



Date: 23rd September 2015

REPORT Standing Committee on

Pharma and Biotechnology

Chair: John C. TODARO
Responsible Reporter: Ralph Nack

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

Q224 is a new committee, created to address issues of concern to the pharma industry. Meetings of the Committee took place by teleconference on June 24/25, 2015 (two calls required due to the various time differences of the members) and members reported on local issues in their country).

The Committee has identified the following key topics for discussion and study in 2015-2016.

A. Differing standards on the admissibility of post filing data in order to establish inventive step.

During patent prosecution, patent applicants often seek to rely on data created after the application filing date, such as the results of experiments with the claimed subject matter conducted after the filing date. Patent Offices around the world have established different standards for when the data may be submitted. For example, until recently the State Intellectual Property Office in China did not permit post-filing data to show sufficiency. While SIPO has begun to permit post-filing data recently for sufficiency, it has often limited the use of post-filing data to demonstrate inventive step. Differences in the admissibility of post-filing data sometimes accounts for different results in patent prosecution around the world.

B. Supplementary Protection Certificates (“SPCs”) and Patent Term Extensions (“PTEs”)

Much of the term of a pharmaceutical patent can be effectively eroded by the lengthy

nature of the regulatory approval process that must be completed before a pharmaceutical product can be commercialised. To address this concern, many countries have introduced systems to grant a further period of exclusivity for pharmaceutical patents beyond the standard 20 year term (for example, SPCs in Europe and PTEs in the US and Japan). These systems are important for incentivising investment in pharmaceutical R&D and the sustainability of the industry.

Many countries, including the US, the EU, Japan, Korea and Australia, have well-established systems for granting further periods of protection for pharmaceutical patents, although the systems adopted in these countries show some variance in their operation. Other countries are in the process of introducing such systems (for example, Canada) and others may adopt them in the future (for example, countries of the Trans Pacific Partnership). Monitoring the operation of the existing systems is of great interest to the pharmaceutical industry and may usefully inform the design of new systems which are likely to emerge in

the future, and the re-shaping of existing systems as they evolve.

C. Overlap of Patent and Antitrust Law in Pharma

There is an inevitable tension between patent law, which provides for the grant of monopolies and antitrust law, which promotes freedom of competition. Patents are key to the financial success of the pharmaceutical industry. However, financial pressure on health providers and governments has created an environment where there is an increasing focus on freedom of competition and the provision of drugs and healthcare at the lowest possible price point. It is therefore no surprise that in recent years, the pharmaceutical industry has been subject to rigorous scrutiny by antitrust authorities.

Areas which have attracted attention from antitrust authorities include, pay for delay deals, abuses in obtaining and enforcing patent rights and (in other industries, but equally applicable to the pharmaceutical industry) no-challenge clauses in patent licence and settlement agreements.

With the spotlight firmly on the pharmaceutical industry and in view of the stiff sanctions that can be applied by antitrust authorities, developments at the interface between IP rights and competition laws are an area of great interest for the pharmaceutical community.

D. Patent Linkage

Patent Linkage system can be taken as an opportunity for generics industry to get strengthened by developing new formulations or products based on expired patents, since some believe that building a clear regulatory system for cooperation between the patent offices and the health authorities would result in the consolidation of the generics companies committed to the development in areas not contemplated by innovator pharmaceutical companies and preserving market exclusivity for innovators.

Patent linkage is the practice of linking a drug marketing approval for a pharmaceutical substance to that of the patent status of such a pharmaceutical substance; such that no marketing approval is granted to any third party for a pharmaceutical substance prior to the expiration of the patent term on such a substance unless consented to by the patent owner.

E. Second Medical Use Patents

The discovery of new uses for known drugs has clear benefits for human health and provides opportunities for pharmaceutical companies to maximise the return on the R&D investment made in a pharmaceutical substance. Allowing patents for second medical uses is an important tool for incentivising research of this kind.

However, the enforcement of such second medical use patents can often present difficulties, frequently because the way in which medicines are prescribed and dispensed do not easily allow for markets to be segregated according to whether a particular use is patented or not, using traditional remedies such as injunctions. These issues were studied by AIPPI last year in Q238.

The monitoring of developments in this area will supplement the work done to date by AIPPI and continue to be an important matter for the pharmaceutical industry.

- 2) Key issues/developments relevant to the Terms of Reference of the Standing Committee (arising during the reporting period or coming up)

Herein Committee Q242 provides an update on IP Developments in the pharma sector in Europe,

including United Kingdom, Netherlands and Belgium, United States, China, Australia, Japan, Brazil, Israel, China and India. In particular, the update contains information on the identified key topics: Second Medical Use Patents, Patent Linkage, Differing Standards on the Acceptability of Using Post-Filing Data in Patent Prosecution and Supplementary Protection Certificates/Patent Term Extensions.

Europe - Duncan Ribbons, Christophe Ronse, András Kupecz, Martin Klok

Recent developments in Europe on Supplementary Protection Certificates (Duncan Ribbons):

Developments in 2014/5

Actavis v Boehringer (C-577/13) - 12 March 2015

This case concerned Boehringer's UK SPC for telmisartan in combination with hydrochlorothiazide. The SPC was obtained on the basis of a basic patent which claimed telmisartan. As originally granted the patent did not include a claim to the combination product. After the application for the combination product SPC had been made, but prior to its grant, a claim to the combination product was added via the post grant amendment procedure. Boehringer had previously obtained an SPC for telmisartan on the basis of the MA for the mono product. The SPC for the combination product was based on a later MA for the combination, and as a consequence had a later expiry date than the telmisartan SPC.

Actavis sought to revoke the SPC for the combination product on the grounds that it was granted on the basis of a basic patent which as at the date of the SPC application was not protected by a basic patent in force within the meaning of Article 3(a) of the SPC Regulation as interpreted by the CJEU in Medeva et al. Further, Actavis contended that having obtained an SPC for telmisartan, Boehringer was not entitled to a further SPC for the combination the combination product was not a distinct and separate invention to telmisartan (i.e. the claim to the combination is not independently valid over the claim to telmisartan).

The second of these issues was decided in line with the previous judgement of the CJEU in Actavis v Sanofi (C-443/12) where the facts were similar: Article 3(c) precludes the grant of an SPC for a combination product where the "sole subject matter of the invention" (in this case telmisartan) has already been the subject of an SPC. In view of its decision on the second issue, the CJEU declined to rule on the first issue.

The outcome on the second issue is not surprising in light of the CJEU's previous case law. However, it is disappointing that the court did not take up the opportunity to rule on the first issue, as this is a question that will likely need to be ruled on in due course.

Anti-trust /competition law (Duncan Ribbons)

Concerns that pharmaceutical companies were restricting or distorting competition led to the launch by the European Commission of a major enquiry into the EU pharmaceutical market in January 2008. The enquiry concluded that pharmaceutical companies were using a toolbox of measures to delay generic entry such as "pay for delay" agreements, patent thickets, patent linkage and aggressive litigation strategies.

The European Commission has since imposed heavy fines on a number of pharmaceutical companies that it has found to be in breach of competition law by entering into pay for delay agreements. These include:

- In June 2013, a fine of €93.8 million imposed on Lundbeck and fines totalling €52.2 million imposed on four of generic pharmaceutical companies (Merck KGaA (now part of Mylan), Arrow, Alpharma and Ranbaxy) who agreed with Lundbeck not to launch citalopram products in return for

- payments and inducements;
- Fines totalling €427.7 million imposed on Servier and five generic pharmaceutical companies (Niche/Unichem, Matrix (now part of Mylan), Teva, Krka and Lupin) in July 2013 for concluding agreements pursuant to which the generic pharmaceutical companies agreed not to launch perindopril; and
- Fines of approximately €10.8 million and €5.5 million imposed on Johnson & Johnson and Novartis respectively in December 2013, whose Dutch subsidiaries (Janssen-Cilag and Sandoz) entered into a “co-promotion agreement”, which delayed the launch of a generic version of fentanyl in the Netherlands.

The grant of SPCs appears to be another area which concerns competition authorities. For example, in June 2005, the Commission found that AstraZeneca had abused its dominant position by making a number of misleading representations to various European patent offices which resulted in it obtaining the grant of SPCs for omeprazole to which it was not entitled or to which it was entitled for a shorter period. This decision was ultimately upheld by the CJEU in December 2012.

