Date: 21st September 2018

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 Sydney AIPPI Congress on October 14, 2017. There were 21 Committee members present (including members of the Biotech Subcommittee), and six guests. The Committee leadership reported on the Committee's accomplishments, and discussed possible Committee projects for the 2017-18 term. The projects discussed were the Committee's Position Paper on Post-Filing Data, which had been recently approved by the AIPPI Bureau. The Committee also discussed the draft AIPPI position paper in response to the UN High Level Panel Report on Access to Medicines. The Committee also started planning on an AIPPI Position Paper for Pharmaceutical Inventions.

The entire Committee met by teleconference on January 25, 2018 and May 14, 2018. During the January teleconference the Committee discussed ongoing projects, including the Biotech Subcommittee's antibody claiming survey, our proposed position paper on pharmaceutical inventions, and the position paper in response to the UN High Level Panel Report on Access to Medicines). At the May teleconference the Committee leadership reported on the status of each of these projects, and also discussed the Post-Filing Data Resolution, to be presented at the Cancun Congress.

In addition to these meetings, there were several teleconferences and extensive email correspondence among those members working on the active projects of the Committee.

b)

were proposals for panel sessions and study questions submitted and/or did your Standing Committee further contribute in this respect (e.g. by providing input to the draft Study Guidelines)?

The Committee made several suggestions for study questions and panel sessions for the Cancun Congress. In particular, in combination with the TRIPS Committee, the Committee suggested a panel discussion regarding the September 2016 Report on Access to Medicines by a High-Level Panel appointed by the United Nations Secretary General. The Committee had worked on an AIPPI position paper in response to this report. Our proposal was adopted by the Bureau, and will be the subject of a panel discussion at the Cancun Congress.

The Committee also suggested a panel session on "patent linkage," the practice of linking of drug marketing approval by a regulatory agency to patent status. The Committtee envisioned a comparison of patent linkage systems for pharmaceuticals (currently, patent linkage is present in various countries, including the US, Canada, Mexico and Korea) . The Committee also suggested a panel discussion on restrictions on patenting “secondary” inventions in the pharmaceutical field. Neither of these topics was selected.

c)
any external representation and participation in working groups on behalf of AIPPI by any member of your Standing Committee (e.g. at WIPO, EUIPO);

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

d)
any contribution by your Standing Committee to any external consultations; and

The Committee contributed to AIPPI's comments to the Draft Report of the Supreme People's Court of China, on "Provisions on Several Issues Concerning the Trial of Administrative Cass Involving the Granting and Affirmation of Patent Right." The Report was submitted 17 August 2018. The Committee contributed comments related to Article 13, on the use of experimentlal data submitted after the patent filing date.

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

The Committee completed a position paper in response to the Panel Discussion regarding the September 2016 Report on Access to Medicines by a High-Level Panel appointed by the United Nations Secretary General. The position paper was accepted by the AIPPI Bureau during the 2017-2018 term.

The Committee also completed a position paper on Pharmaceutical Inventions. The

Pharmaceutical Inventions position paper was approved by the AIPPI Bureau, and was published on the AIPPI website on 11 September 2018.

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.

Argentina

Martin Bensadon, Marval, O'Farrell & Mairal

New Rules for Patents in Argentina

Within the general framework of a wide-ranging attempt to curb bureaucracy and simplify administrative proceedings, in June 2018 the Argentine Congress amended several provisions of the Argentine Patent Law. The new provisions are mainly aimed at simplifying procedural issues.

The main changes affect several terms for submitting various documents, which are reduced considerably. Most importantly, the term for requesting substantive examination was shortened from 36 to 18 months from the filing date. The amendments also attempt to simplify the general procedure. The priority document and its translation, for instance, will now have to be submitted only if the Examiner asks for it in the course of substantive examination. Under the previous law, the priority document had to be filed within 90 days. Similarly, it will only be necessary to submit a Power of Attorney if the PTO requests it.

PPH in Argentina

There is a PPH procedure in force in Argentina which significantly improved the existing system and is applicable to pharma and biotech applications. Under this procedure, the Argentine PTO may deem that substantive patentability requirements have been met provided that (i) a patent has been granted abroad on an equivalent case by a foreign Patent Office, (ii) said foreign Patent office carries out a substantive examination, and (iii) the law in that jurisdiction has the same requirements as the Argentine law.

Applicants may request the application of the PPH procedure on their own initiative. Provided that all requirements are met, patents are being granted within 3 months of the initial request.

