THE PATENTS NEWSLETTER

September 2017

From the Editor's Desk

We are bringing out a fresh edition of our newsletter after a hiatus of more than two years. And to say that much water has flown under the bridge since then would be an understatement. Our Firm, and especially the Patent Department, has grown by leaps and bounds in this period. We have expanded our teams. And the biggest piece of news is that our Founding Partner, Mr. Chander M. Lall has been elevated as a senior and is now a designated Senior Advocate. Now both the founders of Lall & Sethi, Mr. Lall and Mr. Sandeep Sethi are Senior Advocates. This is indeed a matter of pride for us.

The Intellectual Property scene in India looks encouraging. With the Government of India pushing the IP agenda with a never-before-seen zeal, we may be finally on the right path, or so we hope! The Indian Patent Office (IPO) has been upgraded and its processes streamlined. The examination and disposal of patent applications have been expedited to a considerable extent. The number of applications examined this year is twice as many as those examined in 2016 and the number of applications disposed of is three times as compared to that in 2016. It is expected that the huge backlogs will be cleared in the two years' time. As per the Controller General of the Patent Office, IPO is targeting disposal of 72,000 applications this year. The Trademark Registry is doing even better with the pendency for examination of a trademark application being reduced to one month and the examination of trademark applications increasing by 75% as compared to 2016.

The litigation scene in IP is even more interesting, with IP laws either intertwining or being at loggerheads with regulatory procedures. Biosimilars have replaced the more modest chemical compounds to be in the hot seat. India is becoming the hub of Standard Essential Patents' (SEPs) litigation. The Competition Commission of India is facing the heat in the never ending debate between monopoly and fair trade. With the Internet of Things (IoT) set to revolutionize the way we exist, Computer Related Inventions (CRIs) find themselves at cross-roads. Medical device is finding its feet, being finally decoupled from “drug” and getting its own set of rules. We bring you this and much more in this edition. We hope you enjoy! For any queries please contact us at akhanna@indiaip.com or info@indiaip.com.

Anju Khanna
Director, Patents

INDIA
D -17 South Extension-II
New Delhi 110 049
India
E: info@indiaip.com
P: +91 11 4289 9999
F: +91 11 4289 9900

SRI LANKA
Level 10, East Wing,
Ceylinco House,
69, Janadhipathi Mawatha,
Colombo 01
Sri Lanka
E: srilanka@indiaip.com

NEPAL
Lali Gurans Marg,
Ghatte Kulo,
P O Box No. 9760,
Kathmandu
Nepal
E: nepal@indiaip.com

www.IndiaIP.com

SIMILAR BIOLOGICS IN INDIA: Fighting for the bio-space

Indian pharmaceutical industry has been a leader in generics and has been dominating the world market and litigation space in India for several years. In the area of biosimilars or similar biologics, as they are called in India, the pharmaceutical industry has been making significant forays lately. It is a matter of speculation if India will generate the same kind of capabilities and dominance as it has done in the generics space. Going by the global scenario, biosimilars appear to have a promising future. It is expected that by 2020, 25% of the world's biologics sale will be for biosimilars[1]. Capturing this huge market, especially when the Governments around the world are looking for cheaper alternatives to the highly priced biologics will be a challenge, given the nature of these drugs.

There are studies that indicate that Asia (and not necessarily India) may have an advantage to capture the early biosimilar market[2] due to, amongst other reasons, Government support, regulatory framework (lower hurdles), cost advantage etc. The cost advantage that worked in favour of generics however may not work in favour of biosimilars. A biosimilar by its very nature has high cost of production and hence the cost advantage that a generic would have, is not available to a biosimilar. According to a study, empirical evidence points towards low or very little cost advantage[3] and hence where a generic would capture major share of the market within six months of its launch, this may not be true for a biosimilar.

Nevertheless, similar biologics have started to occupy the litigation space in India. Before we bring you a round-up of litigation in this area, we will touch briefly upon the regulatory scene in India vis-à-vis similar biologics.

Regulatory Environment:

In India, regulatory approvals for similar biologics are administered under the Drugs & Cosmetics Act, 1940. The first set of Guidelines on Similar Biologics was issued in 2012 and amended in 2016[4] when a new set of guidelines was issued. The 2016 guidelines (effective from August 16, 2016) are a step ahead in establishing similarity of biologicals and reduce the risk of uncertainty associated with safety and efficacy of similar biologics and overcome the limitations of the earlier guidelines. Definition of similar biologic is provided by the new Guidelines as[5] *"A Similar Biologic product is that which is similar in terms of quality, safety and efficacy to an approved Reference Biological product based on comparability."*

The new guidelines bring more clarity to the regulatory procedure. A few major points are highlighted here. The definition of "reference biologic" is now drawn to include a biologic that has been approved/licensed and marketed in International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH) country, whereas previously the definition was narrower and a "reference biologic" had to be either authorized in India or it should have been licensed and marketed for at least four years with significant safety and efficacy data, before it could be selected as a reference biologic. The quality comparison between the similar biologic and the reference biologic is now governed by **Quality Attributes** (QAs) i.e. Critical Quality Attributes (CQA) and Key Quality Attributes (KQA). The quality data submitted should indicate that there are no differences in Critical Quality Attributes (CQAs), and that all Key Quality Attributes (KQAs) are well controlled in order to allow the initiation of clinical evaluation. Further clarification is provided on Pharmacokinetic (PK) and Pharmacodynamic (PD) Studies which are now similar to Schedule Y (8)(iii) of The Drugs & Cosmetics Act, 1940 that allows PK studies to be conducted with Phase III clinical trials. Further If PD marker is not

[1] *https://advisory.kpmg.us/content/dam/kpmg/healthcarelifesciencesinstitute/pdf/2015/biosimilars.pdf* from Thomson Reuters. Biosimilars: A global perspective of a new market. BioWorld, 2014.

[2] Will Asia Go Big In Biosimilars Adoption And Manufacturing? *By Zafar Momin, Calvin Wijaya, and Paul Bernardo, L.E.K. Consulting;* Article, May 18, 2017

[3] Scientific American; Guest Blog; Will "Biosimilar" Medications Reduce the Cost of Biologic Drugs? Not necessarily - By Richard Mortimer, Alan White, Christian Fro is on March 9, 2017

[4] http://cdsco.nic.in/writereaddata/CDSCO-DBT2016.pdf

[5] http://cdsco.nic.in/writereaddata/CDSCO-DBT2016.pdf

available and the PK can be done in patients then the PK study can be combined with phase III clinical study. Clarification is also provided on Upstream Process Development (earlier known as fermentation Process) and Downstream Process.

Further the new Guidelines require an Applicant to run Phase III trials and rely on clinical references to biologic drugs not marketed yet in the country. Post-Marketing Studies (Phase IV Study) are revised in the new guidelines which defines the post marketing stage, and requirement of additional safety data to be collected is to be collected by conducting a pre-defined single arm study of more than 200 evaluable patients and compared with historical data of the reference biologic product within two years of marketing permission/manufacturing license.

Approval of a biosimilar in India involves various steps involving several government organizations such as Central Drugs Standard Control Organization (CDSCO), Review Committee on Genetic Manipulation (RCGM), Institutional Biosafety Committee (IBSC), the Genetic Engineering Advisory Committee (GEAC), the Food & Drugs Control Administration (FDCA) and the Institutional Animal Ethics Committee (IAEC). Regulatory approvals for biosimilars are sought by filing applications to initiate studies that are approved by CDSCO and RCGM. Once an approval to initiate studies is granted, the Applicant is required to furnish information with regards to the manufacturing process and product characterization.

As evident from the table above the regulatory process has been much streamlined. Implementation and merits of the new guidelines will be established only when the same is put to test in Courts.

Litigation

In past few years, biosimilar litigation has raised questions on the procedure to be followed by the regulatory authorities while granting approvals for a similar biologic. One of the major litigations is by Roche for the drug Trastuzumab, used in the treatment of cancer, against Biocon, Mylan, Cadila and Reliance.

Roche Products (India) Pvt. Ltd(Roche) sued Biocon Limited (Biocon) and Mylan Inc. (Mylan) restraining launch of their respective biosimilar drugs, CanMab and Hertraz.[6] Roche asserted its rights on the innovator molecule **"Trastuzumab"** sold under the brand name of HERCEPTIN, alleging passing off, trademark infringement, copyright infringement *inter alia*, reliefs in the suit. On February 5, 2014, on interim order was passed against Biocon and Mylan in claiming any similarity with Plaintiff's drugs.