UK and Italian developments in 2014/5

Latanoprost

On 12 February 2014 Italy's highest administrative court upheld a decision of the Italian Antitrust Authority (the “IAA”) dated 11 January 2012 which fined Pfizer €10.6 million for obtaining SPC protection for latanoprost on the basis of a divisional patent in circumstances where in other European countries it had applied for corresponding SPCs on the basis of the parent patent.

In the IAA's view, the following factors indicated that Pfizer had artificially created legal uncertainty surrounding the date of expiry of its protection for latanoprost:

- Pfizer did not launch a new drug following the grant of the divisional when in the IAA's view, such a launch would be normal;
- Pfizer sought an SPC in Italy several years after it applied for SPCs in other EU countries; and
- Pfizer did not use the divisional as the basis for requesting SPCs in other EU countries.

There was no question that Pfizer had misled the Italian patent office or acted in any way contrary to the provisions of the SPC Regulation (as was the case in AstraZeneca). The IAA appeared to be influenced by concerns raised in the Commission's pharmaceutical sector inquiry that applying for multiple divisional patents to create ‘patent thickets’ can create barriers to entry for generics companies and distort the proper functioning of the pharmaceutical market.

Bevacizumab/ranibizumab

On 27 February 2014, the IAA imposed fines on Roche and Novartis of €90.5m and €92m respectively. The IAA's investigation concerned two anti-VEGF antibodies, ranibizumab (marketed by Novartis under the brand name Lucentis) which is approved for the treatment of age-related macular degeneration (“AMD”) and bevacizumab (marketed by Roche under the brand name Avastin), which is approved for the treatment of certain types of cancer (but which is also prescribed off label to treat AMD). Lucentis is significantly more expensive than Avastin. Both Roche and Novartis had a financial interest in the success of Lucentis (because Roche receives royalties on sales of Lucentis because of certain patent licensing arrangements), but that success was compromised by the off-label prescription of Avastin for AMD. The IAA found that Roche and Novartis had improperly colluded by spreading concerns about the safety of off-label use of Avastin to treat AMD in order to increase the sales of Lucentis and hiding data which supported such off-label use.

Paroxetine

In the UK, the Competition and Markets Authority (“CMA”) is currently investigating agreements concluded between GlaxoSmithKline (“GSK”), Generics (UK) (part of Mylan) and Norton Healthcare relating to the supply of paroxetine (sold by GSK under the brand name ‘Seroxat’). According to the CMA, GSK made “substantial payments” to the generic companies in return for their commitment to delay their plans to supply paroxetine in the UK. Note that the investigation has not yet concluded and a decision on whether there has been a breach of competition law is expected in autumn 2015.

Patent/Antitrust - Netherlands (András Kupecz, Martin Klok)

In relation to antitrust issues and settlement agreements, it is noted that there have been no specific pharmaceutical decisions in the Netherlands that we are aware of. We do note however that the District Court of the Hague (which has sole jurisdiction over patent cases) has rendered a number of rulings in telecoms cases relating to standard essential patents and FRAND. Under specific circumstances, patent enforcement could amount to a (forbidden) abuse of a dominant market position. There seems no reason to exclude pharmaceutical patents a priori from such abuse, provided there is a dominant market position (cf. the AstraZeneca (“AZ”) case in which the European Court of Justice fined AZ for abusing its dominant position, Case C-457/10 P).

Second Medical Use Claims (Duncan Ribbons)

UK Developments in 2014/5

Pregabalin

In Warner-Lambert v Actavis [2015] EWCA Civ 556, the English Court of Appeal was called on to provide guidance on the construction of Swiss form claims (i.e. use of X for the manufacture of a medicament for the treatment of Y) in the context of an infringement claim brought against a generic product with a “skinny label.” At first instance ([2015] EWHC 72 (Pat)), Arnold J interpreted the underlined “for” as meaning “suitable and intended for” and that the relevant intention was the subjective intention of the manufacturer. However, the Court of Appeal disagreed and held that the skilled person would understand the word “for” in this context to mean that the manufacturer has actual or constructive knowledge, or can reasonably foresee, that some of his drug will intentionally be used for treating pain.

At first instance, Warner-Lambert’s claim for indirect infringement (i.e. the supply of means essential to putting the invention into effect) was struck out, notwithstanding that a recent decision from the Dutch courts where Sun’s supply of zoledronic acid under a skinny label was found to be an indirect infringement of Novartis’ second medical use patent. The Court of Appeal showed greater deference to the Dutch decision and a decision from the German courts which was consistent with it and allowed Warner-Lambert’s claim for indirect infringement to proceed to trial.

However, the Court of Appeal did acknowledge that there were difficulties with the indirect infringement claim because the Swiss form claim is a manufacturing (process) claims and no further manufacturing steps take place downstream of the generic manufacturer. A possible solution to this difficulty proposed by the Court of Appeal was to consider whether the invention might be put into effect by the actions of more than one person. For example, a manufacturer and customer who uses the drug to treat pain might be said to be collectively putting the invention into effect.

A further noteworthy dimension to this dispute is that Warner-Lambert sought a variety of novel forms of interim relief both against the generic manufacturers and the NHS designed to help prevent cross label

use of the skinny label generic products. The relief against the generic manufacturers was refused. This included requiring the generic companies to write to pharmacies and prescribing doctors informing them that their product was only approved for the non-patented indications, including a notice to this effect on the product packaging and making it a term of any supply contracts that the dispensing pharmacist would take steps to determine the indication for which the drug had been prescribed. However, the relief sought against the NHS was granted (and was largely unopposed by the NHS and the generic companies). This required the NHS to issue guidance to doctors advising them to write the brand name (rather than the INN) on scripts when prescribing the drug for the patented indication (substitution not being allowed in the UK).

The trial of the infringement case was heard at the end of June 2015 and the judgment is expected in September / October 2015.

Second Medical Use - Netherlands (András Kupecz, Martin Klok)

In relation to the enforcement of second medical use claims, the Court of Appeal in the Hague gave a landmark ruling on “skinny labels” (Novartis v. Sun 27 January 2015). The Court of Appeal held that offering a generic drug whilst the generic manufacturer knew (or had to know) that the drug would also be sold for a patented indication constituted indirect patent infringement despite the skinny label. The competition law defense raised by Sun (abuse of a dominant position) was dismissed as insufficiently supported. In respect of second medical use claims and skinny labeling, the Court of Appeal seems to make a distinction between “real” second medical indications (i.e. treatment of a new disease) and treatment of a specific patient subgroup within a known indication, the latter having a narrower scope of protection (Schering v. Teva 14 July 2014).

Patent Enforcement - Belgium (Christophe Ronse)

Validity challenges in Belgian preliminary injunction and saisie proceedings

Traditionally, Belgium has been a very patentee-friendly jurisdiction for the provisional enforcement of patents. In the framework of saisie proceedings and actions for a preliminary injunction, the Belgian tier of a European patent was considered prima facie valid unless the alleged infringer could show that the patent had not been properly validated in Belgium or that the patentee had failed to pay annuities. Revocations of the counterparts of the patent in other jurisdictions were not considered relevant to contest the presumption of validity, nor were other defenses such as prior art that had not been considered during substantial examination. This meant that preliminary injunction actions and saisies were very effective tools to enforce patents, even where validity was heavily contested.

In 2012 and 2013, generic manufacturers failed to set that case law off-course. In its judgment of 5 January 2012 in Novartis v Mylan, the Cour de Cassation confirmed that Novartis could rely on its patent for a sustained-release formulation of fluvastatine to obtain interim relief, even though the European patent had been revoked by the Opposition Division of the European Patent Office. The court referred to Article 106 of the European Patent Convention, implying that Novartis’ appeal to the Technical Board of Appeal had suspensive effect and therefore neutralized the OD decision. In Lundbeck v. Eurogenerics (24 June 2013), that reasoning was taken one step further to hold that an appeal against a Belgian national court’s judgement to revoke a patent implied that the patentee could still seek interim relief on the basis of that patent against another alleged infringer.

A judgment of 12 September 2014 issued by the Cour de Cassation in Syral v. Roquette Frères appears to have put a dent in European patents’ armour of presumed validity in saisie proceedings. In this judgement, the Cour de Cassation held that foreign decisions regarding the validity of a counterpart of the patent invoked in Belgium could not be cast aside merely because they have no legal effect in Belgium. Nor does the suspensive effect of an appeal against a substantive decision regarding validity

take away the relevance of the considerations on validity in that decision. The Cour de Cassation held instead that, in assessing validity in *saisie* proceedings, all relevant circumstances should be taken into account. Since this judgment, the President of the Brussels commercial court – the court that has exclusive jurisdiction to hear patent cases in Belgium since 1 January 2015 – has issued conflicting decisions on *prima facie* validity. These decisions suggest that while it is clear that the previous criterion of quasi-irrefutable presumption of validity no longer applies, the court has not yet been able to figure out an alternative. Further guidance from the Brussels court of appeal and, ultimately, the Cour de Cassation seems necessary. The assessment of patent validity in provisional enforcement actions in Belgium is a pendulum in search of a new equilibrium.