Australia

Andrew Blattman, Spruson & Ferguson

Full Federal Court Decisions

Idenix Pharmaceuticals LLC v Gilead Sciences Pty Ltd [2017] FCAFC 196 (7 December 2017)

This decision from the Full Federal Court of Australia addresses issues of lack of utility and sufficiency. The patent in question held by Idenix, is related to pharmaceutical compounds and methods for the treatment of viral diseases. Gilead Sciences contended that the patent was invalid on the grounds of lack of sufficiency and utility. Arguments were made by Idenix asserting that the methods of synthesizing the compounds as forming part of the common general knowledge were sufficient. However, regarding the common general knowledge, the Court found that it is not enough that information can be "found in a journal or other publication, even if that publication is widely read". Additionally, the Court held that a requirement to establish a lack of utility by experimentation would raise the "evidentiary bar too high for parties attempting to revoke an inutile patent". The Court affirmed the first instance decision, that Idenix's patent was invalid on the grounds that the specification did not provide sufficient details to perform the invention and lacked utility on the basis that the claims encompassed compounds that the evidence indicated could not be made. Thus, the appeal was dismissed.

Federal Court

Infringement

Bayer Pharma Aktiengesellschaft v Generic Health Pty Ltd [2017] FCA 250 (16 March 2017)

This sets the benchmark for Australian damages awarded in an infringement case related to biopharmaceuticals. Bayer holds the patent to the oral contraceptive known as "Yasmin", in 2012 Genetic Health entered the market with a competing oral contraceptive known as "Isabella". Bayer sought to amend some of the original claims of their patent after Isabella entered the market, with the amendments focusing on the features of "Isabella" including the dosage form and testing for solubility, these amendments were subsequently allowed. It was found that the patent had been infringed as a result of sale of Generic Health's product Isabelle. The Court awarded damages of over $25m to Bayer, plus interest assessed on Bayer's pre-tax losses.

APO decisions

Rozenberg & Co Pty Ltd. v Velin-Pharma A/S [2017] APO 61 (5 December 2017)

This decision gives guidance to interpretation of the grace period provisions which were held to encompass "whole of contents" novelty documents with a publication date after the filing of the subject applciation. Section 24 of the Patents Act provides in certain "prescribed circumstances" (set out in the Patent Regulations) a period of 12 months within which to file a complete application where there has been an unauthorized or self-disclosure. The decision set forth that the 12-month grace period did apply to circumstances where the "whole of

contents" citation had a publication date occurring *after* the filing of the complete application. That is, the Regulations were held to establish an end date by which an application must be filed (i.e. 12 months from disclosure/publication) but not a start date.

Kineta, Inc. [2017] APO 45 (31 August 2017)

The patent application filed by Kineta Inc. was directed to compounds and methods for treating viral infections in vertebrates. The Deputy Commissioner of Patents found that the specification, in the context of the common general knowledge, provided no guidance to the method used to prepare the compounds. The compounds were obtained from a third-party but the information for their preparation was not included. Given the lack of disclosure of the method to obtain the compound, the objection raised in the Examination was maintained. The addition of information regarding the best method of synthesizing the compounds into the application would be construed as added matter and therefore not allowable. This case highlights the importance of including the "best method" in the specification when filing an application in Australia.

Brazil

Rana Gosain, Daniel IP

The Brazilian PTO published Rule # 217/2018 on 9th May 2018, which modifies former Rule # 80/2013 related to fast-track examination of patent applications related to pharmaceutical products and processes, as well as equipment and material related to public health. The novelty brought by the new Rule is that in addition to AIDS, cancer and neglected diseases, patent applications covering rare diseases, Chikungunya and Zika (the last two included in the list of neglected diseases) are also eligible for fast-track examination. According to the World Health Organization (WHO) and Brazilian guidelines for treatments under the National Healthcare System (SUS), a disease is characterized as rare when affecting up to 65 people per 100,000 subjects or 1.3 people per 2,000 subjects.

As a result, new Rule # 217/2018 broadens the possibilities to request fast-track examination of patent applications in the pharma and biotech field.

Canada

Andrew Montague and Charles Boulakia, Ridout & Maybee LLP

Changes to the Patent Medicines (Notice of Compliance) Regulations

There were dramatic changes made to Canada's linkage regulations. Of these, the most

substantial is the elimination of parallel litigation. Under the previous regime, a patentee who was unsuccessful in its attempt to obtain a court order blocking market authorization of a follow-on drug could still sue the manufacturer for infringement once the drug reached the market. This limited the rights of appeal for unsuccessful patentees (since they could simply sue again) and created legal uncertainty for follow-on manufacturers. This lead to patents found invalid and/or not infringed under the *Regulations* subsequently being declared valid and/or infringed in a later infringement lawsuit.

The revised *Regulations* provide for a final resolution of all patent issues at the market authorization stage. In order to accomplish this, the court process has been expanded from an abbreviated 'application' format to a more traditional 'action'. Parties continue to be subject to a compressed 24-month timetable and so the initial notification stage has been expanded to include an accelerated discovery process. Patentees must also make important strategic decisions early in the process, as the failure to take action may result in a waiver of the right to sue the follow-on manufacturer under the patent at a later date.

Certificates of Supplementary Protection

Patent term extension has been introduced for pharmaceutical patents. Canada's Certificates of Supplementary Protection system is largely based on the European model, with notable differences. Chief among these is a two year limit on all patent term extensions.

