly).

Lilly alleged divided patent infringement, since the parties agreed that no single actor performed the administration of all three agents. Lilly relied on Teva's proposed label, which instructed patients that "to lower your chances of side effects of [pemetrexed], you must also take folic acid and vitamin B12 prior to and during your treatment with [pemetrexed]." The trial court found infringement, under the induced infringement standard developed by the U.S. Supreme Court in the 2016 decision *Akamai Technologies v. Limelight Networks*, 134 S.Ct. 2111 (2014).

The CAFC affirmed, commenting that under *Akamai* "[t]he performance of method steps is attributable to a single entity in two types of circumstances: when that entity 'directs or controls' others' performance, or when the actors 'form a joint enterprise.'" 845 F.3d at 1364. The CAFC also noted that directing or controlling includes instances when the actor "(1) conditions participation in an activity or receipt of a benefit upon others' performance of one or more steps of a patented method, and (2) establishes the manner or timing of that performance." 845 F.3d at 1365. The CAFC also found that Teva's product label demonstrated its intent to infringe the claim, and determined that there was induced infringement by Teva.

The *Eli Lilly* decision is important case law for pharmaceutical companies seeking to enforce method of treatment claims in which all the steps of the claim are not performed by a single actor.

Developments in the UK (Duncan Ribbons):

Objective test for infringement of Swiss form second medical use claims

In October 2016, the Court of Appeal confirmed that the test for infringement of Swiss form second medical use claims depends upon the objective knowledge of the generic manufacturer.

The generic manufacturer will infringe the claim if it knows or is it is reasonably foreseeable that its product will be used for the treatment of the patented indication. However, the generic manufacturer will not infringe if it has taken all reasonable steps to prevent the use of its product for the patented indication.

Warner-Lambert v Mylan & Actavis [2016] EWCA Civ 1006.

Clearing the way before grant

In March 2017, the Patents Court granted a novel form of declaratory relief (known as an Arrow declaration), providing the claimant with immunity from suit upon grant of a pending patent application. The relief takes the form of a declaration that the claimant's product would have been novel and/or obvious at the priority date of the patent application in suit. The legitimacy of this form of relief was been endorsed by the Court of Appeal in an earlier judgment, and distinguished from a challenge to the validity of a pending patent application (which would be impermissible). In granting the relief, the Patents Court stressed the unusual nature of the case, suggesting that this form of relief will only be available in exceptional circumstances.

Fujifilm v Abbvie [2017] EWHC 395 (Pat)

New life for doctrine of equivalents and file wrapper estoppel

In July 2017, the Supreme Court held that a generic product comprising perimetrexed potassium would infringe a claim for perimetrexed disodium on the basis that it was an immaterial variant of the claimed compound. In doing so, the court has breathed new life into the doctrine of equivalents in UK patent law.

The Supreme Court also clarified that the prosecution history can be used as an aide to claim construction in limited circumstances, namely where (i) a point that is ambiguous based on the specification and claims, and the prosecution history clearly resolves the point or (ii) it would be contrary to the public interest to ignore the prosecution history.

Actavis v Eli Lilly [2017] UKSC 48

Developments in China (Amy Feng):

Post-filing data

In the amended Guidelines for Patent Examination entering into force as of April 1, 2017, it is provided that "as for the post-filing data, the examiners should examine the post-filing data. The technical effects to be proven by the post-filing data should be those that can be obtained by a person skilled in the art from the contents of the application." It is still unclear whether the post-filing data is acceptable to show enablement or support of an invention in practice.

In practice, we have seen that there are a number of cases in which the Patent Reexamination Board and the courts in China still reject the post-filing data demonstrating the inventiveness of inventions in the pharmaceutical area.

Patent Linkage System and Regulatory Data Protection

The CFDA issued Circular 55 on May 12, 2017 with the intention of encouraging drug and medical device innovations and protecting the interests of innovators. The main proposals of Circular 55 include: 1) establishing a patent linkage system; and 2) providing applicants with regulatory data protection (RDP). The CFDA is drafting the patent linkage system and we expect that it may be finalized in the near future.