United States - Li Feng, John Todaro

Patent Eligibility (Li Feng)

In the recent few years, the US Supreme Court has established a more rigorous framework for assessing patent subject matter eligibility. In the realm of pharmaceutical and biotechnology patents, the Supreme Court found that a claim for treating a disease that employs a natural law using “well-understood, routine, conventional” steps is not eligible for a patent. The high Court also found that an isolated DNA segment is a product of nature, thus not patentable, but that cDNA is patent eligible because it is not naturally occurring. The Court of Appeals for the Federal Circuit has been strictly following the guidance of the Supreme Court, for example, recently striking down claims covering a successful genetic test for prenatal defects, because the claims at issue involved conventional, routine, and well understood applications of a natural phenomenon. While the court’s decisions may be vague regarding certain particular situations, practitioners may find the examination guidelines on patent eligible subject matter by the United States Patent and Trademark Office (“USPTO”) useful, as the guidelines set forth specific examples of what the USPTO considers patent eligible or not.

Use of Post-Filing Evidence in Support of Patentability (Li Feng)

In the US, post-filing evidence has long been a critical component in an analysis involving nonobviousness. The pharmaceutical industry, in particular, has relied extensively on secondary considerations such as unexpected results. Recently, the Federal Circuit instructed that, to rebut an obviousness challenge, the unexpected results must be a difference in kind rather than a difference in degree. For example, the court considers that results that differ by small percentages are differences in degree rather than in kind.

Post filing evidence is usually not allowed in the US to establish whether a claimed invention is enabled because enablement is determined as of the filing date of a patent application. However, post-filing publications may be relevant to show that a person of ordinary skill in the art could practice the invention as of the filing date without undue experimentation by providing evidence of the state of the art at the relevant time period.

Post-Grant Proceedings (Li Feng)

The America Invents Act introduced several options in the US, including Post Grant Review (“PGR”) and Inter Partes Review (“IPR”), for challenging patents before the Patent Trial and Appeal Board at the USPTO. PGR can be filed within 9 months of patent issuance with a broad range of challenges, while IPR can be filed within the later of 9 months after issuance or conclusion of a PGR, if any, but is limited to challenges based solely on patents or printed publications.

A super majority of the post-grant petitions filed relates to electrical/computer or mechanical/business method patents and only a small percentage (~10%) of the petitions filed have challenged bio/pharma patents. The petitioners have been quite successful in these post grant proceedings. For example,

institution rate (i.e., the acceptance rate for the proceedings to move forward) for bio/pharma IPR petitions is over 60% and claim cancellation rate for bio/pharma patents is around 75%.

In view of the high claim cancellation rates, lower expenses, and quicker turn around, many patent owners are concerned that post grant proceedings will become the go-to method by generic drug manufacturers to challenge pharmaceutical patent validity instead of challenging the patents in a district court, which usually affords name brand companies a regulatory stay of the generic drug application. Moreover, hedge fund managers, who typically would have no standing to participate in a district court litigation challenging a drug patent, have begun to file IPRs attempting to manipulate pharmaceutical company stock prices. In light of the anticipated onslaught of challenges, pharmaceutical companies are calling on Congress to institute a standing requirement for post-grant proceedings to prevent third party abuse of the proceedings by “reverse patent trolls.”

Nevertheless, it is still too early to tell what sort of impact the post grant proceedings will have on generic drug litigations. The early statistics suggest that it is an attractive alternative to district court litigation for generic manufacturers, but the sample size for bio/pharma IPRs and PGRs is too small to draw any concrete conclusions.

Patent/Antitrust Issues in Pharma (John Todaro)

Reverse Payment Settlements

In its decision *FTC v. Actavis*^[1], the U.S. Supreme Court ruled that pharmaceutical patent infringement settlements, including settlements of Hatch Waxman litigation, are subject to antitrust scrutiny under the “rule of reason” approach. The case concerned a Hatch Waxman settlement in which the patent owner Solvay entered a “reverse payment” settlement of litigation with generic manufacturer Actavis. Under the settlement terms, Actavis agreed to keep its product off the market until expiration of the Solvay patent term, and the patent owner Solvay agreed to pay Actavis.

The Supreme Court reversed the Court of Appeal’s ruling, which would have provided something close to antitrust immunity for reverse payment settlements. However, the Court declined to accept the FTC’s argument that reverse payment settlements are presumptively unlawful under the antitrust laws. Instead, the Court ruled that reverse payment settlements are subject to a rule of reason analysis. The Court expressly refused to provide much specific guidance to the district and court of appeal courts, stating that “[w]e . . . leave to the lower courts the structuring of the present rule-or-reason antitrust litigation.”

A jury trial on the *FTC v. Actavis* standard was decided in November 2014, in *In re Nexium*.^[2] The jury determined that the settlement agreement was anticompetitive. The settlement at issue did not involve reverse payments from the innovator to the generic, but rather consisted of an exclusive license and manufacturing and distribution agreement. Despite the finding that the settlement was anticompetitive, the case was decided in favour of the defendants Astra Zeneca. The jury found a lack of causation, in that there was insufficient evidence that the generic would have been able to obtain FDA approval of its product.

In 2015, the U.S. Court of Appeals for the Third Circuit ruled that under the Supreme Court’s *FTC v. Actavis* decision, pharmaceutical settlements will face antitrust scrutiny under the rule of reason test even if the agreements do not call for cash payments.^[3] In contrast, a district court in the First Circuit has dismissed an *FTC v. Actavis* antitrust challenge to a pharmaceutical patent settlement on the grounds that the agreement did not call for a cash payment.^[4] The *Loestrin* case is now on appeal to the First Circuit Court of Appeals.

The Supreme Court of California decided in May 2015 that reverse payment settlements are subject to antitrust scrutiny under state law.^[5] The state Supreme Court relied on the *FTC v. Actavis* decision. The court outlined a rule of reason test under California law, and remanded to the trial court for trial under

the California standard.

Product Reformulations

In May 2015, the U.S. Court of Appeals for the Second Circuit enjoined Actavis from phasing out its original NAMENDA product in favour of its newer once daily extended release version (NAMENDA XR).^[6] Generic competition for NAMENDA IR would enter the market in July 2015. The Court found that Actavis' action in announcing that it would effectively discontinue NAMENDA IR in favor of its patented NAMENDA XR product.

The court found a violation of section 2 of the Sherman Act, which prohibits monopolies. The decision suggests that pharmaceutical companies will be subject to antitrust challenge if they seek to withdraw a product before generic competition, and to move patients to a second generation product.

Patent Licenses Requiring Premerger Approval

The Court of Appeals for the District of Columbia upheld an FTC rule that a pharmaceutical exclusive distribution agreement in which the patent licensor retains manufacturing rights must still undergo premerger notification and FTC review under the Hart Scott Rodino Act (HSR).^[7] The FTC rule had been challenged by the Pharmaceutical Research Manufacturers' Association as outside the authority of the FTC administrative agency. PhRMA relied in part on the argument that the rule targeted a single industry (the pharmaceutical industry). The court ruling upholds the authority of the FTC to issue broad regulations under HSR.

Japan - (Takashi Fujita, Makoto Ono)

Interpretation of Product by Process Claims for Determining Patent Infringement (Takashi Fujita)

Japanese Patent Number 3737801, derived from WO02/30415, claimed:

Pravastatin containing less than 0.5w% of pravastatin lactone and less than 0.2w% of epiprava produced by a process comprising the following steps of :

- (a) forming a condensed organic solution of pravastatin,
- (b) precipitating pravastatin as its ammonium salt,
- (c) purifying the ammonium salt by recrystallization,
- (d) transposing the ammonium salt to pravastatin sodium, and
- (e) isolating pravastatin sodium.

Allegedly infringing product:

Medicament "pravastatin sodium salt 10 mg", which contains less than 0.5w% of pravastatin lactone and

less than 0.2w% of epiprava.

Summary from Holdings:

(1) Technical scope

The IP High Court decided in gist that, (1) for an invention of a product, when the scope of claims states a process to manufacture the product, it is impermissible to interpret the technical scope excluding said manufacturing process unless there are special circumstances that it is impossible or difficult to state the constitution of the product, and (2) determined that the process to manufacture the appellee's products does not fulfill the requirements for the manufacturing process of Invention 1.