It is only possible to apply for a CSP if: (a) the drug in question has not previously received a market authorization in Canada; (b) the patent in question is still in force and includes at least one compound, product-by-process, or use claim directed to the active ingredient in that drug; and (c) no other CSPs have been granted for the drug. Notably, process claims are not sufficient to render a patent eligible for a CSP. Due to the way in which the term extension is calculated, the patent's filing date should also be at least 5-7 years before market authorization was granted in Canada.

Strict deadlines apply. An application for a CSP must be filed before the earlier of: (i) 120 days from market authorization in Canada; or (ii) 12 months of the earliest marketing approval in the USA, EU, Australia, Switzerland, or Japan. Conflicting CSP applications are also resolved on a first-to-file basis, which may require drug companies to coordinate with their commercialization partners.

Once issued, the CSP takes effect on the expiry of the underlying patent and provides many of the same rights as a patent, for up to two years. There are, however, some notable limitations, including that: (a) the CSP can only be enforced against a product that contains the active ingredient for which the CSP was granted; and (b) the CSP cannot be used to block export of a drug from Canada.

Diagnostic Methods

On April 6, 2018, CIPO announced a joint working group with the patent bar to review CIPO's existing practice notice on diagnostic methods. That practice notice has been particularly problematic for applicants and it is hoped that this may lead to positive changes.

Pharmaceutical Solid Forms

In July of 2018, CIPO also announced new examination guidelines for pharmaceutical solid forms, which are currently under consultation.

France

Mathilde Rauline, August Debouzy

Pharmaceutical patent and SPC (supplementary protection certificate) French developments in 2018.

On SPCs, the French PTO has confirmed how to apply for the extension of SPC duration in application with the Seattle Genetics CJEU decision (C-492/16). Since Seattle Genetics, the PTO takes into account the date of notification of grant of the MA (marketing authorization) and not the MA grant date as in its former practice. The PTO confirmed it would do so also for SPCs granted before October 6, 2015. SPC holders can require extension of their protection duration if (1) the SPC is still in force, and (2) the MA used as a basis for the SPC is a community MA, via a simple request to the French PTO. As a result of this change of calculation, an extension of up to several days of the duration of protection conferred by the SPC might occur.

French Courts have also applied the CJEU case-law on SPCs.

- On articles 3c) and 3d) of Regulation (EC) No 469/2009 in decisions relating to the combination of ezetimibe and simvatsatin (first instance [ref 1] and appeal [ref 2] decisions, in PI proceedings – action on the merits pending). On article 3d), the Court of appeal ruled that as ezetimibe had been granted a marketing authorization in which the combination with a statin (simvastatin being a statin) was mentioned, the combination product of ezetimibe with simvastatin has already been the subject of a first marketing authorization. The MA on the fixed dose combination was therefore not the first MA on the combination.
- On article 3a) of Regulation (EC) No 469/2009 in decisions relating to the combination of tenofovir and emtricitabine (first instance action on the merits [ref 3] - decision not final). The

Court judged that the combination of tenofovir with "*any other therapeutic ingredient*" does not fulfill Art 3a) of the regulation. In particular, in the case of a combination of active ingredients, each active ingredient must be mentioned in the claims or, failing that, must be necessarily and specifically identifiable individually.

Patents

On **patents**, 2018 has seen the first PI [ref 4] granted against a generic company since a few years. The generic company had launched its product (a fixed-dose combination of valsartan and amlodipine) while the action on the merits was on-going. The generic company was injuncted and was ordered to pay a provision on damages amounting to 13.1 million € (5.8 million to the patentee, and 7.3 million to its French licensee). The Judge has based this provision on revenues for the generic company calculated to be of 14.6 million €. The action on the merits is still on-going; due to some procedural specificities, the appeal of this PI decision cannot be filed before the decision on the merits is issued.

[ref 1] TGI Paris, 5 Apr 2018, MSD v. Biogaran, RG 18/52397

[ref 2] CA Paris, 26 Jun 2018, MSD v. Biogaran, RG 18/06769

[ref 3] TGI Paris, 25 May 2018, Biogaran v. Gilead, RG 17/09565

[ref 4] TGI Paris, 7 Jun 2018, Teva v. Novartis, RG 16/15196

Finland

Johanna Lilja, Roschier

In Finland, the most noteworthy legal development in the pharmaceutical sector so far during 2018 been the *Astellas Pharma* case, which was referred to the Court of Justice of the European Union ("CJEU") by Finland's Supreme Administrative Court.

The CJEU rendered its ruling in the case C-557/16[http://curia.europa.eu/juris/document/document.jsf?text=&docid=200241&pageIndex=0&doclang=EN&mode=lst&dir=&occ=first&part=1&cid=645426] (*Astellas Pharma*) regarding the exclusivity period for pre-clinical and clinical trials data for pharmaceuticals in March 2018.