Developments in Turkey (Ezgi Beklaci Gulkokar):

Turkey has entered into a new era for intellectual and industrial property rights, with enactment of the new Industrial Property Law (“**IP Law**”). As a result, the country’s long discussed patent law practices are on the verge of substantial changes. The finalized **IP Law** was published in the Official Gazette on 10 January 2017, with the majority of provisions entering into effect on the same date.

Even though the new provisions of the IP Law are quite promising and introduces important changes in general with respect to prosecution, the IP Law unfortunately remains still on biotechnological inventions and other debatable subjects such as second medical use patents.

With respect to biotechnological inventions, The IP Law expands the scope of non-patentable inventions with Article 82 of the IP Law. Accordingly, biological processes regarding plant or animal varieties or production thereof are considered non-patentable, since these are being protected under Law On Plant Breeder’s Rights Regarding New Plant Varieties numbered 5042. An exception applies to microbiological process, or products obtained by means of such process.

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.

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 be deemed as a patentable invention.

However, the IP Law notably still lacks an explicit definition of “biotechnological inventions”, as outlined by Article 52 of the EPC and Rules 27 and 29 of the Implementation Regulations.

When the preamble of Article 82 is examined in order to clarify the IP Law’s approach, it may be concluded that biotechnological inventions indeed can be patented. According to the preamble, the phrase “simple discovery” refers to isolating or producing the parts of human body with simple or known techniques without explaining the criteria of being applicable to the industry. Since such “simple discoveries” of parts of the human body, without adding significant technical information, can only be deemed as revealing what is already existent in nature, such inventions cannot be patented. However, the preamble also underlines that an element isolated from the human body or otherwise produced by means of a technical process (such as production through identifying, purifying or classifying or production outside of human body), including the sequence or partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element. The production techniques are defined as techniques which human beings alone are capable of putting into practice and which nature is incapable of accomplishing itself. For such inventions, it has been noted that the explaining the function, i.e. the applicability of the invention to the industry, is very important. In this case, the scope of protection of these patents will be determined considering its applicability to the industry, and patent rights will not be granted to the human body parts in its natural environment.

Another significant headline for pharmaceutical sector is second or further medical use patents. It is safe to say that Turkey has maintained its neutral position to the second (or further) medical use patents. Indeed, the IP Law’s patentability criteria does not include provisions which correspond to Articles 5 and 54/4 of the European Patent Convention as revised in 2000. Therefore, Turkish legislation continues to not explicitly permit or prohibit second (or further) medical use. Actually, the main actors in the pharmaceutical field expected a more clear approach, since the courts practice are not quite settled. In practice, the Turkish Patent and Trademark Office (“TPTO”) accepts any type of claims especially via validation through the EP route without conducting any further examination.

Other significant headline changes under the IP Law include the new post-grant opposition system, the ownership of inventions by scientific staff in higher educational institutions, the expansion of compulsory license criteria, omission of protection for patents granted without substantive examination, and the ability to revive abandoned patents due to non-payment of maintenance fees.

The new IP law consolidates many articles of the Decree Law regime and accordingly many articles have been changed. Since the new legislation has now been enacted, it will soon be evident how the TPTO and first instance courts will apply the new provisions, as well as their approach to unregulated issues, such as second medical uses and biotechnological inventions.

Developments in Brazil (Rana Gosain):

On April 12, 2017, Brazilian PTO and ANVISA (Brazilian Health Surveillance Agency) signed the Joint Ordinance # 1/2017, which regulates the procedures for the application of Article 229-C of Brazilian IP Law # 9,279/1996 inserted by Law # 10,196/2001. This Joint Ordinance will come into force on June 12, 2017.

The Ordinance establishes the procedures to be adopted by the Brazilian PTO and ANVISA concerning the analysis of pharmaceutical patent applications, and clarifies some issues extensively discussed in the past related to the allowance/denial of prior approval from ANVISA. According to this Joint Ordinance, ANVISA's attribution is to analyze whether a subject matter of a patent application represents a risk to health, whereas the Brazilian PTO's attribution is to analyze patentability requirements of the subject matter.