However, the Supreme Court stated that the above (1) in the IP High Court decision is in error, and held that the effect of a product patent encompasses any product that is the same as the patented product in respect of structure, characteristics etc., irrespective of its process of manufacture. Thus, even if a process to manufacture is mentioned in a product claim, the technical scope of the patented invention is determined to be any product identical with the product produced by the process in respect of structure, characteristics etc., that is, technical scope of the patented invention covers the product per se.

(2) Clarity of Claim

Patent system is intended to contribute to the development of industry by stimulating innovation through granting an exclusive right of patent to those who disclose the invention.

Section 36 Paragraph 6 Item 2 states that description of a claim must meet requirements that the invention for which a patent is sought is clear.

The product-by-process claim is considered to meet requirements under section 36 paragraph 6 item 2 only when there exist special circumstances where it is impossible or obviously impractical to define the product directly through its structure, characteristics etc.

Acceptability of Post Filing Data in Japan (Makoto Ono)

Inventive Step

The IP High Court ruled in Procter & Gamble v. Japan Patent Office (handed down July 15, 2010) that, in general, the specification as filed should describe the effects of the claimed invention, and therefore the JPO should not accept Post Filing Data that are submitted to show advantageous effect which is not described in the specification as filed. However, the Court also ruled that the JPO should accept Post Filing Data as evidence of inventive step if the specification as filed reasonably conveys to those skilled in the art that the Applicant had contemplated the unexpected results.

Enablement

In Japan, another important issue related to Post Filing Data is enablement. The JPO has just made an official announcement that it will amend the Examination Guidelines in this regard. Specifically, the existing Examination Guidelines include specific requirements for medical use applications (i.e. those claiming a method of treating patients, a compound or composition for use in treating patients or Swiss-style) which stipulate that the specification as filed must provide pharmacological test results (essentially in vivo test results) and that it is not allowed to show the pharmaceutical test results by Post Filing Data.

However, new Examination Guidelines will delete these requirements, though the guidelines still state that the JPO will not accept Post Filing Data if they aim at curing insufficiency of disclosure and will only accept the data if they aim at confirming the teachings of the application.

Australia - (Carolyn Harris, Andrew Blattman)

Australian Report - July 2015 (Carolyn Harris)

A. Legislative Changes

Australia's TRIPS obligations have been implemented by the Intellectual Property Laws Amendment Act 2015 (Cth) which was assented to in February 2015. To assist a least developed country with public health problems, Australian pharmaceutical manufacturers can now apply to the Federal Court of Australia to obtain compulsory licences to manufacture and export generic versions of patented pharmaceutical products. These compulsory licences are issued with particular requirements including payment to the patentee as ordered by the Federal Court.

B. Reviews

The Therapeutic Goods Administration (TGA) has been reviewing the nomenclature system it uses for biosimilars. Final decisions have not been made but consideration has been given to the system proposed by the WHO's INN Expert Group. The TGA is also reviewing its guidelines in relation to the evaluation of biosimilars.

C. Case Law

Apotex Pty Ltd v Sanofi-Aventis Australia Pty Ltd [2013] HCA50

This case confirmed that methods of medical treatment of humans are patentable under Australian law.

Warner-Lambert Co LLC v Apotex Pty Ltd [2014] FCAFC 59

This case confirms that 'skinny labelling' will not necessarily avoid a finding of indirect infringement of a patent. If it is clear that the supplier has 'reason to believe' the pharmaceutical supplied would be used as claimed, the use of skinny labels and/or material directed to pharmacists or medical practitioners recommending use only in relation to registered indications will not avoid infringement.

Otsuka Pharmaceutical Co., Ltd v Generic Health Pty Ltd (No 4) [2015 FCA 634

Swiss-style claims have not previously received judicial consideration. This case establishes that Swiss-style claims are directed to a method or process of manufacturing a medicament and not to the product itself.

Patent Term Extensions (Andrew Blattman)

In *Alphapharm Pty Ltd. v. H Lundbeck A/S* [2014] HCA 42, the majority of the High Court of Australia has confirmed that extensions of time to apply for PTEs are permissible in Australia.

The decision confirms that where because of a genuine error or omission a patentee fails to apply for an extension of a pharmaceutical patent term within the prescribed time frame (six months from either the date the patent was granted or the date of inclusion on the Australian Register of Therapeutic Goods (ARTG)), the Commissioner of Patent may grant the patentee an extension of time to do so provided both the application for extension of time and the application for PTE are filed while the patent is still in force.

Patent Term Extension Prompts Reexamination (Andrew Blattman)

In *Biogen Idec International GmbH* [2015] APO 17, the Commissioner instigated reexamination of Patent No. 752733 which relates to pharmaceutical compositions during the course of assessing an extension of term application. As a result of the re-examination the patent was found to be invalid.

During the course of assessing the extension of term application, the Commissioner re-examined the patent of her own volition and found the patent to be invalid. Biogen was allowed a period of 2 months in which to file amendments.

Briefly, the decision highlights that an application for an extension of term may serve as a catalyst for re-examination of a patent. As such, any questions concerning validity of the patent ought to be considered prior to making an extension application.

Brazil - (Rana Gosain)

Update on ANVISA's Examination of Pharmaceutical Patent Applications

Resolution RDC 21/2013 resulted in a new workflow for pharma patent applications. With the advent of the new workflow, pharma cases are sent directly to the National Sanitary Surveillance Agency (ANVISA) for examination supposedly taking into consideration public health issues. ANVISA Examiners determine whether or not an application poses risks to public health and this will result in either a grant or denial of "prior consent" in respect of the pharma applications. Those patent cases which receive "prior consent" will be returned to the PTO for further prosecution.

In practical terms, the applicant receives an unfavorable opinion denying "prior consent" and has ninety days from receipt of said opinion to submit a reply. If the applicant fails or chooses not to submit a reply, ANVISA will deny "prior consent." All written opinions reporting the conclusion of ANVISA's analysis regarding "prior consent" (both granting and denial) are published in the Brazilian Official Gazette. If "prior consent" of an application is denied by ANVISA, the applicant can file an administrative appeal to the Appeal Board of ANVISA within sixty days of receipt of the opinion. In the event the appeal is held to be unfounded, the denial of "prior consent" will be ratified by ANVISA. After ratification of the denial, the application will be sent back to the PTO. At this point, the PTO will essentially "shelve" the application for an unknown period of time. Presently, no patent application for which "prior consent" has been denied, under the current workflow, has been shelved by the PTO.

The majority of Brazilian attorneys hold the "shelving" of a patent application without substantive examination by the PTO a violation of the law and unconstitutional. The rationale is that on paying an examination fee to the Agency (PTO), an applicant is entitled to have its application examined by the Brazilian PTO (which is specifically authorized under the Brazilian constitution to review patent applications).

In the event an application is "shelved" by the PTO, the applicant can file an administrative appeal. Administrative appeals filed at the Brazilian PTO are analyzed by a Board of Examiners. If the appeal is

rejected, the only available recourse for the applicant is to file a lawsuit in a Brazilian Federal Court against ANVISA's intervention in the substantive examination of the pharmaceutical patent application and against the PTO's refusal to examine the application.

Approximately twenty lawsuits have been filed against ANVISA in connection with its denial of "prior consent" under the previous workflow (where applications were first examined by the PTO and then sent to ANVISA for examination based on public health issues). In the majority of these lawsuits, the court has reversed ANVISA's denial or "prior consent". In these cases, the court has held that ANVISA must limit its review of an applicant's patent application solely to health issues, meaning that the PTO approved a patent application directed to a pharmaceutical product or process then a patent should be granted.

Court decisions in favor of patentees have been issued in District Courts in Brasilia. Some Courts issued preliminary injunctions ordering ANVISA to grant "prior approval" of patent applications on the grounds that ANVISA did not have the competence to conduct "patentability" examination.

A recent unexpected decision from the Federal District Court in Rio de Janeiro denied a preliminary injunction and ruled that ANVISA is competent to examine a pharma patent application in terms of patentability requisites. In all likelihood this decision will be used by ANVISA to assert its legitimacy to examine pharma patent applications and Patentees and Brazilian attorneys will have to be creative to overrule this decision.