In essence, the case concerned the duties and powers of national pharmaceutical authorities and national courts to verify whether the data exclusivity period[1][#5113497-v-

-Annual_Reports.DOCX#_ftn1] during the so-called decentralized procedure has expired before a marketing authorization for a generic pharmaceutical product can be issued. The CJEU confirmed that the authorities of the concerned Member States have such a duty and, if necessary, the beneficiary of the data exclusivity may also bring legal action in the concerned Member State to determine whether or not the data exclusivity period has expired.

The Court of Justice stated that, in the decentralized procedure for granting a marketing authorization the competent national regulatory authority has a duty to verify that all the preconditions for issuing a marketing authorization have been met. According to the Court of Justice, this includes verifying that the data exclusivity period has expired. The Court of Justice also confirmed that the holder of the marketing authorization for the reference pharmaceutical product (*i.e.* the beneficiary of the data exclusivity) can also bring legal action against the authority of a concerned Member State to determine the data exclusivity period. Accordingly, the Court of Justice rejected the opposing view that, generally speaking, only the relevant authority and courts in the reference Member State are competent to determine when the data exclusivity period has expired.

Israel

David Gilat, Gilat, Bareket & Co., Reinhold Cohn & Partners

The most prominent development in 2018 relates to the field of Biosimilar drugs, and deals with the question whether data exclusivity protection should be afforded to biological drugs.

On 31 July 2018, the Israeli Ministry of Health (MoH) published a “call for action”, inviting the public to participate in the process of examining the need to amend Section 47D of the Pharmacists’ Ordinance, so it will also cover the protection of confidential data submitted in connection with the registration of biological drugs.

Section 47D of the Pharmacists’ Ordinance already provides marketing exclusivity. However, the MoH took the position, in its letter, that the current regime applies to new chemical entities only.

As indicated in the MoH letter, a team has been assembled, which includes representatives from several government offices, that will conduct a regulatory impact analysis (RIA) procedure, all in accordance with a formal Government decision (no. 2118).

The public was requested to provide its written position in the matter at hand, by September 16th, 2018 to the following email address: regulation@moh.health.gov.il[1]. Interested parties who wish, additionally, to orally present their position to the team, should indicate such in their submission, and will be invited to a meeting in due course.

As background, registration of biosimilars drugs is effected according to Work Procedure 127

of the Ministry of Health ("MoH") issued in 2014 and revised in 2016. The Work Procedure defines Bio-Similar Pharmaceutical as a biological pharmaceutical comprising a biological active ingredient that is similar to the active ingredient of an original biological pharmaceutical ("Reference Medicinal Product"). A Bio-Similar Pharmaceutical should be similar to the Reference Medicinal Product in aspects of quality characteristics, biological activity, safety and efficacy, as established in comparative tests.

In general, according to the Work Procedure, the MoH adopts EMA policies in the relevant issues at hand, relating to Bio-Similar Pharmaceuticals, customized to the need of the State of Israel.

The Work Procedure provides two accumulative conditions that must be fulfilled in order to register a Bio-Similar Pharmaceutical in Israel:

(i) The Bio-Similar Pharmaceutical must be registered with the EMA, FDA, Canada, Australia, New Zealand, Japan or the Swiss Agency for Therapeutic Products ("Swissmedic").

(ii) The registration file must include data that proves that the Bio-Similar Pharmaceutical is similar to the Reference Medicinal Product and that there is no significant difference in aspects of quality, safety and efficacy;

As a general rule, the registration of a Bio-Similar Pharmaceutical will not be allowed if the Reference Medicinal Product is not registered in Israel. However, in certain exceptional cases, in which a national clinical need exists, the registration of a Bio-Similar Pharmaceutical may be considered even if the Reference Medicinal Product is not registered in Israel, provided that the Bio-Similar Pharmaceutical was approved by one of the recognized regulatory authorities (the FDA, the EMA or Swissmedic). Such exceptional cases will be brought before an advisory committee for bio-similars that was established by the Work Procedure and will be eventually decided by the management of the MoH.

The suggested revision of the data exclusivity provisions, if accepted, would apparently enhance protection for innovative biological drugs.

PERU

Carlos Fernández-Dávila W., *Fernández-Dávila & Bueno*

National Intellectual Property Policy

In May 2018, the National Institute for the Defense of Competition and the Protection of Intellectual Property - INDECOPI, agency hosting among others the Peruvian Patent & Trademark Office, presented the strategy to elaborate the National Intellectual Property Policy. It represents an instrument for the economic and social development and will allow the promotion of the innovation and the transfer of technology.

INDECOPI along with more than 40 Peruvian institutions are working on the formulation of the aforementioned Policy. Besides, INDECOPI has signed an agreement with the World Intellectual Property Organization (WIPO) in order to obtain technical and methodological support during the preparation of the said Policy.

It is expected to have the National Intellectual Property Policy officially approved towards the first quarter of 2019, so that it can be implemented by different sectors and stakeholders in Peru.