While the instant case was being heard another suit was filed by M/s Genentech Inc. (Genetech), Roche Products (India) Private Limited and F. Hoffmann-La Roche AG along with interim application against Reliance Life Sciences Private Limited on October 29, 2015[7], challenging the regulatory approvals obtained by Reliance for their drug TrastuRel i.e. biosimilar of Roche's drug Trastuzumab. Genetech sought an injunction restraining the Drugs Controller General of India from issuing further approvals to Reliance and a declaration to the effect that Reliance's drug 'TrastuRel' is not a biosimilar. On November 2, 2015, after hearing, a limited *ad-interim* order was passed not to launch the drug which was yet to be introduced.

The above two suits were clubbed and on April 25, 2016, an interim order was passed by the Ld. Single Judge imposing restrictions on sale of the biosimilar drugs by Biocon, Mylan and Reliance. Defendants were allowed to manufacture, market and advertise their product under the approved names without calling their product as "biosimilar", however they were restricted in using the INN name "Trastuzumab" stand alone on the carton or package insert as a brand name in a prominent manner. In view of *prima facie* findings the Ld. Single Judge was of the opinion that the use of the data by the defendants in the product insert without undergoing the entire process of the trials was

[6] *Roche Products (India) Pvt. Ltd &Ors. v. Drugs Controller General of India CS(OS) 355/2014*

[7] *Genentech Inc and Ors. v. Drugs Controller General of India and Others CS(OS) No.3284/2015*

misleading. The defendants were restrained from using the data relating to manufacturing process, safety, efficacy and tests conducted for the safety of the drugs as complained of by the plaintiffs till the time the final decision on the issue of the bio similarity was made in the suit.

The said order was challenged by Biocon and Mylan before the Division Bench of the Delhi High Court, wherein vide order dated March 3, 2017 both the companies were allowed to manufacture and market their biosimilar drugs and the restrictive conditions were stayed. Said restrictive conditions were also challenged by Reliance before the Division Bench of the Delhi High Court in appeal and is currently pending adjudication.

The matter is pending before the Division Bench for final adjudication. Meanwhile Roche went in to appeal by filing an SLP (Special Leave Petition) at the Supreme Court challenging the order of the Division Bench. The Special Leave Petition was dismissed as withdrawn on August 11, 2017.

In another suit Cadila Healthcare filed a declaratory suit against Roche for permanent injunction from restraining the launch of Cadila's biosimilar drug "Vivitra" (Trastuzumab)[8]. The suit is still pending before the Bombay High Court. Later Roche sued Cadila, restraining the latter from manufacturing and marketing its biosimilar drug. The judgment in said suit has been reserved, even prior to issuance of notice.

In another suit, Roche filed a suit against Hetero Drugs Ltd., for restraining the manufacturing and marketing the biosimilar version of Bevacizumab under the brand name "Avastin"[9]. The matter is currently pending adjudication before the Hon'ble Delhi High Court.

The Competition Twist:

In response to the slew of litigations filed by Roche for the drug Trastuzumab, Biocon Limited and Mylan Inc. filed a complaint against F. Hoffmann-La Roche AG and its group companies under Section 19(1)(a)[10] to the Competition Commission of India alleging abuse of dominance[11]. To give a brief background, due to restrictions on obtaining a product patent on a pharmaceutical product at the time, Roche obtained an EMR[12] to sell Trastuzumab, under the brand name HERCEPTIN. Thereafter, Roche introduced Herceptin in India in 2002. It also received approval from DCGI for, inter alia, import, manufacture, distribution and sale of drugs in India. In addition to regulatory approvals, registration of trademark HERCEPTIN was also obtained by Roche. In between Roche withdrew HERCEPTIN from the Indian market and introduced a lower cost version of TRASTUZUMAB, known as BICELTIS and later another low-cost version was introduced under the brand name HERCLON.

Simultaneously the Biocon and Mylan initiated the development of a biosimilar drug for Trastuzumab and manufacturing license for the same was granted by DCGI. Thereafter, the launch of biosimilar Trastuzumab was announced under the brand name of CANMAB and HERTRAZ. Allegedly the prices of these brands were much lower than those of BICELTIS and HERCLON.

At this juncture Roche filed suits against Biocon and Mylan and various other players. In the complaint to the CCI, it was

---

[8] Roche Products (India) Private Limited and Others v Cadila Healthcare Limited and Ors. CS(COMM) 1119/2016

[9] F Hoffmann-La Roche ltd. &Ors v Drugs Controller General of India &Ors. CS(COMM) 540/2016,

[10] **Section 19(1)** The Commission may inquire into any alleged contravention of the provisions contained in sub-section (1) of section 3 or sub-section (1) of section 4 either on its own motion or on—

(a) receipt of a complaint, accompanied by such fee as may be determined by regulations, from any person, consumer or their association or trade association; or

(b) a reference made to it by the Central Government or a State Government or a statutory authority.

[11] CCI Order in the matter of Biocon Ltd. &Ors. v. F. Hoffmann-La Roche AG &Ors. Case No. 68 of 2016

[12] Prior to 2005 India did not have the provision for granting product patents to of pharmaceutical compounds. However due to its obligations as a WTO member and by virtue of TRIPS agreement for granting product patent in all fields, as an interim measure, provision was made in the Patents Act (Chapter IVA) for granting Exclusive Marketing Rights (hereinafter referred to as 'EMR').

claimed that Roche is a dominant player in the Trastuzumab market and has indulged in a series of abusive practices to evade the entry of the informants' products and/or hamper their growth which was construed to be against Section 4 of the Act[13]. It was alleged in the complaint that Roche, along with its group, had a market share of 70% in terms of value of sales and had a comparative advantage over its competitors on account of being the innovator of the biological drug, Trastuzumab, in a market which has high entry barriers. It was alleged that Roche tried to prevent the market entry of biosimilars by misinforming doctors and hospitals about the pending civil suits and also influenced government agencies and hospitals for getting tender conditions in their favour. In view of these allegations the said complainants prayed to the Commission to direct the Director General (DG) to investigate into the alleged anti-competitive practices and abusive conduct adopted by Roche and its group of companies.

On the contrary, Roche raised the issue of jurisdiction before the Commission wherein, it was argued that the issues enlisted in the complaint are to be dealt with by the High Court. Further, Roche argued that because of the introduction of biosimilars by the various players, Roche's market share had fallen drastically. In view of the submissions of both parties, the Commission found it appropriate to analyze whether the opponent group holds a dominant position in the relevant market or not. The Commission, after weighing all the factors *prima facie* held that the Roche was dominant in the relevant market and could operate independently of the market forces. Further, it was *prima facie* held that Roche had indulged in abusive practices and hence, asked the DG to carry out a detailed investigation into the matter. Mean while Roche has challenged this investigation order in a writ petition before the Delhi High Court. The Court issued notice and partly heard the matter, the matter is now pending adjudication.

In the already complex world of similar biologics, what with their complicated structures and tedious regulatory approvals, litigations and competition complaints have added a new twist to the entire saga. While the regulatory and approval process has been much streamlined in view of new guidelines and additional requirements for clinical data therein; the implementation, level of compliance and capitalization by the industry is yet to be tested. Further the stake holders are looking up to the Courts to provide clarity in the ongoing litigations with regards to the complex regulatory issues involved in the approval of similar biologics.

Contributed by **Manika Arora**

---

[13] **4. Abuse of dominant position** (1) No enterprise shall abuse its dominant position.

(2) There shall be an abuse of dominant position under sub-section (1), if an enterprise, —

(a) directly or indirectly, imposes unfair or discriminatory—

(i) condition in purchase or sale of goods or services; or

(ii) price in purchase or sale (including predatory price) of goods or service; or Explanation. —For the purposes of this clause, the unfair or discriminatory condition in purchase or sale of goods or services referred to in sub-clause (i) and unfair or discriminatory price in purchase or sale of goods (including predatory price) or service referred to in sub-clause (ii) shall not include such discriminatory conditions or prices which may be adopted to meet the competition; or

(b) limits or restricts—

(i) production of goods or provision of services or market therefor; or

(ii) technical or scientific development relating to goods or services to the prejudice of consumers; or

(c) indulges in practice or practices resulting in denial of market access; or

(d) makes conclusion of contracts subject to acceptance by other parties of supplementary obligations which, by their nature or according to commercial usage, have no connection with the subject of such contracts; or

(e) uses its dominant position in one relevant market to enter into, or protect, other relevant market.