India - (Hari Subramaniam, Malathi LaskhmiKumaran)

Summary of Patent Issues in 2015 (Hari Subramaniam)

The past couple of years have witnessed several judicial pronouncements by various High Courts and by the Intellectual Property Appellate Board (IPAB) that have resulted in significant changes in practice due to interpretation and clarification of existing statutory provisions. The IPAB and the High Courts of New Delhi, Mumbai and Chennai have been active in patent law interpretation on both procedural and substantive issues. These decisions have resulted in certainty in some areas of practice and caused a bit of concern in respect of the others. Some of these decisions are discussed below:

I Legislative Update

Patent Rules amended

Effective February 28, 2014, the new Patents (Amendment) Rules 2014 have come into force. The new Rules primarily revised the government fees four hundred percent for large entities. It has also categorized the applicants as "small entity" or medium entity".

II Recent Developments at the Patent Office

Indian Patent Office starts functioning as International Searching Authority (ISA) and International Preliminary Examining Authority (IPEA).

On September 8, 2014, a new building with state of art facility was inaugurated for the functioning of the Indian Patent Office as International Searching Authority (ISA) and International Preliminary Examining Authority (IPEA) under the Patent Cooperation Treaty (PCT). Work has already started on this front and India has marked its name among the other ISA/IPEA recognized under the PCT.

Electronic filing of applications and payment of fees online has now become a reality.

Guidelines for examination of patent applications: With a view to streamline the examination of patent applications and to give critical guidance to examiners for examining applications from various technical domains, the Patent Office has initiated issuance of guidelines for examiners. Till now, such guidelines have been issued and made public for Biotechnology related inventions as well as Traditional Knowledge and Biological Materials. In the last year, draft guidelines have been made available for examination of Computer Related Inventions (CRI) and Pharmaceutical inventions. Stakeholder meetings have been held and the final versions will be issued shortly.

III Judicial pronouncements

The Supreme Court has held that a person cannot keep attacking a patent

In *Dr. Aloys Wobben and Ors. vs. Yogesh Mehra and Ors.* (Supreme Court, 2014), the Supreme Court of India has passed a landmark judgment restraining a person from taking multiple shots at a patent.

In particular, the judgment laid down the following rules:

- If prior to the infringement suit, a defendant has filed revocation under Section 64(1) before the IPAB, then the defendant would be disentitled to file a counter claim;
- If the defendant counter claims for revocation in a suit, he cannot thereafter file revocation under Section 64(1) before the IPAB; and
- If any interested person has filed a post-grant opposition under Section 25(2), he is barred from filing revocation before the IPAB under Section 64(1) or filing a counter claim as a defendant in an infringement suit.

Mumbai High Court upholds compulsory license to NATCO

In 2012, the Indian Patent Office granted a compulsory license in favour of Hyderabad based Natco Pharma Limited (“Natco”) for the anti-cancer drug, Sorafenib Tosylate, used for palliative treatment of liver and renal cancer. The drug is claimed by an Indian patent, being no. 215758 that was granted to Bayer Corporation (“Bayer”) in 2008. The drug, sold by Bayer under the brand name ‘Nexavar’, was launched in India in 2008. Bayer appealed the Controller’s order at the IPAB. IPAB ruled in favour of Natco, reaffirming the conclusion arrived at by the Controller General. The IPAB however clarified that import per se would qualify as “working the patent” within the scope of the Patents Act. However, the Patentee will be required to give reasons as to why the drug cannot be manufactured locally.

Bayer had appealed before the Bombay High Court against the IPAB order which upheld the Compulsory License for Nexavar issued by the Indian Patent Office to Natco. In a recent order, the Bombay High Court upheld the IPAB decision that the grant of compulsory licenses is to be considered on a case to case basis. The High Court held that “reasonable requirements with respect to the patented product was not satisfied” because, Bayer’s drug could meet only 2% of the demand, and that too was at a huge cost which Bayer could not justify.

Interim injunctions granted in several pharmaceutical patent cases

The Indian High Courts, particularly the Delhi High Court is no longer restrained in granting interim injunctions in pharmaceutical patent matters where there is (a) a prima facie case of infringement; (b) a prima facie case of validity of the patent; (c) absence of delay in initiating action; and (d) balance of convenience in favour of the Patentee.

Novartis patent suits for Vildagliptin:

Novartis initiated a series of quia timet actions before the Delhi High Court against various Indian pharmaceutical companies for the enforcement of its Indian Patent No. 212815 for Vildagliptin.

Novartis is marketing Vildagliptin in India as two separate pharmaceutical products. While one contains Vildagliptin only as the Active Pharmaceutical Ingredient (API) under the brand name GALVUS, the other comprises Vildagliptin and Metformin Hydrochloride sold under the brand name GALVUSMET. Vildagliptin is believed to be the first gliptin developed, second being Sitagliptin (marketed by Merck under the brand name JANUVIA). Incidentally, Merck had successfully obtained interim orders of injunctions against several Indian companies in the previous year, which prima facie, violated its patent for Sitagliptin.

Novartis initiated infringement suits before the Delhi High Court against the entities who had been granted permission to manufacture and sell Vildagliptin and/or Metformin Hydrochloride pharmaceutical products.

In all, Novartis has initiated quia timet action by way of infringement suit filed before Delhi High Court against seven pharmaceutical companies namely Zee Laboratories Ltd., Wockhardt Ltd., Biocon Limited, Alembic Pharmaceuticals Ltd., Cadila Healthcare Ltd., Glenmark Generics Ltd. and Bajaj Healthcare Ltd.

Novartis' main contention was that, since the Defendants had been granted the permission to manufacture Vildagliptin pharmaceutical products it was established that the Defendants intended to launch such product which will constitute infringement of the suit patent. Novartis also successfully contended that since the Defendants had not yet launched their products in the market, the balance of convenience was in favour of granting injunctions against them.

Note on the Position of Law in India pertaining to Acceptability of Post Filing Data to Overcome Lack of Inventive Step Objection (Malathi LaksmiKumaran)

The question as to permissibility of such post-filing data has been dealt with in India only at the level of the IPAB, a specialized tribunal created to adjudicate appeals from the decisions of patent offices as well as applications for revocation of patents. While the Patent Office and the IPAB as a matter of practice have relied on such data for the purposes of overcoming objections under Section 3 of the Patents Act, 1970 (hereinafter referred to as the Act); however regarding the question of admissibility of post-filing data for determination of inventive step, the IPAB has held that the Act does not permit the same.

Statutory provision

There are no express provisions under the Act that either permit or forbid the admissibility of post-filing data for the purpose of proving inventive step, or to show that the claimed invention does not fall within the scope of any of the provisions under Section 3 of the Act.

In fact, this issue has not been addressed either in the Manual of Patent Office Practice and Procedure (published on March 22, 2011) or in the Guidelines for Examination of Patent Applications in the Field of Pharmaceuticals, published by the Office of Controller General of Patents, Designs and Trademarks in October 2014.

However, as stated above, the Patent Office and the IPAB as a matter of routine practice relies upon post-filing data for the purpose of overcoming objections under Section 3 of the Act, specifically objections with respect to Section 3(d) and Section 3(e) of the Act^[8].

Judicial Position

The issue of post-filing data for the purpose of establishing inventive step has specifically come to be considered at the IPAB level on the following two occasions, and in both situations the interpretation by the IPAB has been that the Act does not allow for such data to be considered to establish inventive step.

In the case of Fresenius Kabi Oncology Ltd. v. Glaxo Group Ltd. & Ors.^[9] Glaxo's patent directed to "Quinazoline Ditosylate Salt Compounds" (Patent No. 21171) was challenged by Fresenius Kabi before the IPAB as lacking inventive step and thus liable to be revoked under Section 64(f) of the Act. In response to said objection, Glaxo while relying upon the decision of a US Federal Circuit in Pfizer v. Apotex^[10] dealing with a similar issue submitted the following secondary considerations to emphasize the inventiveness of the impugned invention.:

- TYKERB® is the only approved reversible dual protein kinase inhibitor for the treatment of breast cancer.
- The commercial success of TYKERB® has been provided by the affidavit of Mr. Kaizad Hazari.
- There has been a long felt need in the world of medicinal chemistry as shown in Respondent No.1 Exhibit 1 of M.P. filed on 15th January 2013.
- The unexpected result achieved by TYKERB® as an effective treatment for breast cancer has unique potential benefits beyond those of Trastuzumab, a large molecular weight molecule (Herceptin) which is a recombinant humanized monoclonal antibody.
- Granted patents have been issued in more than 30 countries.

The IPAB while analyzing the above submission held that under the Act, a patent is revoked if the invention is shown to be obvious and such a conclusion cannot be altered by relying upon any secondary considerations. It was further held that the prior art cited by the applicant were sufficient to render the invention obvious.