Establishment of Technology and Innovation Support Centers (TISCs)

With the support of the WIPO, 22 Technology and Innovation Support Centers (TISCs) have been established in Peru. The TISCs are part of a project of the WIPO that aims to provide researchers and innovators with assistance for searching technical information in patent databases or scientific publications, training in analysis, strategies and techniques for searching in patent databases, and guidance on intellectual property instruments in research and innovation processes.

To form the CATI network, INDECOPI has signed agreements with several institutions such as the National Institute of Health, Chamber of Commerce of Lima, National Agrarian University La Molina, National University of Engineering, Pontifical Catholic University of Peru, among others.

Access to WIPO CASE platform

In June 2018, INDECOPI informed that the access to the International System WIPO CASE has been achieved. This is a platform developed by WIPO that allows reviewing search reports and patent examinations provided by the main industrial property offices worldwide. Peru has become the second country in South America, after Chile, to have such access.

Peruvian patent examiners are able to access and use the WIPO CASE platform permanently to search and analyze documents related to equivalent patent applications presented in other participating offices of the system. It is expected that the time taken to the patentability examination can be reduced, given as a result greater efficiency and quality of services provided by INDECOPI.

Turkey

Gaye Ramazanoglu, Toksozgrup

New Rules for Patents in Turkey

The new IP Law, Law on Industrial Property No. 6769 has been in force since January 10, 2017 repealing Decree Law no. 551 on Patents and Utility Models.

The structural changes related to the patent rights are briefly provided in below:

Biotechnological Inventions: There is no provision in the new IP Law regarding to the protection about biotechnological inventions but some terminology has been determined in Art.2 like “plant variety, biological material” and Non-Patentable subject matters related to biotechnological inventions are determined in Art.82(3). These provisions cite the “non patentable biotechniological inventions”.

Second medical use: The new IP Law is still silent on the subject of second medical use despite the recent Supreme Court case law ruling that the second medical use inventions are patentable. There is no provision added in No.6769 which is similar to the Art 54(4) and (5) EPC. On the other hand, the patents validated through EPC route of to which Turkey is a party benefit from the protection provided for second medical use patents.

Reversal of burden of proof in Process Patents: “where the patented process results in a new product or substance, those claiming the contrary in respect of products or substances having the same characteristics shall have to bring evidence thereof”

Introduction of Post-grant Opposition (only for patents) : Time limit for opposition after publication of grant is limited to 6 months.

System for Granting a Patent Without (Substantive) Examination is abolished leading to two instruments to proceed: a) full term patent of 20 years with mandatory substantive examination b) Utility model of 10 years with mandatory state-of-the-art search report while branching out from and to these systems is maintained.

Patent-of-Addition is cancelled

No criminal sanctions for infringement of patents and utility models. Criminal provisions of previous legalization have been abolished.

Adoptation of reinstatement : Re-establishment of rights and Further Processing procedures are added

The Employee Inventions: New Regulations are in force in 29.09.2017

Inventions made in University Bodies has more importance now because universities may claim right to the inventions of the university staff. According to the new IP Law, all inventions made by scientific staff, students as well as interns in the course of their functions are deemed to belong to the concerned University

Utility model certificates are amended: Request for Search is mandatory now within 2 months after filing.

Requirements for granting **Compulsory Licensee** are extended, 3 new conditions are added to Art.129 (1) which are a) for acts resulting in a restriction or breach of competition rules b) for exportation of pharmaceutical products for addressing public health needs in other countries c) for being unable to develop a new plant variety without infringing a patent

Turkey Becomes PIC/S Member

The Turkish Medicines and Medical Devices Agency ("**TÄ°TCK**") announced on October 5, 2017, after following a four-year evaluation and inspection process, it became a member of the Pharmaceutical Inspection Co-operation Scheme (the "**PIC/S**").

The PIC/S is a convention founded by the pharmaceutical inspection authorities from various countries; it is the most reputable and recognized pharmaceutical inspection committee. Membership to PIC/S is subject to a detailed and strict inspection process. Switzerland, the USA, the UK, Ireland, Germany, Canada, Japan and Australia are among the member countries to PIC/S. The TÄ°TCK's membership to the PIC/S enables worldwide recognition of the TÄ°TCK's inspections and inspection findings.

The quality and safety of the medicines produced in Turkey is now globally recognized and may aid in overcoming the technical difficulties preventing the medicines produced in Turkey from reaching the global market. The TÄ°TCK's membership to the PIC/S is effective as of January 1, 2018.

Changes to Pharmaceutical Packages: TÄ°TCK Announces Mandatory Braille Alphabet Usage

The Turkish Medicines and Medical Devices Agency announced on February 28, 2018, the necessary actions to fulfil the requirement of Braille alphabet usage under the Regulation on Package Information, Manuals and Tracking of Medicinal Products for Human Use (the "**Braille Regulation** ").

UK

Claire Baldock, Boult Wade Tennant LLP, Duncan Ribbons, Celixir

Late 2017 saw two disputes concerning pharmaceutical patents with claims to specific dosage regimens come before the English Courts. In both cases the relevant claims were held to lack inventive step, although the reasons for the findings were significantly different.