COMPUTER RELATED INVENTIONS IN INDIA: Internet of Things (IoT) perspective

A computer-related invention (or computer-implemented invention) (CRI) involves the use of a computer, computer network or other programmable apparatus, where one or more features are realised wholly or partly by means of a computer program[1]. Patentability of CRIs has been a contentious issue not only in India but across the globe with mixed results in various jurisdictions. Of several reasons for such a contention, one reason is that technology in this area has developed at an unimaginable in the past 20 years and laws have not been able to keep pace. Just like 200 years ago the First Industrial Revolution changed the way humans lived, the digital revolution, popularly known as the Fourth Industrial Revolution, is changing the way we live today and how we will live in the coming years. Patent Offices, Courts and Governments are trying hard to cope with the blitzkrieg of innovation in this area.

In India we have been grappling with the patentability aspect of CRIs for some years now. While we were content to be the backroom boys of the global software industry for many years, but the recent spurt in disruptive technologies like the Big Data analytics, Artificial Intelligence and the Internet of Things is forcing us to look at innovation in a different way. As the heat from pharmaceutical litigation is cooling off in India, CRIs are in the hot seat, what with the recent spurt in SEP (Standard Essential Patent) litigation and the pressure on every industry to go digital. CRIs are a critical topic in patent law, since a too relaxed an approach in awarding grants for these kind of inventions may include a risk of allowing a double protection for computer programs: copyright as well as patents. The risk also involves eligibility for protection of mere abstract ideas. It is crucial at this juncture to ensure that the patentability threshold for CRIs be determined in a rational manner keeping in mind the fact that all industries across the board, by virtue of being digitised, are getting affected.

The Internet of Things

In this article we explore the CRI landscape in India vis-à-vis the Internet of Things (IoT). The Internet of Things (IoT) has revolutionized the ubiquitous computing with multitude of applications built around various types of sensors. A vast amount of activity is seen in IoT based product-lines and this activity is expected to grow in years to come with projections as high as billions of devices. With most of the issues at device and protocol levels solved during the past decade, there is now a growing trend in integration of sensors and sensor based systems with cyber physical systems and device-to-device communications. 5th generation wireless systems (5G) are on the horizon and IoT is taking the center stage as devices are expected to form a major portion of this 5G network paradigm.

In today's world, the impact of IoT on patents can be observed. A cursory search on inPASS[2] reveals more than 5000 applications published in this subject area. We believe that the IoT provokes a redefinition of the concepts of novelty and originality for purposes of assessing patent ability, essentially because of the network structure associated with smart devices and therefore, patentability may be derived from interaction between smart devices[3]. Further, due to the composite nature of the smart devices novelty might be the way a single device interacts. Thus, there appears to be a significant involvement of software technology with the innovations related to IoT. As mentioned above, since software patentability is a contentious issue it will follow all the way along the IoT inventions.

Below we touch briefly on the evolution of the subject matter eligibility on software related inventions in India.

Evolution of Subject Matter Eligibility of CRIs in India

The path towards the introduction of determination of subject matter eligibility for software patents has been gradual. The Patents (Second Amendment) Bill, 1999 enlarged the exclusions to patentability as given in section 3 of the Patents Act 1970. Section 3(k) was added in the Bill which excluded the following from patenting in India:

3(k) "a mathematical or business method or a computer programe or algorithms".

The Bill was referred to a Joint Parliamentary Committee (JPC) by both Houses of the Parliament for their comments

[1] https://www.epo.org/news-issues/issues/software.html
[2] http://ipindiaservices.gov.in/PublicSearch/PublicationSearch/Search# ; the patent search portal on the Indian Patent Office website
[3] https://www.omicsonline.org/open-access/patents-on-computerrelated-inventions-in-india-2375-4516-1000S1-009.php?aid=82521&view=mobile

and suggestions. The Joint Committee recommended the insertion of the phrase "per se" in Section 3(k) that now read as:

3(k) "a mathematical or business method or a computer programe per se or algorithms".

Currently Section 3 (K) needs as recommended by the JPC.

To remove the ambiguity surrounding the examination of CRIs, the Patent Office decided to publish a set of Guidelines. The first set of draft guidelines were published in 2013 and opened for public comment[4]. The Patent Office held several rounds of discussions with the stakeholders and after nearly two years of deliberations the Patent Office issued the Guidelines for Examination of CRIs on 21st August 2015. The 21st August Guidelines sought to give clarity with regards to what would constitute technical advancement, technical effect and gave pointers to the examiners for the examination of applications related to CRIs with the limitations of section 3(k). The guidelines reaffirmed that computer programs per se were excluded from patentability and stated that for being considered patentable, the subject matter should involve either "a novel hardware, or - *a novel hardware with a novel computer program, or - a novel computer program with a known hardware which goes beyond the normal interaction with such hardware and affects a change in the functionality and/or performance of the existing hardware."*[5]

However these were abruptly put in abeyance in December 2015 and a new set of guidelines was issued on 19 February 2016. The guidelines made the requirement of "novel hardware" essential.

In particular, the CRI Guidelines of February 19, 2016 provided examiners with a three stage test in examining CRI applications:

(1) Properly construe the claim and identify the actual contribution;

(2) If the contribution lies only in mathematical method, business method or algorithm, deny the claim;

(3) If the contribution lies in the field of computer programme, check ***whether it is claimed in conjunction with a novel hardware*** *and proceed to other steps to determine patentability with respect to the invention. The computer programme in itself is never patentable. If the contribution lies solely in the computer programme, deny the claim. If the contribution lies in both the computer programme as well as hardware, proceed to other steps of patentability.*[6]

IoT inventions and CRI Guidelines 2016

The CRI Guidelines of 2016 proved to be an impediment in path of fostering innovation in the field of software technology. The Guidelines handicapped almost all the inventions related to software including IoT and smart devices with respect to the requirement of "novel hardware." The Guidelines of 2016 denoted the specific requirement of "novel hardware" which would have certainly prejudiced the growth of the IoT inventions. Based on the CRI Guidelines of 2016, the protection of most of the IoT inventions became a distant thought.

Status of IoT inventions with 2017 Guidelines

After a lot of efforts with submissions and discussions, the stakeholders, including innovators, were able to convey the difficulties associated in protecting the innovation in software technology to the Government. At our law firm we made submissions to all levels of Government, including the Prime Minister's Office. A fresh set guidelines was issued on June 30, 2017. The fresh guidelines put emphasis on the underlying substance of the invention, not the particular form in which it is claimed. The most noted amendment in the present set of guidelines has been the withdrawal of the requirement of "novel hardware". Hence with effect from June 30, 2017, it has been accepted by the Indian Patent Office that in patentability cases, the focus should be on the underlying substance of the invention, not the particular form in which it is claimed. While discussing sufficiency of disclosure the Guidelines state: *"the claims in the field of Computer related inventions need to be construed to ascertain the substance of the claim without wholly relying on the forms and types of the claims." And "It*

[4]Draft guideline for Computer Related Inventions (CRIs)2013, June 28, 2013
[5]Guidelines for Examination of Computer Related Inventions (CRIs) 2015, August 21, 2015
[6]Guidelines for Examination of Computer Related Inventions (CRIs) 2016, February 19, 2016

is well-established that, in patent ability cases, the focus should be on the underlying substance of the invention, not the particular form in which it is claimed"[7]

Thus, the guidelines of 2017 do not outrightly reject the claims directed to a novel computer program with a known hardware. Instead, the Guidelines of 2017 focus on the interactions between the novel software and the known hardware. When such interactions go beyond "normal" interactions", and bring "a further technical effect," the claims may not be considered as excluded subject matter under Section 3(k).

In other words, by demonstrating that an IoT invention is "rooted in computer technology" or "directed to a specific improvement to the way computers operate," patentees may be able show at the outset of the guidelines that the invention is not abstract and thus patent-eligible. To support the validity of their IoT patents, companies should consider preparing their patents in a way that highlights the technological root of the invention or the improvement the invention makes to existing computing technology.

Conclusion:

Since the Patent office is considering the substance of the invention as a whole linking the patentability of CRIs to inventions which constitutes an inextricable mixture of software and (novel) hardware, the new CRI guidance may be a formidable input to the developments of IoT inventions, now supported with more legal clarity and certainty. We believe that these guidelines will go a long way in achieving the Patent Office's stated goal of fostering uniformity and consistency in the examination of Computer Related Inventions including the IoT.