The steps related to the flow of examination of pharma patent applications are detailed in said Joint Ordinance and the main points are summarized below:

- I. After the examination is requested, the Brazilian PTO will publish a notification in the Brazilian PTO's Journal indicating that the patent application is being forwarded to ANVISA;
- II. ANVISA will analyze such application based on public health issues and will consider it contrary to the public health if the pharmaceutical product or process contained therein represents a risk to health. Risk to health is understood as pharma product comprising, or pharma process resulting in a substance whose use is prohibited in Brazil, such as narcotic substances (ANVISA's Decree 344/1998). Therefore, if ANVISA denies the prior approval for this patent application, the case will be sent back to the Brazilian PTO that will be responsible for the publications of ANVISA's decision denying prior approval and final dismissal thereof;
- III. For the patent applications containing pharmaceutical product or process considered of interest to policies of medicines and pharmaceutical assistance concerning the Brazilian Public HealthCare System ("SUS"), besides indicating the prior approval, ANVISA may issue technical opinions based on patentability requirements. Nevertheless, such opinions will be considered by the Brazilian PTO as observations for aiding the examination, based on Article 31 of the Brazilian IP Law. The opinions formulated by ANVISA will be published in the Brazilian PTO's Journal, that is, they will be made available to the public;
- IV. Following Item III above, upon analyzing the opinions issued by ANVISA, if the Brazilian PTO disagrees with them, they must technically justify the reasons of such disagreement; and
- V. For the patent applications that received the prior approval from ANVISA, once the Brazilian PTO concludes the examination of the patent application and decides that the subject matter contained therein meets all the patentability requirements, the Brazilian PTO will officially send a list of the allowed patent applications to ANVISA along with the final claim set thereof.

The provisions of this Ordinance are also applied to patent applications that are currently pending at the Brazilian PTO or ANVISA and those whose ANVISA's administrative phase has been closed.

Developments in India (Malathi LakshmiKumaran)

Patents & Exports - Recent cases in the Delhi High Court

Bayer Intellectual Property GmbH v. Ajanta Pharma Ltd. & Ors., CS(COMM) 1648/2016

In an interim decision dated January, 4, 2017, a single Judge of the Delhi High Court in *Bayer v. Ajanta* allowed the defendants to make and export a drug protected by patent, viz. Vardenafil. This decision modified an earlier ex-parte interim injunction granted in favour of Bayer, the Plaintiff.

Several grounds were raised for vacating the earlier ex-parte interim injunction, granted against Ajanta, the Defendant, but the Court only considered two points – one relating to the non-working of the patent and the other relating to export by the Defendant. There was no dispute on the fact that Bayer had not worked the invention since its grant in 2002, whereas Ajanta had been making and exporting the product since 2009-2010. In these circumstances, the Court felt that equity did not permit an absolute interim injunction against Ajanta since that would result in loss of employment as well as revenue to the State. However, the Court also clarified that non-working of the patent will not be a defence to infringement.

The Court continued the interim injunction on the offering for sale, selling or distributing for use or consumption in India, the infringing products, but allowed the manufacture, distribution, offer for sale for export.

Bayer Corporation v. Union of India, W.P.(C) 1971/2014 decided with *Bayer Intellectual Property GmbH v. Alembic Pharmaceuticals Ltd.*, CS(COMM) No.1592/2016

The former case is a writ petition filed by Bayer seeking a mandamus to the Customs Authorities to seize the consignments for export containing products covered by the Patent No. 215758 directed to the anti-cancer drug Sorafenib tosylate (Bayer's Trade name-Nexavar), manufactured by Natco by virtue of the compulsory license to said patent issued by the Controller General of Patents in 2012. Natco in said writ petition asserted that its exports of the active pharmaceutical ingredient (API) of Nexavar to China falls within the scope of Section 107A of the Patents Act, 1970 (Act) as its exports are for the purpose of conducting development/clinical studies and trials. Section 107A is the Indian version of the "*Bolar Exemption*". The latter case is a commercial suit instituted by Bayer seeking a permanent injunction against Alembic from infringing its Patent No. 211300 directed to the blood thinning drug Rivaroxaban. Alembic in said suit asserted that it had not commercially launched the drug Rivaroxaban and had only exported the drug for the purposes under Section 107A of the Act. Alembic also undertook that it will provide Bayer a months' notice before commercially launching the drug to enable Bayer to avail of its remedies. Accordingly, the common question of law before the Single Judge adjudicating both matters was whether Section 107A(a) of the Act includes the act of "export" of the patented invention, strictly for the purposes mentioned therein.