Generics (UK) Ltd and Synthon v Yeda Research and Development Ltd

On 26th October 2017 a decision was handed down from the English High Court concerning dosage regimen patent, EP(UK) 2949335 of Yeda Research and Development Ltd. The patent was concerned with low frequency glatiramer acetate (GA) therapy . GA comprises acetate

salts of synthetic polypeptides containing L-glutamic acid, L-alanine, L-tyrosine and L-lysine and is used for treating relapsing forms of multiple sclerosis.

Claim 1 of the patent was directed to glatiramer acetate for use in a regimen of three subcutaneous injections of a 40mg dose of glatiramer acetate every seven days with at least one day between each subcutaneous injection for use in treating a patient who is suffering from a relapsing form of multiple sclerosis or who has experienced a first clinical episode and is at high risk of developing clinically definite multiple sclerosis and the pharmaceutical composition further comprises mannitol.

At the time of filing the Yeda patent it was the established practice to administer by injection 20mg of GA daily. There had also been studies published of administration of 40mg daily (the FORTE trial) and one document, the Pinchasi reference , confirmed that the 40mg dose increased efficacy without a corresponding increase in adverse reactions. Pinchasi also suggested periodic administration of 40mg every other day but did not provide any data on the efficacy of such a regimen. Another published study (Caon) compared the established 20mg daily regimen with 20mg every other day and concluded that when administered on alternate days, GA was just as effective and efficacious as daily administration.

The claimants argued that claim 1 was obvious over the Pinchasi reference because the claimed dosage regime of three injections every seven days with at least one day between each subcutaneous injection was nothing more than a simple variation of Pinchasi's teaching of 40mg on alternate days. It was an obvious alternative because the skilled person would think that missing one dose a fortnight was unlikely to have a detrimental effect on the efficacy of treatment but would have the advantage of greater tolerability and be more convenient for patients who wanted fixed day administration and weekends injection free. Thus, the claimed regimen was obvious to try and there would be a fair expectation of success, both in the sense that the regimen would be efficacious compared to placebo and in the sense that it would be acceptable in efficacy to the established 20mg daily regime.

Mr Justice Arnold accepted the claimant's arguments in respect of inventive step in their entirety and found claim 1 to lack inventive step over the Pinchasi reference.

The decision is one which does not diverge from the traditional approach of the English Courts to the assessment of inventive step as it continues to apply the "obvious to try with an expectation of success" test.

Actavis v Icos

On 1 November 2017, the UK Court of Appeal handed down its decision in Actavis v ICOS in which the first instance decision of Mr. Justice Birss was overturned.

This case concerned Patent No. EP(UK) 1,173,181 containing claims to a composition comprising 1 to 5mg tadalafil in a unit dosage form suitable for oral administration up to a maximum total dose of 5mg per day for use in treating sexual dysfunction.

The prior art under consideration was a patent application which taught the use of PDE5 inhibitors (such as tadalafil) for the treatment of erectile dysfunction and contained examples of a tablet containing a 50mg dose of tadalafil. It explained that doses would generally be in the range of 0.5mg to 800mg/day for the average adult patient. It did not specifically disclose a tablet containing 5mg of tadalafil, nor that such a low dose would be effective.

The appeal decision included findings on various grounds, but it is the contentious finding on inventive step, which is of the most relevance.

While acknowledging that the efficacy of the claimed low 5mg dose was not necessarily expected, Lords Justice Kitchen, Floyd and Lewison found that in the first instance decision too much weight had been given to the expectations of the skilled team and too little to the routine nature of the research that resulted in the unexpected discovery.

Lord Justice Kitchen stated: "*The fact that the skilled team could not make any prediction at the outset that a dose of 5mg of tadalafil per day would be safe and efficacious is of little weight because at least one of the purposes of carrying out the Phase IIb studies is to better understand the dose response relationship of the drug and so identify the appropriate dose range for the target population*"

This view was mirrored by Lord Justice Floyd, who noted that "*a patent will not be granted for an invention which, though not obvious in this a priori sense, is nevertheless an invention which would be arrived at by a line of routine and uninventive enquiry which would be carried out by a skilled team*".

Lord Justice Lewison agreed and concluded that an expectation of success is not an integral component of an "obvious to try" case.

The judges' comments imply that, as long as the skilled team is motivated to continue moving through the phases of clinical research and they have an expectation of successfully obtaining the *type of information* that each phase of clinical research is designed to provide, there can be no invention, even if the results obtained were surprising to the skilled team. Any expectation of success is entirely irrelevant in such a circumstance.

This conclusion is at odds with the analysis applied by Justice Arnold in the earlier Generics v Yeda case discussed above. Based on this decision, it could be concluded that the patenting of novel dosage regimes in the UK will be significantly harder than it once was and might not be possible at all.

However, an appeal to the Supreme Court has just been accepted during which it is hoped the harshness of this decision may be mitigated.