Although, the secondary considerations cited above are not typically the post-filing data routinely submitted to emphasize the inventive step of pharmaceutical inventions, it was this observation that was relied upon by the IPAB to deny admissibility of the typical post-filing data routinely submitted in the subsequent case of Ajanta Pharma Ltd. vs. Allergan Inc. & Ors.^[11]

In said case, the IPAB was faced with Ajanta's application for revoking Allergan's patent directed to "Hypotensive Lipid (prostaglandin derivatives) and Timolol composition and methods of using same" (Patent No. 212695) on the ground of lack of inventive step under Section 64(f) of the Act among other grounds.

In response to said challenge, Allergan adduced post-filing data in the form of an affidavit which comprised of a tabulated result of safety and efficacy studies using a fixed combination of bimatoprost and timolol, serial administration of bimatoprost and timolol and bimatoprost monotherapy to prove striking advantages such as reduced side effects. Further, Allergan relied upon the following US case law to assert the admissibility of post-filing data to prove inventive step of the impugned invention:

Genetics Institute, LLC. Vs. Novartis Vaccines and Diagnostics (655 F.3d 1291)

Knoll Pharmaceutical Company, Inc. v. Teva Pharmaceuticals USA, Inc. (367 F.3d 1381)

The IPAB while relying upon its earlier judgment cited above (IPAB Order No. 161 of 2013) held that post-filing evidence cannot be considered for obviousness analysis. The impugned patent in said case was ultimately revoked for lacking inventive step and violating Section 8 of the Act.

In conclusion, it is stated that the above judgments of the IPAB suggest that post-filing data for the purpose of establishing inventive step is not permitted under the Act. However, it is important to note that no higher judicial forum (High Courts or the Supreme Court) has ever been espoused with adjudicating this issue to date and thus there exists a possibility that said determinations of the IPAB will be reversed. Moreover, in view of the above mentioned judgments of the IPAB it does not seem that the patent applicants while arguing to allow post-filing data for determining inventive step, emphasized on the importance of post-filing data or evidence in patent applications directed to pharmaceutical inventions. Hence, it is to be seen whether such an argument as to the special circumstance of pharmaceutical inventions will find favour with the IPAB and other higher judicial fora.

Note on the Position of Law in India Pertaining to Patent Linkage (Malathi LakshmiKumaran)

In India, any person interested in introducing a pharmaceutical drug in the market is required to obtain a marketing approval from the Drug Controller General of India (DCGI) under the Drugs and Cosmetics Act, 1940 (hereinafter referred to as the DCA). The legislative intent behind the DCA is to examine the safety and security of drugs and good manufacturing practices which are to be applied by every manufacturer or importer of a drug. Whereas Act establishes a regime for the grant of patent rights for any invention that is novel, inventive and capable of industrial application.

Thus, the question to be answered is whether there exists the above mentioned concept of patent linkage under the aegis of the Act and the DCA.

Position of law in India:

Statutory provision

There are no express provisions either under the Act or under the DCA that suggest that the DCGI, while granting an approval to a pharmaceutical drug under the DCA, is required to enforce a patent granted under the Act and thereby deny marketing approval to a generic version of a patented drug manufactured by a non-patentee.

Moreover, the scheme of the DCA along with the Drugs and Cosmetic Rules, 1945 (hereinafter referred to as the DCR) envisage an application for grant of marketing approval for generic version of a patented drug, in respect of which marketing approval has already been granted to the patent holder (Appendix 1A to the DCR). Further, it mandates that in such a scenario, the applicant is only required to satisfy the DCGI that its drug is bio-available and bio-equivalent to the patented drug. Therefore, the DCA read with the DCR clearly envisage a situation where marketing approval may be sought by a manufacturer of the generic version of a patented drug.

Judicial Position on Patent Linkage in India

The question as to whether Indian laws allow for Patent Linkage has come up in several cases before Indian Courts and the leading case on this aspect is Bayer Corporation & Ors. v. Cipla, Union of India & Ors.^[12]. This case decided by the Delhi High Court has established the law in India on this issue. The interpretation by the Delhi High Court in said case has been affirmed by the Supreme Court of India to the extent that it dismissed the Special Leave Petition filed by Bayer challenging the findings of the Delhi High Court on the issue of patent linkage.

Bayer filed a writ petition before the Delhi High Court seeking to restrain the DCGI from granting a drug license to Cipla Ltd. to manufacture, sell and distribute its drug for the API, Sorafenib tosylate used in the treatment of advanced renal cell carcinoma. It is pertinent to note that Bayer holds the patent (Patent No. 215758) in India for Sorafenib tosylate, which it markets under the trade name Nexavar, and Cipla sought approval from the DCGI to manufacture Sorafenib tosylate under the trade name Soranib.

One of Bayer's main contentions was that on a conjoint reading of Section 2^[13] of the DCA and Section 48^[14] of the Act the concept of patent linkage was manifest. The other major contention advanced by Bayer pertained to the fact that Cipla's drug being an imitation or a substitute to its own drug falls within the definition of a "spurious drug" under Section 17B(b)^[15] of the DCA and thus should not be granted a marketing approval.

Cipla, on the other hand essentially argued that the grant of drug regulatory approval by the DCGI cannot, by itself amount to a patent infringement. This argument was further supported by the fact that the existence of patent infringement cannot be assumed merely because the patentee states so, but has to be clearly established. It was averred that such an assessment is beyond the statutory powers of the DCGI, which is institutionally incapable of dealing with complex issues of patent scope, validity and

infringement.

Furthermore, Cipla also argued that Section 107A^[16] of the Act which embodies the Bolar Exemption clearly exempts from patent infringement any of acts of making, using or even selling a patented invention, in so far as such acts are necessary to obtain information for the filing of a drug regulatory application before the DCGI. Thus it was argued that the aim of this section is to ensure that generic drugs are introduced into the market as soon as the patent expires or is invalidated, so that consumers may benefit from this early entry of affordably priced drugs. Therefore, Cipla asserted that accepting Bayer's contentions would run contrary to the implementation of Section 107A of the Act.

Pending final adjudication in said matter, an interim order was passed by the Single Judge of the Delhi High Court on 7th Nov, 2008 restraining the DCGI from passing a final order on the application made by Cipla for grant of marketing approval for Soranib. Essentially, the Single Judge of the Delhi High Court was faced with adjudicating the following two issues based on the submissions made above:

- Whether a combined reading of the DCA and the Act leads to the conclusion that no marketing approval can be granted to applicants for drugs or formulations, of which others are patent owners, by reason of Section 2 of the DCA read with Sections 48 and 156^[17] of the Act;
- Whether drugs or formulations which infringe patents are "spurious drugs" under the DCA.

The Single Judge of the Delhi High Court by order dated 18th Aug, 2009^[18] held that Section 2 of the DCA and Section 156 of the Act do not establish the concept of patent linkage and that drugs which could possibly be infringing patent rights cannot be considered "spurious drugs" under the DCA. Interestingly, in this case the Single Judge also imposed costs to the tune of 6,75,000 INR on Bayer on the basis that the present litigation was a speculative foray and an attempt to tweak public policies through court mandated regimes. The Judge also stated that Bayer's attempts resulted in stalling an independent examination of Cipla's application before the DCGI and that it would be a travesty of justice if the court did not direct realization of costs in this case.

The Single Judge stated the following reasons for arriving at the above conclusion:

- The distinct and disparate objectives of both legislations, i.e. the DCA and the Act and the specific roles of the officials administering the provisions of the above legislations signify that there was no legislative intent to invest regulatory authorities under the DCA with functions that are exclusive to the Act.
- On a comparison with express statutory provisions in other jurisdictions such as US and China that mandate patent linkage, the lack of the same in India cannot be set right by the Courts by encroaching upon the functions of the legislature.
- An interpretation that confers adjudication as to patent infringement which is otherwise established by a court of law under the Act on regulatory authorities is beyond the Drug agencies' jurisdiction, or under law. This would result in conferring jurisdiction on one set of agencies under the DCA who do not have such jurisdiction or the wherewithal to exercise it, and simultaneously results in denuding the powers, jurisdiction and meaningful role conferred lawfully on another set of specialized statutory authorities, under the Act.
- The introduction of a patent linkage system as contemplated by Bayer would result in undermining the Bolar Exemption under Section 107A of the Act that encourages quick access to the post patent markets for generic medicines. Given India's host of public health challenges, this provision is essential to address such challenges.