By Judgment & order dated March 08, 2017, a Single Judge of the Delhi High Court interpreted the exemption to infringement under Section 107A of the Act to hold that said exemption permits exports from India of a patented invention solely for uses reasonably related to the development and submission of information required under any law for the time being in force, in India or in a country other than India, that regulates the manufacture, construction, use, sale or import of any product. The Single Judge held that the word "selling" under Section 107A of the Act includes within its ambit the meaning of the term "export" and thus held that the absence of the word "export" under Section 107A of the Act does not lead to any inference that said provision does not include "export" within its scope.

The Court noted that the Indian provision expressly dealt with the development of information for the purposes of regulatory approvals outside India as well. This is different from similar provisions in other jurisdictions. Thus, in the Court's view, it was the legislative intent to allow even exports out of India, even if it was for profit. The Court further held that a compulsory licensee who has only been granted the right to make and sell in India, could not be deprived of its independent right under Section 107A of the Patents Act.

The Single Judge thus disposed of the instant writ petition and commercial suit by directing that Natco and Alembic are entitled to export the patented invention for the purposes of Section 107A of the Act subject to both Natco and Alembic filing an affidavit by way of undertaking of their respective Director

duly supported by the Resolution of the respective Board of Directors, with advance copy to the counsels for Bayer, to the effect that they, during the term of the respective patents, will not export the respective patented invention for purposes other than those specified in Section 107A of the Act. The Single Judge also directed that Bayer has the liberty to take appropriate proceedings if it makes out a case that the exports effected or to be effected by Natco and/or Alembic were or are for purposes other than those specified in Section 107A of the Act.

Amendment to FORM - 44

Under the Drugs & Cosmetics Rules, 1945, Form 44 is the prescribed form for seeking permission to import or manufacture a new drug or undertake clinical trial. The Ministry of Health and Family Welfare, vide Notification G.S.R. 329(E) dated 3rd April, 2017, amended Form 44 in the Drugs & Cosmetics Rules, 1945. Vide the said notification, item (8), under paragraph 1 relating to the "Particular of new drug" has been omitted. The omitted item (8) pertained to "Patent status of the drug" in respect of which the application under Form 44 was to be made.

In 2008, Bayer Corporation filed a writ petition in the High Court of Delhi, for restraining the DCGI (Drug Controller General of India) from granting a licence to Cipla to manufacture, market its drug *Soranib*, which they claimed to be an imitation/ substitute of their patented drug "*sorafenib tosylate*" on the ground that since the DCGI was aware of Bayer's patent, the DCGI was under an obligation to decline Cipla's application for marketing approval for *Soranib*. The entry in Form - 44 requiring the applicant to indicate the 'patent status' of the drug formed a central part of the contentions raised by Bayer. Ultimately, however, both the single judge of the High Court of Delhi and the Appeal Court did not agree with Bayer that this entry would suffice to imply a patent linkage in India.

With the present amendment, this controversy has been laid to rest.

Developments in Japan (Makoto Ono):

The IP High Court's Grand Panel Decision regarding the Scope of Patent Rights during Patent Term Extension (IP High Court Decision on January 20, 2017, H28 (ne) No.10046).

With regard to the scope of patent rights during extension, Article 68-2 of the Patent Act states:

"Where the duration of a patent right is extended ... such patent right shall not be effective against any act other than the working of the patented invention for the product which was the subject of the disposition designated by Cabinet Order under Article 67(2) which constituted the reason for the registration of extension (where the specific usage of the product is prescribed by the disposition, the product used for that usage)".