In light of the recent guidelines from the Patent Office, companies working in this space need to ensure that their IoT patents are as strong as possible in light of subject matter eligibility to provide the best protection for their valuable intellectual property. Moreover, identification of key technology with strong patents with respect to subject matter eligibility would be important.

Contributed by **Abhinav Agarwal**

[7]Revised Guidelines for Examination of Computer-related Inventions (CRIs) 2017, June 30, 2017

Section 8: climb to the Everest diluted

The famous words of Justice Prabha Sridevan sum up the section 8 conundrum. In Fresenius vs. Glaxo[1] hearing a revocation petition in the IPAB (Intellectual Property Appellate Board) Justice Sridevan said ***"When George Mallory was asked "Why do you want to climb Mount Everest?"he is supposed to have replied, "Because it is there."*** To the question "Why should we comply with S.8? The Answer is "Because it is there." That section 8[2] became the Achilles heel of many a patentee trying to enforce its patents is well known. It all started in 2009 with ***Chemtura Corporation vs Union of India & Ors***[3] where in grant of an interim injunction in a patent infringement suit was vacated on the grounds of non-compliance to sections 8(1)(b) and 8(2). Meanwhile a revocation petition against the suit patent was filed at the Intellectual Property Appellate Board (IPAB), wherein the (suit) patent was revoked on various grounds including non-compliance of Section 8. In the years to follow Courts, the IPAB and the Patent Office in India used section 8 for easy disposal of a case without going into the merits of patentability or any other technical grounds.

Section 8 requires the applicant to inform the Patent Office regarding filings in other jurisdictions corresponding to the same or substantially the same invention as filed in India.

[1]ORA/22/2011/PT/KOL, dated 27th July, 2013

[2]8. Information and undertaking regarding foreign applications.—
(1)Where an applicant for a patent under this Act is prosecuting either alone or jointly with any other person an application for a patent in any country outside India in respect of the same or substantially the same invention, or where to his knowledge such an application is being prosecuted by some person through whom he claims or by some person deriving title from him, he shall file along with his application or subsequently within the prescribed period as the Controller may allow—
(a)a statement setting out detailed particulars of such application; and
(b)an undertaking that, up to the date of grant of patent in India, he would keep the Controller informed in writing, from time to time, of detailed particulars as required under clause (a) in respect of every other application relating to the same or substantially the same invention, if any, filed in any country outside India subsequently to the filing of the statement referred to in the aforesaid clause, within the prescribed time.
(2)At any time after an application for patent is filed in India and till the grant of a patent or refusal to grant of a patent made thereon, the Controller may also require the applicant to furnish details, as may be prescribed, relating to the processing of the application in a country outside India, and in that event the applicant shall furnish to the Controller information available to him within such period as may be prescribed."

[3]CS (OS) No. 930 of 2009

There is a stipulated time frame for filing such information. In addition to that the applicant is required to keep the Patent Office informed about the processing of such applications during the pendency of the application in India up till the grant.Failure to disclose information under Section 8 is a ground for revocationof a patent under section 64(m)[4], a ground for pre-grant opposition under section 25(1)(h)[5] and also a ground for post grant opposition under section 25(2)(h)[6].

Traditionally the Indian Courts and Tribunals have taken a strict approach towards compliance to Section 8. The purpose of Section 8 was captured initially in the Justice Rajagopala Ayyangar Committee report in the 1960s. At that time, there was no access for the Indian Patent Office to the portals of Patent Offices of different jurisdictions. However with increasing access, Courts are taking a less stringent view. This is evident by contrasting Delhi High Court's order in Chemtura Vs. UOI, IPAB in Fresenius Kabivs Glaxo Group wherein either injunction was refused or patent was revoked on this ground alone to Philips and Ericsson wherein the view has been less stringent.

The Courts are now insisting on ***substantial compliance*** as against earlier strict compliance to section 8. In *Sukesh Behl vs. Philips*[7] the Division Bench of the Delhi High Court held that violation of section 8 did not merit automatic revocation. It also held that the Court would also consider whether the omission on the part of the patentee (for violating requirement under section 8) was *intentional* or whether it was *merely clerical and a bonafide error*. In *Telefonaktiebolaget Lm Ericsson v. Intex Technologies*[8] the Court held that section 8 should not be interpreted in the manner to mean "that every shred of paper filed in every foreign country has to be filed before the Indian Patent Office". Further, it was held that as long as Indian Patent Office was informed of all the major jurisdictions in which patents have been granted and substantial details are placed on record, the obligation of complying with Section 8 stood satisfied.

Substantial compliance has been explained in *Ericsson v. Intex*[9]:

- Details of major jurisdictions (USA, EP, Japan etc.) are provided;
- Copies of finally granted patents are filed before the Patent Office;
- Section 8 should not be interpreted in the manner to mean that every shred of paper filed in every foreign country has to be filed before the Indian Patent Office.

In the meantime and this may be seen as Chemtura coming full circle, Chemtura's Patent has been restored by the Bombay High Court[10] on June 19, 2017. The Order passed by the IPAB revoking Chemtura's patent on grounds, including non-compliance of Section 8, was overruled. The Ld. Bench observed that the IPAB had erred in revoking the patent when the applicant seeking revocation had already filed a petition for unconditional withdrawal of its opposition.

Though the Courts have, by way of recent decisions, diluted the stringent requirements as laid down previously for compliance of section 8, however, since the Patent Acts sanctions for non-compliance, Section 8 requirement still requires ***substantial compliance***.

---

[4] 64. Revocation of patents.-(1) Subject to the provisions contained in this Act, a patent, whether granted before or after the commencement of this Act, may, be revoked on a petition of any person interested or of the Central Government by the Appellate Board or on a counter-claim in a suit for infringement of the patent by the High Court on any of the following grounds, that is to say-.....
(m) that the applicant for the patent has failed to disclose to the Controller the information required by section 8 or has furnished information which in any material particular was false to his knowledge;"

[5] 25. Opposition to the patent. - (1)Where an application for a patent has been published but a patent has not been granted, any person may, in writing, represent by way of opposition to the Controller against the grant of patent on the ground.....
(h) that the applicant has failed to disclose to the Controller the information required by section 8 or has furnished the information which in any material particular was false to his knowledge;"

[6] 25. Opposition to the patent :--(2) At any time after the grant of patent but before the expiry of a period of one year from the date of publication of grant of a patent, any person interested may give notice of opposition to the Controller in the prescribed manner on any of the following grounds, namely:-.....
(h) that the patentee has failed to disclose to the Controller the information required by section 8 or has furnished the information which in any material particular was false to his knowledge;"

[7] SukeshBehlVs. Koninklijke Phillips Electronics (Division Bench. Maj. Behl v. Philips (order dated November 07, 2014 in FAO(OS) No.16 OF 2014)

[8] order dated 13 March, 2015 in I.A. No. 6735/2014 in CS (OS) No.1045/ 2014

[9] order dated 13 March, 2015 in I.A. No. 6735/2014 in CS (OS) No.1045/ 2014

[10] Chemtura Corporation v. Union of India Through Secretary, Dept. of Industrial Policy and Promotion and Ors. (W.P. No. 1919/2014),

MEDICAL DEVICES: The Sunrise Sector In India

The medical device industry in India is being called the sunrise segment in the healthcare space. Globally this sector has seen a healthy growth. The global medical devices market is expected to increase by 7.8% from 2010 to 2020[1], from USD 164 bn in 2010 to USD 332 bn in 2020. In terms of sales, Asia is the third largest market. India is amongst the top twenty markets for medical devices in the world and is the fourth largest market in Asia after Japan, China and South Korea[2]. However India accounts for only a small segment of this market, with approximately 1.7% in 2015[3]. This is expected to grow at a rate of 16% and is expected to touch 8.16 bn by 2020[4]. With India's population growing at 1.2% per year with the share of aged population expected to increase to 6% of the total population by 2021, it is expected India will continue to be a huge market for medical devices and technology.

Regulatory and Infrastructure environment

There has been a paradox of sorts in the growth story of medical device industry. While there is immense potential for growth and the market for devices continues to grow (due to various reasons[5]), the lack of regulations has held the industry back, especially the development of indigenous industry. The Government of India has now taken a few steps in the right direction, one of them being notification of the Medical Devices Rules 2017 (referred to as "MDR 2017" henceforth), effective January 2018[6].