The Single Judge also referred to the problems and concerns cited by European Union in its reports against the introduction of the concept of patent linkage, which is unlawful under Regulation (EC) No 726/2004 and Directive (EC) No. 2001/83.

Subsequent to the above order of the Single Judge of the Delhi High Court, Bayer preferred an appeal before the Division Bench (Two Judge Bench) of the Delhi High Court assailing the order of the Single Judge. The Division Bench by order dated 9th February, 2010 upheld the order of the Single Judge and held the following:

- The function of the DCGI is not to enforce the rights of a patent holder under Section 48 of the Act. The DCGI's powers and jurisdiction are circumscribed by the DCA and not the Act.
- Assuming that the concept of patent linkage exists as suggested by Bayer, patent holders seeking only marketing approval and not manufacturing approval in respect of life saving drugs under the DCA, would be able to block off all generic manufacturers who might have been able to make the drug available in the market at affordable prices, subject of course to their being able to successfully resist injunctions in infringement suits instituted by the patent holder. Furthermore, if the patent holder does not even apply for a marketing approval, then the drug will be virtually unavailable in India until such time the patent holder decides it should be available. Clearly, such a situation cannot be countenanced.
- The decision whether to introduce the concept of patent linkage is essentially a policy decision to be taken by the government and not by the Courts.

In conclusion, unless there is a dedicated legislation addressing the concept of patent linkage or appropriate amendments made to the DCA and the Act, India does not allow for patent linkage.

Israel - (David Gilat)

The Need to Prove the Veracity of Statements in the Patent Specification

In the background for this issue there is a tacit allegation of opponents challenging the existence of the 'problem to be solved' presented in the patent application or the veracity of the data produced by the inventor showing the advantage or utility of the invention.

This line of argument advanced by opponents (e.g. generic companies) is new and stands in misalignment with traditional concepts. It has always been assumed that the applicant requests an invention of a "true inventor" (c.f. section 6 of the Statute of Monopolies 1623). Therefore, mere claiming in a patent specification that certain results were obtained is taken to be a true statement. Making false statements would be regarded as fraud on the patent office. This is one of the basic foundations of the patent system. According to general jurisprudence, whenever a party raises a claim of fraud or like allegation, the onus on such party to show the same is heavy. Drawing parallel from general jurisprudence to patent law, one ought to conclude that the onus of proof to show that statements made in a specification are false should be very heavy. Consequently, the opponent should be obligated to conduct experiments in order to show that the applicant's statements in the specification are flawed. This seemed to be the *communis opinio* that governed patent litigations.

Discovery of documents is normally deemed unacceptable in opposition proceedings, since the question of patentability is an objective question decided on the basis of laid-open publications as viewed by a person skilled in the art on the determining date. For example, in *Pfizer Products Inc. v. Teva* (2008) it was held by the patent office that lab notebooks setting out the process of developing the invention ought not be discovered by the applicant.

Moreover, in Israel opposition proceedings are held before a patent is granted, and therefore too lengthy and cumbersome procedures, such a discovery of documents, may cause undue delay to the patent grant.

It is against this background that it has been held time and again that discovery of documents in opposition proceedings would be allowed only in exceptional cases (e.g. *Bio Technology General Corp. v. Genetech* (June 1999)).

This approach of the ILPTO was adopted regardless of the fact that the onus of proof in such proceedings rests on the applicant to show that the invention is patentable. In one exceptional case however the Registrar of Patents allowed discovery of documents in order to answer an unusual factual question relevant to the dispute: "Did a certain material (crystal) disappear and reappear?" as argued by the applicant. In this case the applicant was the only entity that could provide the necessary information to

prove the factual claims, which were relevant to the patentability of the invention (Smithkline Beecham P.L.C v. Teva (2001)).

However, recently in the framework of opposition proceedings before the patent office in Israel, there have been cases where opponents petitioned for discovery of applicant's laboratory report, in order to challenge the veracity of the statements made in the specification. Thus, in January 2014 a request for discovery of laboratory notebooks was denied because it was not directed to specific experiments and was submitted at the early stage of the proceedings, before the evidence stage [Teva v. Novartis (2014)]. Nonetheless, in said decision it was observed in an obiter dictum of the Deputy Registrar, that the requested lab notebooks may need to be revealed at the stage of evidence, in case the applicant addresses said experiments in its statement of claims or evidence.

The above discussion relates to experiments and data produced in a patent specification and has nothing to do with experiments that are conducted for the purpose of the opposition proceedings in order to show advantage etc. An order to discover data relating to such experiments was made in the matter of Unipharm v. Otsuka Pharmaceutical Co., Ltd. (2015). In said case Otsuka conducted experiments to support its claims in the opposition in order to prove novelty over the prior art [the opponent in the Otsuka case contended that the claimed crystalline form A was in fact the previously known crystalline form B]. It was held that the condition of the experiments and the interpretation of results were extremely relevant in such circumstances; therefore, the Registrar made an order for discovery.

Conclusion: It is imperative that the basic assumption of veracity of data and contentions in patent specification be maintained and the onus should remain on the opponent to show otherwise. This should be true regardless of whether the applicant relies on the patent specification in the course of the evidence or not.

PTE issues

In Israel (and as far as I am aware also in some other jurisdictions) the rules governing the obtaining of a patent term extension for pharmaceutical patents are rather strict. By way of example, a PTE application must be filed within 90 days of the drug's first registration by the Israeli Ministry of Health ("MoH"). In case the Patentee missed the deadline, the ILPTO is not empowered to retroactively extend the time for making the submission. Consequently, failure to meet the deadline may now result in loss of rights. Similarly, it is not possible to obtain more than one extension of time for response to an Office Action during the examination period of a PTE application submitted after the Commencement Date. Also, a notification regarding the grant of a U.S. PTE or a European SPC can be made up to 90 days after the expiration date of the patent, provided that the corresponding U.S. PTE and European SPC were granted before said expiration. This deadline is also non-extendible. Again, failure to meet the deadline may result in a loss of rights.

China - (Gesheng Huang)

Administrative case relating to invalidation dispute over patent named "pharmaceutical compositions and preparation method thereof for treating hyperplasia of mammary gland"^[19]

[Case Brief]

Basic information of the patent

Beijing Yadong Pharmaceutical Co., Ltd (hereinafter referred as Yadong) is patentee of the invention patent named "pharmaceutical compositions and preparation method thereof for treating hyperplasia of mammary gland".

Invalidation decision made by PRB

A third party, Shandong Huayang Pharmaceutical Co., Ltd (hereinafter referred as Huayang), asked the Patent Re-examination Board (PRB) to invalidate said patent, and evidence 1, 3 submitted by Huayang related to indication function, prescription and relevant preparation method of a medicine name “Rukuaixiao Tablet” published in the *China Pharmacopeia*. After examination, the patent was wholly invalidated by PRB for lack of inventiveness. Yadong therefore was not satisfied with said invalidation decision made by PRB and asked the First Intermediate People’s Court of Beijing for judicial review on said invalidation decision.

Trial at courts of both 1st and 2nd instance

After trial, the court of 1st instance held that, “according to counter-evidence submitted by the patentee, the total effective rate of the patented granule is 95.7%, which is higher than the total effective rate of 89.32% of the tablet of evidence 1 submitted by the invalidation petitioner, Huayang, therefore the patent possesses inventiveness required by PLC.” The invalidation decision made by PRB was therefore revoked by the court of 1st instance.

PRB was not satisfied with said decision made by the court of 1st instance, and then appealed to the Higher People’s Court of Beijing. After Trial, as court of 2nd instance, the Higher People’s Court of Beijing revoked the court decision made by court of 1st instance and supported the invalidation decision made by PRB.

Retrial at the Supreme People’s Court (SPC)

The patentee was not satisfied with decision made by court of 2nd instance, and therefore applied to the SPC for a retrial. After the retrial, SPC held that, as counter-evidence 4 did not disclose the specific detected method for the total effective rate, the court cannot tell whether the total effective rate shown in counter-evidence 4 and that of the patent were determined by the same detected method under circumstance of equal dosage and effect, therefore said comparison data of the total effective rate cannot be used to determine inventiveness of the patent. SPC further pointed out that, even if said comparison data can be accepted by the court, decompression drying steps was omitted while preparing the patented granule, so influence on active pharmaceutical ingredients was correspondingly reduced, and person skilled in the art may reasonably predict that omission of decompression drying step would improve overall efficiency of the medicine, however, the patentee did not prove with evidence that technical effect brought by the patented method had gone beyond reasonable prediction of person skilled in the art. SPC then rejected Yadong’s retrial application.