However, it is unclear how to define "the product which was the subject of the disposition". The IP High Court Decision (May 30, 2014, H25 (gyo-ke) No. 10195), which considered the requirement for admission of a patent term extension before the Japan Patent Office, was the first to consider the scope of patent rights during extension. It noted they must be regarded as "equivalent to" or "substantially the same as" the product which was the subject of the disposition. Albeit, this notation was made in obiter and the actual method to determine such scope was not determined by the High Court. The subsequent Supreme Court Decision (November 17, 2015, H26 (gyo-hi) No. 356) was completely silent on this point.

The IP High Court Grand Panel (GP) ruled that "the products which were the subject of the disposition", as stated in Article 68-2 of the Patent Act, are to be defined by their "ingredients" (including non-active agents), "quantity" (as examined in the drug approval), and the "specific usage of the product" (as defined by "dosage", "administration", "indication" and "effect").

The GP also presented a rule to determine the scope substantially the same as "the products which were the subject of the disposition". However, the rule only applies where the target product and "the

products which were the subject of the disposition" have differences in their "ingredient", in numerical values of "quantity", "dosage" or "application", and where the patented invention is categorized as an article directed to a pharmaceutical ingredient. Given such conditions, the GP ruled that the scope of substantially the same is to be determined by considering whether such differences are merely formal or insignificant by:

- comparing the alleged infringing product and the "product" defined by the "ingredient, quantity, dosage, administration, indication and effect" in their technical features and the identicalness of their workings and effects;
- in relation to the nature of the patented invention; and
- in view of the common general knowledge of those skilled in the art.

The GP exemplified four cases where an alleged infringing product should be considered as substantially the same as "the products which were the subject of the disposition" despite some differences as follows:

1. where the patented invention under PTE is only characterized by the active agent of the pharmaceutical drug; where the target product has some addition or conversion in part of the "ingredient" other than the active agent to "the product" (which was a well-known and conventional technique when the target product applied for drug approval).
2. where the patented invention is directed to the stability, formulation and such of a pharmaceutical drug with a known active agent; where some part of the target product is added to, or converted with, different ingredients based on well-known and conventional techniques when the target product applied for drug approval; where the both products have identical technical features, workings and effects.
3. where there is a numerically insignificant difference between "quantity", "dosage" or "administration" as defined by the disposition.
4. where there is difference between "quantity", but they can be considered identical in view of "dosage" and "administration".

Additionally, the Court ruled that the file wrapper estoppel should be applied to the extended patent right.

Developments in Argentina (Martin Bensadon, Ivan Poli)

On September 12, 2016 the Argentine PTO issued Regulation No. P-56/2016 which introduced a PPH procedure that significantly improved the existing system.

Under this regulation, which became effective on October 15, 2016, the Argentine PTO is authorized to consider that the substantive patentability requirements (novelty, non-obviousness and industrial applicability) have been met and the international search has been carried out in those cases where a patent has been granted abroad on the corresponding application (regardless of whether its priority has been claimed or not) by a foreign Patent Office carrying out a substantive examination in a country whose Patent Law has the same requirements as the Argentine law.

In such cases the patent is to be granted provided that:

1. the scope of the claims of the Argentine application is the same as or narrower than that of the foreign patent;
2. there are no domestic anticipations;
3. there are no foreign anticipations that became public after the foreign application's filing date and before the filing date of the Argentine application or its priority date;
4. the subject matter is not barred from patentability by the Argentine Patent Law;
5. third-party objections, if any, have been studied; and
6. the foreign patent office that studied the foreign patent applies the same patentability standards as the Argentine PTO

This regulation differs from earlier provisions having the same purpose in two critical points. First, it

expressly allows petitioners to request that it be applied to their pending cases. Under the earlier regulations, the Argentine PTO had to “invite” the applicant to adjust the application to the parallel foreign patent (although de facto it was allowed for the applicant to make this request sua sponte). Second, and more importantly, under this regulation the Argentine PTO must issue a decision (grant, refusal of the PPH request or new objections) within 60 working days from the date on which petitioners have submitted the request; prior to Regulation No. P-56/2016 the PTO had no such deadline.