The rules are framed around the guidelines of the Global Harmonization Task Force on Medical Devices (GHTF)[7], now International Medical Device Regulators Forum (IMDRF)[8]. The MDR 2017 are designed to bring India at par with Global Standards and bring the largely unregulated medical devices market in India under proper regulatory standards, thereby bringing regulatory clarity to manufacturers and quality assurance to the consumers.

As of now, only 22 of more than 10,000 medical devices used, manufactured, or imported in India are regulated (notified)[9]. This is poised to change substantially as the MDR 2017 come into force with effect 1st January 2018. In fact, a draft list[10] of hundreds of different medical devices that would come under the ambit of the MDR 2017 has been floated by the Central Drugs Standard Control Organization based on risk based classification introduced in the MDR 2017. Risk based classification is not new and is very similar to the United States and European way of classifying Medical Devices. The risk based classification in the MDR 2017 includes low risk, class A; low moderate risk, class B; moderate risk, class C; and high risk, class D. The MDR 2017 go on to describe in detail the process for obtaining a license for manufacture, sale, distribution, import and labelling of medical devices according to their risk based classifications. The rules also provide detailed directions for conducting clinical investigations for medical devices with or without any predicate device. Most of these rules are at par with global standards, for example, the Quality Management System mentioned in the Fifth Schedule of the MDR 2017 is identical to ISO 13485[11] by the International Standards Organization.

The rules also describe establishment of a complete new regulatory framework and agencies around the MDR 2017. The most important being a Central Licensing Authority and a State licensing Authority, in consonance with the federal governance structure of the country without causing much regulatory disparity between different states. This is done by giving hold of high risk (classes C & D) factor device regulations to the Central Licensing Authority

[1] file:///D:/L&S/US%20visits/US%202017/Newletter/Medical%20Devices/medicaldevicemanufacturinginindia-asunrise-170221053503%20(1).pdf

[2] http://pharmaceuticals.gov.in/sites/default/files/Draft%20National%20Medical%20Device%20Policy%20-%202015.pdf

[3] Espicom, India Medical Devices Report 2016, KPMG Analysis from file:///D:/L&S/US%20visits/US%202017/Newletter/Medical%20Devices/medicaldevicemanufacturinginindia-asunrise-170221053503%20(1).pdf

[4] Ibid. at 1

[5] "Growing population, ageing population, increase in chronic disease' burden, increase in health insurance penetration, growing medical tourism, increase in demand for healthcare infrastructure, emerging healthcare service formats, quality and accreditation of hospitals" from file:///D:/L&S/US%20visits/US%202017/Newletter/Medical%20Devices/medicaldevicemanufacturinginindia-asunrise-170221053503%20(1).pdf

[6] Medical Device Rules 2017 http://www.cdsco.nic.in/writereaddata/Medical%20Device%20Rule%20gsr78E.pdf

[7] http://www.financialexpress.com/industry/why-2017-is-a-landmark-year-for-the-medical-device-industry-in-india/550425/

[8] http://www.imdrf.org/

[9] http://www.ijdra.com/images/IJDRA186.pdf

[10] http://www.cdsco.nic.in/writereaddata/notice%2029_6_2017.pdf

[11] https://www.iso.org/standard/59752.html

and low risk factor devices (classes A & B) to the State. The rules also give the Central Licensing Authority the power to regulate import of all classes of medical devices in the country. Another pair of bodies formed by the rules is the National Accreditation Body/Board and Notified Body. The Notified Body, similar to their European Counterparts[12] are private organizations that will help the Licensing Authorities oversee regulation of medical devices in the vast Indian market and the National Accreditation Body is tasked to lay standards and procedures for these Notified Bodies. Then there are Central Medical Device Testing Laboratory, Medical Device Officer, Medical Device Testing Officer, all pivotal functioning components of the new regulatory infrastructure that is being put in place.

Regarding infrastructure the first National Accreditation Board for Certification Bodies ("Board")[13] has been recognized under the MDR 2017 with effect from January 31, 2017 itself. The Board has started entertaining applications for registration as Notified Bodies from July 1, 2017 through SUGAM Portal. The Board has also formed a task force to finalize audit requirements based on the MDR 2017 and prepare a common report format to be used by Notified Bodies for the purpose. On May 4, 2017, CDSCO released an Office Memorandum, with regard to interpretation of the shelf life of the Medical devices. In July 2017, the DGCI issued a notice in which a draft of guidance document on Essential Principles for Safety and Performance of Medical Devices was annexed, and all the stakeholders were requested to share their comments and suggestion on the same within a period of 3 weeks. All these steps are being taken to prevent any delays from the deadline of 1 January 2018.

Patent activity

Medical device patent protection has always been robust in India, inviting few controversies, unlike the big brother, the pharmaceutical patent. However one needs to watch out for section 3 patent eligibility vis-à-vis section 3 (i) [19], 3(d) or even section 3(k). Methods of treatment and methods of using a device for treatment are not allowed in India under section 3(i). With the Patent Office gone into an over drive of clearing humongous backlog of pending applications, it is indeed a good time for the sunrise sector that is driven by innovation. In 2017 alone till the first week of September the number of applications granted is nearly three times that of 2016's. And the number of applications examined till the first week of September is more than double as compared to 2016's.

Litigation round up

Not too many conflicts have been seen in this sector and one of the major ones is for patent and design infringement of a knee joint prosthesis[20]. The Ld. Single Judge of the Madras High Court did not grant an interim injunction vide order dated April 29, 2009 stating that mere functional similarity of the products of the patent holder and the alleged infringer would not warrant the grant of an injunction. It was held that the 'prosthesis' of both the parties were different in the polymer, rotating hinge mechanism and extending mechanism. However, considering the relevance of prosthesis to those who are in need of the same as a lifesaving equipment, Court ordered the trial Court to complete the infringement proceedings within four months. On January 23, 2014, in a comprehensive order citing several precedents from

[12] https://ec.europa.eu/growth/single-market/goods/building-blocks/notified-bodies_en

[13] http://www.qcin.org/nabcb/

[14] http://www.cdsco.nic.in/writereaddata/30maymedical%20device.pdf

[15] Sugam Portal of CDSCO: https://cdscoonline.gov.in/CDSCO/homepage

[16] http://www.qcin.org/nabcb/newsletter/

[17] Office Memorandum by the CDSCO, available at http://www.cdsco.nic.in/writereaddata/office%20memorandum4_17.pdf, last seen on 17/8/17.

[18] Notice from the Office of DGCI, available at http://www.cdsco.nic.in/writereaddata/Essential%20Principles%20for%20safety.pdf, last seen on 17/8/17.

[19] 33 What are not inventions. -The following are not inventions within the meaning of this Act,-
(d) the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant. Explanation. -For the purposes of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy;]
(i) any process for the medicinal, surgical, curative, prophylactic 23 [diagnostic, therapeutic] or other treatment of human beings or any process for a similar treatment of animals 24 [***] to render them free of disease or to increase their economic value or that of their products.
(k) a mathematical or business method or a computer programe per se or algorithms;

[20] M.C. Jayasingh v. Mishra Dhatu Nigam Limited CS(OS) 562/2007

various jurisdictions, the Ld. Single Judge of the Madras High Court upheld the validity of the patent and design, however did not find infringement. The case is important since it lays down the distinction between rights and liabilities under the Patents Act and the Design Act.

In *Braun vs. Rishi Baid the*[21] Court denied an interim injunction vide order dated April 15, 2009 for a patent infringement suit filed by Braun over an alleged infringement of its patent covering safety catheters/cannulae. The Court held that mere grant of a patent did not in itself entitle the plaintiff to an injunction. The fact that needle guards were used by companies for decades, as well as due to the difference in products, led the Court to deny an injunction. This matter was appealed and the Division Bench affirmed the order of the Single Judge. The patent suit was withdrawn by Braun at the stage of trial.

In 3M *Innovative Properties vs Venus Safety*[22] for a "flat fold respiratory protection device" an interim injunction was granted by way of order dated December 19, 2013. However, in 2014, the interim injunction was vacated by the Court on the basis of counter claim of Venus with three prior art citations challenging the inventive merit of the said patent, alleging the prior arts disclosed the essential features used by Venus' product. On appeal against the order by 3M, the Division Bench of the Delhi High Court allowed the appeal, granted an injunction in favour of 3M, set aside the 2014 order and confirmed the 2013 order till disposal of the suit.