Legal Significance of the Case

In the retrial adjudication, SPC gave its opinions as follows:

1. Technical contribution which is not recorded in the specification cannot be used to claim a patent protection. And while determining whether there is unpredicted technical effect of an invention, features of technical filed to which the invention belongs shall be comprehensively considered, especially factors like predictability of the technical effect, and technical teaching of the prior art;
2. Determination of a distinguishing technical feature shall be in accordance with technical feature recorded in the patent claim;
3. As to issue of inventiveness, technical problem to be practically solved by the invention shall be determined by person skilled in the art, through reading specification of the patent involved, and in accordance with role, function or technical effect brought by the distinguishing technical

- feature in technical solution protected by the patent claim;
4. Technical effect of an invention is important factor for determining inventiveness. Compared with the prior art, if there is obvious change of technical effect in terms of quantity or quality, which is brought by the invention involved, and such change of technical effect goes beyond reasonable prediction of person skilled in the art, it can be determined that the invention involved possesses unpredictable technical effect. And while determining whether there is unpredictable effect, features of technical filed to which the invention belongs shall be comprehensively considered, especially factors like predictability of the technical effect, and technical teaching of the prior art. Generally, the more specific the technical teaching is, the higher predictability of the technical effect will be.

Patent Invalidation case relating to patent named “Benzamide Histone deacetylase inhibitors with differentiation and anti-proliferation activity and its pharmaceutical formulation ”

Patentee: Shenzhen CHIPSCREEN BIOSCIENCES LTD.

Third Party: Dr. Hunt Lab LTD. (translated from its Chinese name)

[Case Brief]

This case related to the core patent of the compound of the Chidamide which was a Chinese self-innovative drug, and the Patent No was ZL03139760.3. This drug has good therapeutic effect on the treatment of T cell lymphoma and has been approved by China Food and Drug Administration in December, 2014. The Phase I clinical trial research in U.S. Food and Drug Administration has also been completed for this drug. Against this patent, the petitioner deemed that it did not comply with Article 22(3) of the Patent Law etc, and thus the patent should be invalidated. The PRB had constituted a Panel including 5 Examiners and based on the amended claims filed by the patentee, made a Decision with No. 24591 in which the patent right was maintained as valid.

Specifically, the case related to the amendments in the invalidation procedure in which the compounds in the Markush claims were amended into a specific compound. The PRB believed that although this amendment did not belong to the deletion of the technical solutions, i.e., not belong to the specified amending ways in the Guidelines for Examination, the specific compound after the amendments was recited clearly in the specification and belonged to the core of the present invention.

Moreover, the legislative purpose of the Patent System is to encourage the invention and creation. The specific compound after amendments has been disclosed as core content in the specification and has been covered by the protection scope of the original claims. In addition, the allowance of the amendments will not lead to problems regarding to the publication to the society. Therefore, in order to contribute to concentrating to the essence of the invention during the confirmation of the Patent right when judging the technical contribution of the patent, the PRB believed that the amendments complied with the purpose of limiting the amending way by the Guidelines for Examination and thus the amendments can be accepted as exceptions.

[Comments]

This case reflects a trend that the Chinese medicine manufacturer has changed its attention from “Chinese manufacture” into “Chinese creation” and thus has deep influence in the pharmaceutical industry. This case related to the amendments on the claims during the invalidation procedure. During the Examination, the PRB had studied the relevant examination criterions. Therefore, this case has provided positive and meaningful reference for the further examination on similar cases and for the improvement of the relevant examination criterions.

Footnotes

1. [^ 133 S. Ct. 2223 \(2013\).](#)
 2. [^ In Re Nexium \(Esomeprazole\) Litigation, No.](#)
 3. [^ King Drug Co. v. SmithKline Beecham, No. 140-1243 \(3d Cir. June 26, 2015\).](#)
 4. [^ In re Loestrin 24 Fe Antitrust Litigation, No. 14-2071 \(D. Mass.](#)
 5. [^ Cipro Cases I and II, No. S 198616, 2015 Westlaw 2125291 \(Cal. May 7, 2015\).](#)
 6. [^ New York v. Actavis, No. 14-4624 \(2nd Cir. May 22, 2015\)](#)
 7. [^ Pharmaceutical Research and Manufacturers of America v. FTC, 1:13-cv-01974 \(D.C. Cir. June 9, 2015\).](#)
 8. [^ Sun Pharmaceutical Industries Ltd. v. Cipla Ltd. \(Patent No. 206218\); Controller's Order dated 25th Aug, 2014 Section 3\(e\) Monsanto Technology LLC v. Controller of Patents & Ors. IPAB Order No. 146 of 2013 dated, 5th July, 2013 \(Section 3\(d\)\)](#)
 9. [^ IPAB Order No. 161 of 2013 dated, 27th July, 2013](#)
 10. [^ Pfizer, Inc. v. Apotex, Inc., No. 06-1261 \(Fed. Cir. Mar. 22, 2007\)](#)
 11. [^ IPAB Order No. 172 of 2013 dated 8th Aug, 2013](#)
 12. [^ 2010\(43\)PTC12\(Del\)](#)
 13. [^ Section 2 of the Drugs and Cosmetics Act, 1940. Application of other laws not barred.—The provisions of this Act shall be in addition to, and not in derogation of, the Dangerous Drugs Act, 1930 \(2 of 1930\), and any other law for the time being in force.](#)
 14. [^ Section 48 of the Patents Act, 1970 Rights of patentees Subject to the other provisions contained in this Act and the conditions specified in section 47, a patent granted under this Act shall confer upon the patentee— \(a\) where the subject matter of the patent is a product, the exclusive right to prevent third parties, who do not have his consent, from the act of making, using, offering for sale, selling or importing for those purposes that product in India; \(b\) where the subject matter of the patent is a process, the exclusive right to prevent third parties, who do not have his consent, from the act of using that process, and from the act of using, offering for sale, selling or importing for those purposes the product obtained directly by that process in India.](#)
 15. [^ Section 17B in the Drugs and Cosmetics Act, 1940 17B. Spurious drugs.—For the purposes of this Chapter, a drug shall be deemed to be spurious,—\(a\) if it is manufactured under a name which belongs to another drug; or \(b\) if it is an imitation of, or is a substitute for, another drug or resembles another drug in a manner likely to deceive or bears upon it or upon its label or container the name of another drug unless it is plainly and conspicuously marked so as to reveal its true character and its lack of identity with such other drug; or \(c\) if the label or container bears the name of an individual or company purporting to be the manufacturer of the drug, which individual or company is fictitious or does not exist; or \(d\) if it has been substituted wholly or in part by another drug or substance; or \(e\) if it purports to be the product of a manufacturer of whom it is not truly a product.](#)
 16. [^ Section 107A of the Patents Act, 1970 Certain acts not to be considered as infringement For the purposes of this Act,— \(a\) any act of making, constructing, using, selling or importing 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; \(b\) importation of patented products by any person from a person who is duly authorised under the law to produce and sell or distribute the product, shall not be considered as a infringement of patent rights.](#)
 17. [^ Section 156 of the Patents Act, 1970 Patent to bind Government Subject to the other provisions contained in this Act, a patent shall have to all intents the like effect as against Government as it has against any person.](#)
 18. [^ 2009 \(41\) PTC 634 \(Del\)](#)
 19. [^ \(2013\)Zhi Xing Zi No.77/ \(2013\) 知行字第77号](#)
- 3) Any recommendation for AIPPI involvement/action (describe what involvement/action is recommended and why, by whom and relevant time frames)
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The Committee does not have any specific recommendations for action at present other than monitoring the various matters summarized above. However, the Committee intends to be proactive in identifying

opportunities for supporting and promoting Intellectual Property Rights in the pharma sector. Areas of particular concern include the use of post-filing data in inventive step rejections, patent term extension practice around the world, patent/antitrust issues affecting the pharma sector, patent linkage, and second medical use claims. Interim meetings by teleconference will of course be planned at our meeting in Rio.

4) Plan for the activities of the Standing Committee for the next reporting period highlighting any priorities

It is intended that the Standing Committee will hold a meeting in Rio. We will continue to monitor developments within our Terms of Reference and hold telephone conferences with members during the reporting period to gather information, as in previous years. The Committee will focus on Second Medical Use Patents, Patent Linkage, Differing Standards on the Acceptability of Using Post-Filing Data in Patent Prosecution and Supplementary Protection Certificates/Patent Term Extensions.

AIPPI

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