Teva v Gilead –CJEU C-121/17

On 25th July 2018 the Court of Justice of the European Union handed down yet another

Decision concerning the meaning of Article 3(a) of SPC regulation 469/2009. Article 3(a) specifies that a certificate shall be granted provided that the product is protected by a basic patent in force. Whether an authorised pharmaceutical product is considered to be "protected by a basic patent in force" has proved an extremely difficult question to answer and the CJEU has attempted to answer it already on a number of occasions, especially in relation to combination products. However, the guidance of these previous decisions has not been sufficient to prevent the English High Court asking the question of the CJEU yet again.

The referral was made during proceedings between Teva, Accord, Lupin, and Mylan (the Applicants) and Gilead (the Defendant) regarding the Applicants' attempt to invalidate Gilead's SPC (SPC/GB05/041) on the grounds that the SPC does not satisfy Article 3(a) of the SPC Regulation.

Gilead's product, marketed under the name TRUVADA®, is an anti-retroviral used in treating HIV, and comprises tenofivir disoproxil (TD) and emtricitabine. The combination product was granted marketing authorisation in February 2005. Gilead relied upon this first marketing authorisation and upon claim 27 of European patent EP(UK)0915894 as basis for the combination SPC.

Claim 27 of the basic patent recites: "A pharmaceutical composition comprising a compound according to any one of claims 1-25 [claim 25 discloses TD] together with a pharmaceutically acceptable carrier and optionally other therapeutic ingredients".

Importantly, emtricitabine is not mentioned anywhere in the patent.

In the judgment, the CJEU confirmed that active ingredients do not need to be expressly mentioned in the claims to be "protected", and set out the following criteria that a patent must satisfy in order to "protect" a combination for the purpose of obtaining an SPC:

"*Article 3(a) […] must be interpreted as meaning that a product composed of several active ingredients with a combined effect is 'protected by a basic patent in force' within the meaning of that provision where, even if the combination of active ingredients of which that product is composed is not expressly mentioned in the claims of the basic patent, those claims relate necessarily and specifically to that combination. For that purpose, from the point of view of a person skilled in the art and on the basis of the prior art at the filing date or priority date of the basic patent:*

the combination of those active ingredients must necessarily, in the light of the description and drawings of that patent, fall under the invention covered by that patent, and

each of those active ingredients must be specifically identifiable, in the light of all the information disclosed by that patent."

Whether active ingredients "fall under the invention covered by the patent" and are "specifically identifiable in the light of the information disclosed by the patent" are factual enquiries that must be performed by the patent office or national court reviewing the allowability of the SPC. In the case of Gilead's Truvada® SPC, the CJEU remitted these

questions back to be considered by the UK High Court.

It remains be seen how the High Court will apply this guidance to the Gilead SPC but it may be speculated that failure to mention one of the components of the authorised product, emtricitabine, in the patent at all could be determinative as to the validity of the Gilead SPC, given the position set out by the CJEU.

US

John Todaro, Merck & Co., Inc., Kenilworth, New Jersey (USA)

In 2018 the United States Supreme Court decided two important decisions affecting the USPTO's post-grant administrative proceedings. In *Oil States Energy Services, LLC v. Greene's Energy Group, LLC*, 138 S.Ct. 1365 (2018), the Supreme Court affirmed the constitutionality of the inter partes review (IPR) post grant procedure. The petitioner Oil States, whose patent had been invalidated by the US PTO's Patent Trademark and Appeal Board (PTAB) in an IPR, argued that IPR's violate Article III of the Constitution by allowing review of an issued patent by an executive agency (the patent office), rather than a court. Oil States also argued that IPR's violate the Constitution's right to trial by jury, by adjudicating a private right (the patent) without a jury. The Supreme Court disagreed, finding that patents are a "public right" or "public franchise" and that as a result the Constitution permits Congress to authorize the executive branch to take action on the patent.

In *SAS Institute, Inc. v. Iancu*, 138 S. Ct. 1348 (2018), the Supreme Court limited the PTAB's ability to institute IPR challenges on a claim-by-claim basis. The Court ruled that that the PTAB is statutorily required to review and issue a decision regarding every claim that the petitioner challenges. In the case at issue, the patent challenger had sought review ov all granted claims. The PTAB granted review of some but not all claims,. SAS appealed, asserting that the statute required the PTAB to assess the patentability of any claim challenged by the petitioner. The Supreme Court agreed.

In a decision of interest to the pharmaceutical industry, the U. S. Court of Appeals for the Federal Circuit (CAFC), decided Vanda Pharmaceuticals Inc. v. West-Ward Pharmaceuticals Int'l Ltd., 887 F.3d 1117 (Fed. Cir. 2018). This case was an appeal from a district court decision finding that a generic manufacturer infringed a patent covering the drug FANAPT (iloperidone). The patent claimed a method for treating for schizophrenia, comprising first testing a patient for the capacity to metabolize the enzyme CYP2D6, and then determining an iloperidone dose depending on the capacity. The claimed inhibition capacity was a potential marker of the cardiac condition QT prolongation.