Conclusion

The medical device industry is on a growth path in India with the Government removing and easing hurdles in terms of infrastructure, regulations and patent environment. To strengthen the sector several measures have been undertaken, for instance 100% Foreign Direct Investment (FDI) under automatic route in greenfield and brownfield projects, approval of medical device parks and testing labs, subsidies and exemptions to MSME and correction of inverted duty structure. The sunrise sector is indeed set to rise in India, given the right environment to grow.

Contributed by **Aditya Kochhar**

[21] B. Braun Melsungen Ag &Ors. v. Rishi Baid& Others CS (OS) 186/2008

[22] 3M Innovative Properties Ltd. v. Venus Safety and Healthcare Pvt. Ltd. FAO(OS) 292/2014

[23] file:///D:/L&S/US%20visits/US%202017/Newletter/Medical%20Devices/medicaldevicemanufacturinginindia-asunrise-170221053503%20(1).pdf

Developments in Plant Varieties Protection in India

On December 12, 2016 the Hon'ble Delhi High Court struck down **Section 24(5)**[1] of the Protection of Plant Varieties and Farmers' Rights Act, 2001 as unconstitutional, and hence, invalid in *Prabhat Agri Biotech Ltd. &Ors. v. Registrar of Plant Varieties*[2]. Section 24(5) of the Act gives powers to the Registrar of Plant Varieties to issue directions to third parties against committing any abusive acts prejudicial to the interests of a breeder whose application for registration is still pending. Instant provision is in compliance to Article 13[3] of International Union for the Protection of New Varieties of Plants (UPOV) Convention that provides for provisional protection to a Plant Variety in the interim period between the dates of publication and grant.

While striking down the aforesaid section, Hon'ble High Court of Delhi had observed that the section gave very vast and broad powers to the Registrar to issue directions, and said powers could be used by competitors to cause great harm to a genuine creator of a plant variety by filing an application, and thereafter securing grant of an interim order under said Section. The Court also considered the lack of any guidelines being laid down in the Act regarding the manner of grant of interim order or direction under the Section. The Court was also persuaded by the petitioner's contention that the Act did not require the Registrar to be a judicial or *quasi*-judicial officer, but, despite the apparent lack of juridical ability, the Registrar could exercise powers such as issuing *ex-parte* orders under the aforesaid Section.

Against this decision of the High Court, an SLP[4] was filed before the Supreme Court. The Apex Court, however, was not inclined to go into the merits of the judgment, and *vide* order dated July 31, 2017, imposed a stay upon the operation of the judgment appealed against. Thus, Section 24(5) is still valid and subsisting in its current form, until further orders.

[1] 24. Issue of certificate of registration- (5) The Registrar shall have power to issue such directions to protect the interests of a breeder against any abusive act committed by any third party during the period between filing of application for registration and decision taken by the Authority on such application.

[2] Writ Petitions (Civil) 250/2009 and 7102/2011

[3] **Article 13** (Provisional Protection): Each Contracting Party shall provide measures designed to safeguard the interests of the breeder during the period between the filing or the publication of the application for the grant of a breeder's right and the grant of that right. Such measures shall have the effect that the holder of a breeder's right shall at least be entitled to equitable remuneration from any person who, during the said period, has carried out acts which, once the right is granted, require the breeder's authorization as provided in Article 14. A Contracting Party may provide that the said measures shall only take effect in relation to persons whom the breeder has notified of the filing of the application.

[4] SLP No.19195/2017

SEP LITIGATION: The Indian Scenerio

A standard essential patent SEP has been defined as a patent that protects technology essential to a standard[1]. A standard is defined as a document that sets out requirements for a specific item, material, component, system or service, or describes in detail a particular method or procedure.[2] Standards are set by Standard Setting Organizations (SSO). Due to the requirements of interoperability standards are widespread in the telecommunications sector. A technology adopted as a standard naturally steers the market towards that technology creating a sort of a monopoly. In order to curb monopoly the SSOs require the owners of patents covered by the standard to grant licenses on a fair, reasonable and non-discriminatory (FRAND) terms.[3]

There has been a significant rise in SEP litigation around the world in the telecommunication sector in the past three decades.[4] India is not far behind. Though a late entrant in the field, it has caught up fast. There has seldom been any IP litigation in India as intensely contested or with higher stakes than litigation at the Delhi High Court involving Standard Essential Patents.

Ericsson – The mobile phone wars

It was in March 2013, when the first wave of standard essential patent litigation began with the institution of a suit CS (OS) 442 of 2013 by Swedish telecommunications giant Telefonaktiebolaget LM Ericsson against India's home-grown rising star in the affordable mobile devices sector, Micromax, alleging infringement of eight of its patents essential to the 2G and 3G standards. In an ex parte hearing on 06.03.2013, Ericsson was able to establish a prima facie case against Micromax and this led the Court to direct Customs authorities to intimate Ericsson of any infringing phones imported by Micromax and to release the same to Micromax only after taking into consideration any objections raised by Ericsson. Less than two weeks from the date of said order, on 19.03.2013 both parties entered into a consensual arrangement as per which Micromax agreed to deposit in Court on an interim basis royalty calculated at rates negotiated between the parties and recorded in the order of the Court, in exchange for Ericsson providing timely No-Objection certificates to the Customs authorities. Thereafter, while directing trial in the matter to be expedited, the Hon'ble Court vide its order dated 12.11.2014, with consent of both parties, modified the rates in the aforesaid interim arrangement based on existing agreements with similarly situated parties, and directed payments to be made directly from Micromax to Ericsson who would in turn secure the same with bank guarantees. Trial in the matter, however, has since been delayed owing to repeated challenges by Micromax to the aforesaid interim arrangement, and affidavits of evidence are yet to be filed by both parties.

Ericsson followed up its suit against Micromax with similar suits and ad interim injunctions against Gionee[5], Intex[6], Xiaomi[7], Lava[8], and iBall[9]. After a prolonged interim stage battle, Gionee[10] and Xiaomi[11] entered into interim arrangements pending trial with Ericsson along the lines of and on similar terms as the aforesaid interim arrangement between Ericsson and Micromax[12]. iBall, went a step further and after negotiating with Ericsson for eight weeks after being injuncted, settled the infringement suitby entering into a Global Patent License Agreement with Ericsson[13]. Intex and Ericsson filed cross appeals, against

[1] http://ec.europa.eu/competition/publications/cpb/2014/008_en.pdf
[2] 2https://www.cencenelec.eu/standards/DefEN/Pages/default.aspx
[3] HBS Review, Standard-Essential Patents by Josh Lerner and Jean Tirole, Working Paper, 14-038, November 5, 2013
[4] http://ec.europa.eu/competition/publications/cpb/2014/008_en.pdf
[5] order dated 22.10.2013 in CS (OS) 2010 of 2013
[6] order dated 13.03.2015 in CS (OS) 1045 of 2014
[7] order dated 08.12.2014 in CS (OS) 3775 of 2014 and order dated 16.12.2014 in FAO (OS) 522 of 2014
[8] order dated 10.06.2016 in CS (OS) 764 of 2015
[9] order dated 02.09.2015 in being CS (OS) 2501 of 2015
[10] order dated 19.10.2015 by the Division Bench in FAO (OS) 574 of 2015
[11] the order dated 08.08.2016 in CS (OS) 3775 of 2014
[12] recorded in the order dated 12.11.2014 in CS (OS) 442 of 2013
[13] the order dated 29.10.2015 in CS (OS) 2501 of 2015

the interim injunctionorder of the trial Court and said appeals are pending adjudication after more than two years of being filed[14]. Ericsson's case against Lava, has progressed the furthest, with trial having been completed at an expedited rate[15]. However, final arguments in the matter remain, and the matter has not been finally heard since over a year owing to the extended number of hearings required in the matter alleging infringement of eight patents.

Dolby – leading audio coding technology

On October 19, 2016, Dolby filed suits against five parties viz. Oppo, Vivo, Videocon, Onida and Mitashi for unauthorized use of four of its patents essential to the HEAAC v1 and HEAAC v2 audio coding standards in their mobile phones, tablets, television sets etc. and an ad interim injunction was granted on the first hearing itself[16]. Of the parties which are based in India, Mitashi[17] and Onida[18] have settled their disputes with Dolby by entering into license agreements with Dolby. Oppo and Vivo[19], on the other hand have entered into an interim arrangement with Dolby along the lines of the Ericsson suits, and trial in the two suits has been expedited.