As regards the voluntary procedure, when the parallel patent may be accessed online and is in Spanish or English it will suffice to identify said patent and adjust the Argentine claims to the “foreign” claims and to the local formal requirements (characterizing clause; single object; one main claim [first], and all remaining claims directly or indirectly subordinated thereto; non-functional language; etc.). If the foreign patent is not in Spanish or English, applicant must provide a Spanish translation of the claims, and if it is not accessible online it is necessary to submit a certified copy of the patent.

The Argentine PTO may waive applying this regulation for technical and legal reasons, or for reasons of national defense, internal security, sanitary emergency or other reasons of ordre public.

Almost a year having elapsed since it was introduced, it can be safely said now that Regulation No. P-56/2016 has been quite successful: over 500 requests for expedited grant have been favorably decided on some 800-odd applications since it became effective, almost all within the 60-day term for the Argentine PTO to render a decision. The process is indeed fast, and in some cases the decision to grant has taken as little as five days from the PPH request.

The regulation has been more effective with regard to mechanical, electronic and chemical (non-pharmaceutical) applications, but patents have also been granted in connection with pharmaceutical and biotechnological applications, provided the stringent current patentability requirements were met.

While the Argentine PTO has not provided a list of “acceptable” patents (i.e., countries whose patents qualify under Regulation No. P-56/2016), experience has shown that applications based on European, U.S., Canadian, Australian, Japanese and Chinese patents are more successful, while those based on Spanish, Italian, French, Belgian, Irish and Swiss applications are less so (but have still been accepted).

In 2016 and 2017 the Argentine PTO has signed PPH agreements and MOUs with the Prosur (May 6, 2016), JPO (October 5 and 7, 2016), SIPO (October 17, 2016), USPTO (January 20, 2017) and the Danish PTO (March 6, 2017). The PROSUR is a loose association of the PTOs of Argentina, Brazil, Chile, Colombia, Ecuador, Peru, Paraguay and Uruguay which provides a PPH pilot program based on the applications processed in those countries. So far there has not been enough experience with these other PPH systems to assess their usefulness, and for the time being it appears advisable to stick with the system of Regulation No. P-56/2016.

Developments in Canada (Charles Boulakia, Andrew Montague and Kenneth Ma)

Supreme Court of Canada Rejects the “Promise Doctrine”

In a unanimous and relatively short decision, the Supreme Court of Canada firmly rejected the “Promise Doctrine”, which has been frequently invoked to invalidate patents on the basis of a lack of utility.

This decision in *AstraZeneca Canada Inc. v. Apotex Inc.*, 2017 SCC 36[<https://scc-csc.lexum.com/scc-csc/scc-csc/en/item/16713/index.do>] reverses over a decade of previous case law, which saw numerous patents declared invalid in Canada. Under the (now rejected) “promise doctrine”, the utility of an invention could be measured against statements in the patent disclosure regarding the uses of the invention, with the patent being invalid if even one of those promises was not established or soundly predictable from the information in the description. The doctrine had particular impact on pharmaceutical patents, which tend to identify medical uses for the invention without providing clinical data in the description.

The Court concluded that the “Promise Doctrine” conflated the requirements for sufficiency and utility,

which should be separate inquiries. The Court also held that a single use of the invention is sufficient to establish utility, even if this use has a “mere scintilla” of utility, so long as that use is related to the subject matter of the invention.

The *Astrazeneca* decision sets out a two-part test for utility in Canada, which requires the Courts to: (1) identify the subject matter of the claims and (2) determine whether at least one practical use related to that subject matter has been demonstrated or soundly predicted as of the filing date (even if that amounts to only ‘a mere scintilla’ of utility). The Court also re-affirmed the principle that there is no obligation to disclose the utility of the invention within the description.