The alleged infringer argued that the patent covered ineligible subject matter, because the claims "are directed to a natural relationship between iloperidone, CYP2D6 metabolism, and QT prolongation, and add nothing inventive to those natural laws and phenomena." Id. at

1133. The CAFC disagreed, and upheld the claims. The CAFC stated that "the claims here are directed to a specific method of treatment for specific patients using a specific compound at specific doses to achieve a specific outcome." Id. at 1136.

In Jazz Pharmaceuticals, Inc. v. Amneal Pharmaceuticals, LLC,[http://www.cafc.uscourts.gov/sites/default/files/opinions-orders/17-1671.Opinion.7-13-2018.pdf] 895 F.3d 1347 (Fed. Cir. 2018), the patents at issue covered the drug XYREM. The asserted claims recited the steps of using a database to manage prescription requests and detect abuse of the drug. The PTAB found that the patents were obvious over FDA meeting materials, which were accessible on an FDA web page. The web page was identified in a government publication (the Federal Register). On appeal, the CAFC agreed with the PTAB. The CAFC concluded that the meeting materials constituted a "printed publication" under the statue 35 U.S.C. § 102 (b). The Federal Circuit focused on the "public accessibility" of the meeting materials. The court stated that "a reference is considered publicly accessible upon a satisfactory showing that such document has been disseminated or otherwise made available to the extent that persons interested and ordinarily skilled in the subject matter or art, exercising reasonable diligence, can locate it." Id. at 1355.

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[1][#5113497-v1-Annual_Reports.DOCX#_ftnref1] The rules on data exclusivity are set out in Directive 2001/83/EC of the European Parliament and of the Council relating to medicinal products for human use, as implemented in the Member States' national legislation. Data exclusivity for pharmaceuticals is a specific form of intellectual property right which confers on the holder of a marketing authorization for a new pharmaceutical product temporary exclusivity for data from comprehensive pre-clinical and clinical trials. Such data is needed to demonstrate the safety and efficacy of the pharmaceutical product before it is made available to patients. The data is generated by the relevant pharmaceutical company at substantial expense and effort. In return, the company enjoys a period of exclusivity during which the data is not available to other parties and may not to be used as a basis for granting a marketing authorization for a generic pharmaceutical product. In the European Union, the period of exclusivity runs for at least eight years.

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 in.

b)
any other recommendations for AIPPI involvement/action;

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

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

The Committee is continuing to work with the Biotech Subcommittee on its review of antibody patenting. We expect that there will be further efforts on this projects during the 2018-19 term.

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 2019 - one in January and a second in May. Additional teleconferencees will be scheduled as needed. Frequent email comunication will continue.

The Committe hopes to initiate work with the Unitary Patent Court Committee on a paper regarding the litigation of SPC's at the UPC. The Committee also will study issues relevent to the London Study Question on Plausibility, which is of concern to the pharmaceutical industry. The Committee is contemplating joint efforts with the TRIPS Committee and the IP and Genetic Resources/Traditional Knowledge Commitee on the handling of biological resouces data in pharmaceutical patent filings around the world.

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

Names and Functions of Committee Members

Chair	John C. TODARO	United States
Vice Chair(s)	Charles Aaron BOULAKIA	Canada
	Martin KLOK	Netherlands
Members	Orly ALSTER	Israel
	Hameeda ASIF	Pakistan
	Ezgi BAKLACI	Turkey
	Martín BENSADON	Argentina
	Cristina BIGGI	Italy
	Hector E. CHAGOYA C.	Mexico
	Ma. Sophia Editha C. CRUZ-ABRENICA	Philippines
	Magnus DAHLMAN	Sweden
	Li FENG	United States of America
	Amy FENG	China
	Carlos FERNANDEZ DAVILA	Peru
	Alfredo FERNÁNDEZ SANTÍN	Spain
	David GILAT	Israel
	Sevgi GOKCEK AYGOREN	Turkey
	Rana GOSAIN	Brazil
	Simon HOLZER	Switzerland
	Renat KRASNOPEROV	Russian Federation
	Andras KUPECZ	Netherlands
	Johanna LILJA	Finland
	Anja LUNZE	Germany
	Daisy MACHYTKA-FRANK	Hungary
	Eliza MALLON	Australia
	Ana Claudia MAMEDE CARNEIRO	Brazil
	Ilan MILLER	Israel
	Cyra NARGOLWALLA	France
	Carlos Reynaldo OLARTE GARCIA	Colombia
	Makoto ONO	Japan
	Gaye RAMAZANOGLU	Turkey
	Beat RAUBER	Switzerland

Mathilde RAULINE	France
Duncan RIBBONS	United Kingdom
Christophe RONSE	Belgium
Nicolas RUIZ VINCENT	Spain
Joseph SCHMITZ	Switzerland
Joseph SNYDER	United States of America
Elizabeth WRIGHT	United Kingdom