Competition concerns

Meanwhile, in addition to raising a defence citing invalidity of the patents asserted in the suits filed against them by Ericsson, parties such as Micromax and Intex also filed complaints against Ericsson before India's unfair competition regulator, the Competition Commission of India ("CCI") citing abuse of dominance by Ericsson. Acting in response to the aforesaid complaints, the CCI passed orders dated 12th November, 2013 and 16th January, 2014 wherein it found Ericsson to have prima facie violated its FRAND commitments by licensing its essential patents for 2G and 3G technologies on unfair terms, and directed the Director General to conduct a detailed investigation. The aforesaid orders were challenged by Ericsson by way of writ petitions filed before the Delhi High Court wherein Ericsson had claimed lack of jurisdiction of CCI in relation to a claim of royalty by a proprietor of a patent, which jurisdiction would fall under the Patent Act, 1970 and not the Competition Act, 2002. The Hon'ble Court, though without staying the investigation, barred the CCI or its Director General from filing/passing any final reports/orders with regards to the same. After several hearings over almost two years, the writ petitions were decided vide the Hon'ble Court's Judgment dated 30.03.2016, in which the Hon'ble Court held inter alia:

(a) that the Patent Act, which is a self contained code, is a special Act vis-à-vis the Competition Act, and

(b) that the Patent Act and the Competition Act do not have any irreconcilable repugnancy or conflicts since patent laws define the contours of certain rights, and the anti-trust laws are essentially to prevent abuse of rights, and

(c) that both Acts ought to be construed harmoniously and thus, the jurisdiction of CCI under the Competition Act is not automatically ousted in matters relating to patents.

Further, the Court while examining through foreign judgments what would amount as "abuse of dominance" by an SEP holder, refused to delve into the merits of Micromax's and Intex's submissions as to the conduct of Ericsson in the instant case and instead limited its observations only to the issue of whether the CCI had jurisdiction to pass the impugned orders against Ericsson and to initiate an investigation into its conduct.

The aforesaid judgment has since been challenged by Ericsson by way of LPA Nos. 246-247 of 2016, and though an interim order directing the Director General to refrain from passing any order or filing his report continues to be in effect, the matters are yet to be heard substantively.

Despite trials progressing at a much expedited pace, the

[14]FAO (OS) 138 of 2015 and FAO (OS) 233 of 2015 respectively,
[15]CS (OS) 764 of 2015
[16]Order dated 20.10.2016 CS(COMM) 1425/2016
[17]CS(COMM) 1427/2016
[18]CS(COMM) No.1428/2016, IA No.12934/2016 (under Order XXXIX Rules 1&2 CPC) & IA No.14491/2016
[19]CS(COMM) No.1425/2016 and CS(COMM) No. 1426 of 2016

major reasons holding back trials and final adjudication in India's SEP litigations are primarily:

1) indulgence of the Courts in several frivolous applications being filed by the Defendants often over minor procedural issues.

2) lack of any real urgency due to the relatively comfortable positions of the parties wherein the Defendants continue to sell infringing products, subject to payment of a nominal royalty in lieu of bank guarantees being furnished by the Plaintiff, who in turn maintains a positive cash flow collecting said royalties.

3) complicated nature of the subject matter of such suits which requires extended and detailed examination at the trial and final arguments stage.

Conclusion

The beginning of the first SEP litigation began has launched an era of sweeping changes in the way intellectual property litigation is conducted in India and IP holders internationally have begun to take notice of India as an attractive jurisdiction for asserting their IP rights and leveraging the results into international licenses. There are enough indicators to point towards the fact that India may be ahead of its predecessors in SEP jurisprudence. A few instance are that interim injunctions are granted against an "unwilling licensee". Royalty payments are directed at the interim stage itself. And in determining royalties agreements with similarly placed parties are considered by the Court under confidentiality terms. The enactment of the Commercial Courts, Commercial Divisions and Commercial Appellate Divisions of the High Courts Act, 2016 are indications of changes to the Court procedure in dealing with commercial matters, including all IP matters. India is hence set to become the jurisdiction of choice for SEP holders

Contributed by **Rohin Koolwal**

Speedy disposal of pending IPR suits- Orders the Apex Court

The Supreme Court, while hearing a Special Leave Petition (SLP) in **Az Tech India v. Intex Technologies, SLP 18892/2017** arising from a Delhi High Court Division Bench order in an IPR matter, expressed concerns about the long interim stages and lack of speedy disposal of IPR suits in the Delhi High Court and instituted a *suo moto* writ petition titled **"Re: Case Management of Original Suits"** to supervise the steps taken by the Delhi High Court to remedy the situation.

While hearing the matter for the first time on 31st July 2017, the Division Bench of the Apex Court comprising Hon'ble Mr. Justice Ranjan Gogoi and Hon'ble Mr. Justice Navin Sinha, without first delving into specific issues raised by the parties in the instant SLP, commented on the exhaustive nature of interim orders passed by the Delhi High Court and attributed the same to an implicit understanding that interim orders shall continue to govern the parties rights until the eventual and rather distant disposal of the suit. The Bench then proceeded to direct the Registrar General of the Delhi High Court to report to the Supreme Court by 14th August, 2017 *"about the total number of pending IPR suits, divided into different categories, in the Delhi High Court; stage of each suit;* and also the period for which injunction/interim orders held/holding the field in each of the such suits." The Registrar General of the Delhi High Court was further directed to indicate a reasonable way of ensuring the speedy disposal of pending IPR suits, according to the Delhi High Court, and the matter was re-notified for 16th August, 2017.

On the next date of hearing, i.e. 16th August 2017, the Ld. Division Bench after perusing the report submitted by the Registrar General of the Delhi High Court and hearing the Ld. Senior Counsel appearing on behalf of the Delhi High Court, clarified that the instant proceedings were not meant as interference by the Apex Court in the running of the Delhi High Court but ought to be construed as *"an effort on the part of the Judiciary as an institution to work out ways and means to dispose of long pending contested civil suits throughout the country for which purpose the Delhi High Court and, particularly, the IPR matters has been taken as the yardstick. The Hon'ble Judges of the Delhi High Court have to work out ways and means for effective disposal of the IPR matters before it so that a model for disposal of civil suits can be culled out from the ways and means adopted by the Delhi High Court which can form the basis of an uniform action plan for the rest of the country."* Thereafter, the Bench directed the institution of the aforesaid *suo moto* Writ Petition and directed the Registrar General of the Delhi High Court to submit periodical progress reports highlighting the steps being taken to effectuate the aforesaid goal, with the first one due on 24th October 2017.

It is a welcome initiative by the Apex court and such efforts on the part of the Judiciary are necessary for keeping faith in the system and speedy disposal of the disputes. Such initiatives, especially in IPR matters since IPRs have limited lives, it is hoped will go a long way in development of innovation and business environment in the country.

INDIAN PATENT OFFICE WORKING: Positive Developments

The Indian Patent Office is witnessing a major overhaul in its working. During the year, the Intellectual Property Office has been radically transformed through numerous initiatives that have contributed tremendously to easing of access to the IP system, efficiency in processing of IP applications, uniformity and consistency in the examination of applications, transparency and dissemination of IP information, bilateral cooperation at the international level, and raising the awareness level of the public. The different moves being implemented are expected to spur innovation and bring the patent office in line with global practices. For the first time ever, a patent has been granted within a record 113 days in contrast to five to six year period traditionally taken by the Indian Patent office.

Using a new provision, The Patents (Amendments) Rules, 2016, India has introduced 'expedited examination' for patents filed by startups and those entities which select India as the competent International Search Authority. A 'start up' or a PCT applicant nominating Indian Patent Office as ISA or as IPEA can now avail expedited examination, by paying higher fee, or by converting its regular request for examination to expedited examination, by paying the balance fee. The Rules mandates the Controllers to issue First Examination Report (FER) in cases where the expedited examination request is accepted, within 105 days. The response to FER to be filed within 6 months (extension of 3 months available on request), and the Controller, to dispose the applications within 3 months from the date of receipt of last reply, or within 3 months from the last date to put the application in order for grant, whichever is earlier.

The aim of the IPO is to to shorten the time period for grant of patents from the 'filing' of application to its grant to two-three years, down from the current five-seven years. According to the Controller General of Patents, Designs &Trademarks (CGPDTM), Mr. O. P. Gupta, the rules aim to remove bottlenecks in the process, clear pendency and encourage more filings, technological advancement and innovation.