The case at hand involved AstraZeneca’s patent no. 2,139,653, which was directed to optically pure salts of esomeprazole, a proton pump inhibitor (PPI). This drug was said to be useful for reducing gastric acid and reflux esophagitis, and for treating related maladies. The trial and appeal Courts had previously concluded that the patent explicitly promised that this drug would work more effectively for a wider range of persons than previous drugs, with less variation in patient responses, and that this promise was unfulfilled. The Supreme Court rejected this analysis and found that the drug would work as a PPI, which was sufficiently related to the subject-matter of the patent so as to make it useful within the meaning of the Patent Act. As a result, the patent was found to be valid.

The decision is welcome news to patentees in Canada, as it brings more certainty to the law and aligns Canada with the standard for utility of most other countries.

3) Any recommendations 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. For example, please include:

In each case, please explain why such involvement/action is recommended, by whom it should be undertaken and any relevant time frames.

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

The Committee has no other recommendations for AIPPI involvement other than the projects it is currently engaged on.

- b) any other recommendations for AIPPI involvement/action;

No other recommendations.

- c) any recommendations for the work programme of your Study Committee.

The Committee will continue its work with the TRIPS Committee on an AIPPI position paper, responding to the September 2016 report of the United Nations Secretary General’s High-Level Panel on Access to Medicines. The draft position paper submits that the UN Report inappropriately targets intellectual property rights as a barrier to access to medicine, and ignores the many other factors that impact access to medicine.

The Committee plans to begin work on two new projects. The first project will be a collaboration with the Biotech Subcommittee on antibody patenting. The Committee will consider such issues as the claiming of antibodies (whether claims need to recite structure and/or function), and the descriptive information required to support claims to antibodies. The Committee will survey its members on the law in its jurisdiction, and consider whether it can recommend a position paper or resolution for consideration by the AIPPI Bureau.

The second project will be a survey of restrictions on patenting secondary inventions in the pharmaceutical field (such as pharmaceutical formulations, salt forms, polymorphs, etc), and possible

AIPPI position paper. The Committee will consider the restrictions presented in various countries, including section 3(d) in India, and the Argentine PTO Patenting Guidelines. The Committee will consider recommending a position paper or resolution for the AIPPI Bureau.

The Committee hopes to 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. This project will depend on the initiation of the UPC.

The Committee is monitoring EU proposals for studies on the impact of SPC's.

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.

The Committee intends to hold at least two teleconferences in 2018 - one in January and a second in May. Additional teleconferences will be scheduled as needed. Frequent email communication will continue.

The Committee will continue its work with the TRIPS Committee on an AIPPI position paper, responding to the September 2016 report of the United Nations Secretary General's High-Level Panel on Access to Medicines.

The Committee plans to begin work on two new projects. The first project will be a collaboration with the Biotech Subcommittee on antibody patenting. The second project will be a survey of restrictions on patenting secondary inventions in the pharmaceutical field (such as pharmaceutical formulations, salt forms, polymorphs, etc), and possible AIPPI position paper.

The Committee hopes to initiate work with the Unitary Patent Court Committee on a short paper regarding the litigation of SPCs at the UPC.

In addition, the Committee will continue to monitor IP developments around the world that are of particular importance to the pharma industry.

Names and Functions of Committee Members

Chair(s)	John C. TODARO	United States
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
	Magnus DAHLMAN	Sweden
	Li FENG	United States
	Carlos FERNANDEZ DAVILA	Peru
	David GILAT	Israel
	Sevgi GÖKCEK AYGÖREN	Turkey
	Rana GOSAIN	Brazil
	Carolyn HARRIS	Australia
	Simon HOLZER	Switzerland
	Martin KLOK	Netherlands
	Joanna KRAKOWIAK	Poland
	Renat A. KRASNOPEROV	Russia
	Andras KUPECZ	Netherlands
	Johanna LILJA	Finland
	Ilan MILLER	Israel
	Anja LUNZE	Germany
	Cyra NARGOLWALLA	France
	Carlos OLARTE	Colombia
	Makoto ONO	Japan
	Gaye RAMAZANOGLU PARTLAK	Turkey
	Beat RAUBER	Switzerland
	Christophe RONSE	Belgium
Nicolas RUIZ	Spain	
Joseph SCHMITZ	Switzerland	
Joseph R. SNYDER	Unites States	
Ran VOGEL	Israel	