In yet other major development the Office of the CGPDTM, under the commerce and industry ministry, came out with revised guidelines on June 30, 2017 for examination of Computer Related Inventions (CRIs) as there were concerns on the general rules released in February last year. The fresh guidelines has ve diluted the 'novel hardware' requirement that was made mandatory in 2016 guidelines to seek patents for CRIs. The rules appear to indicate that the Indian Patent Office has taken a more favorable approach to the allowance of CRIs as compared to the past.

An example of the effect of the fresh CRI guidelines may already have started showingan impact. Social media major Facebook has received a patent in India for systems and methods providing privacy settings for applications installed in their profiles in the matter of Patent Application No. 6752/CHENP/2009 (Patent Number: 285615).The application came up for a hearing on June 28, 2017. The Patent Office raised various objections, including the method in the first three claims being nothing but an algorithmic method of providing application-based privacy in a social network which was not allowable under section 3(K). Facebook amended its claims and submitted that the method related to third-party applications was available through a privacy summary module, which was a summary of the privacy settings for display. The Controller observed that the invention was not just about providing privacy settings, but also provided privacy settings for controlling data that third-party applications could share with other users. It also included a hardware limitation by providing privacy settings to users at the application level showing the necessary physical interactions among the hardware components and thus did not fall under the Section 3(K) of the Indian Patents Act, 1970.

The subject matter of the above patent assumes significance in the debate over Right to Privacy on Internet space. The social media network majors, like Facebook, Instagram and WhatsApp amongst others, have brought in various privacy settings and provide various options for customized privacy settings for content provided by users,

giving them control over who can access the content in their posts. On August 24, 2017, in a unanimous ruling, a nine-judge bench of the Supreme Court of India upheld the Right to Privacy as a fundamental right under the Constitution.

Further the effect of The Patents (Amendments) Rules, 2016 has now started showing up. With the decrease in time limit for putting an application in order for grant under Section 21 from 12 months to 6 months from the date of First Examination Report (FER), the prosecution of patent applications has been substantially expedited. This limit can be extended by only maximum up to three months. With the amended rules, the hearings are being conducted through video-conferencing or audio-visual communication devices. For adjournment of a hearing, only a maximum of two adjournments may be requested by paying fees, with each adjournment limited for upto 30 days. Post hearing submissions are now required to be filed within 15 days from the date of hearing. Also, the decision of patent hearings is being issued at the earliest.Therate of application disposal has increased with the recruitment of new Examiners in all the subject domains. Additionally the miscellaneous applications for amendments, request for certified copies, assignment recordal, issuance of foreign filing license etc. has been expedited. A comparative analysis of the status of issued examination reports is tabulated in the annexed charts.

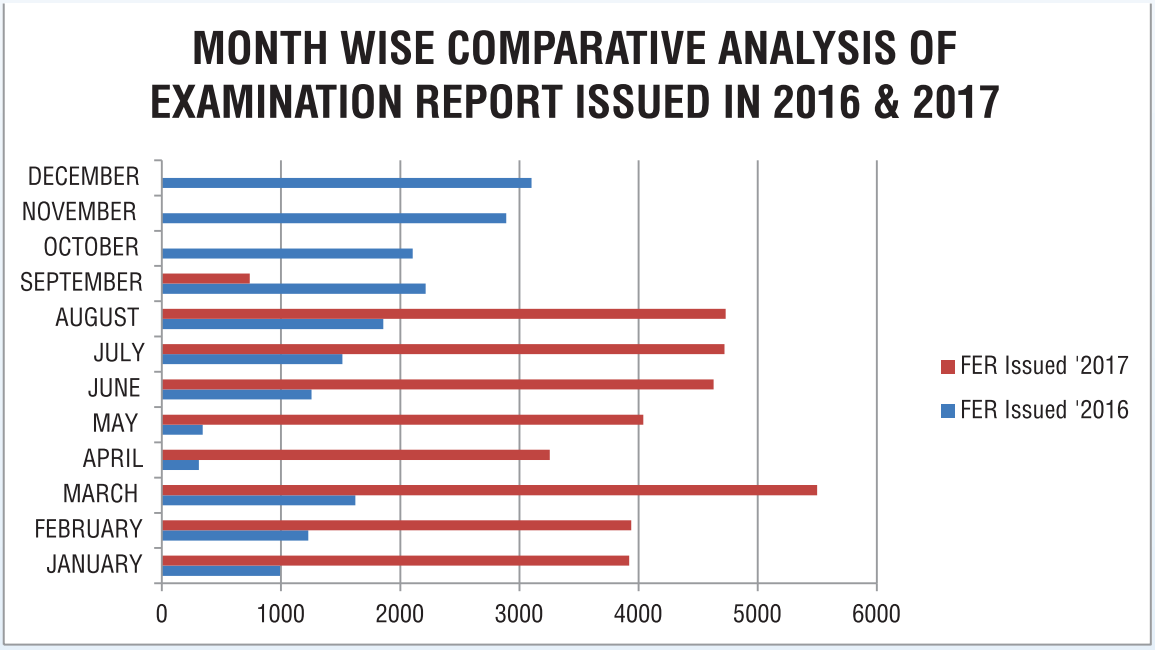

Fig. 1

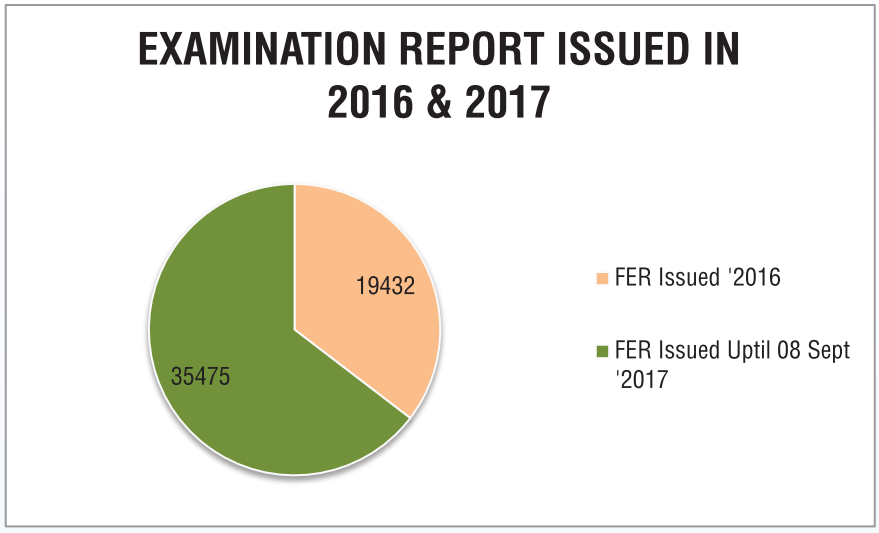

Fig. 2

Similarly grants have increased substantially too as is clear from the Fig. 3:

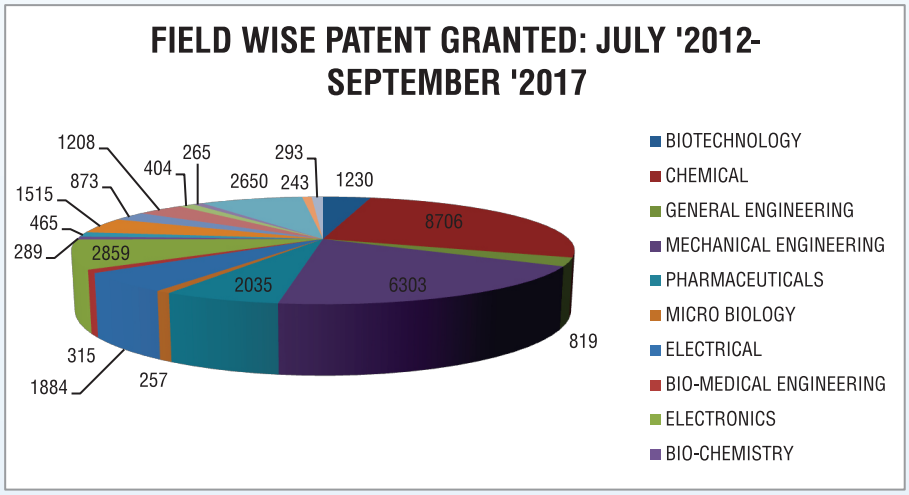

Fig. 3

Given the initiatives taken by the Indian Government through the IP reforms, we believe the IP ecosystem is marching towards positive and efficient changes. For ensuring high-quality examination of IP titles, specialized technical groups have been established to ensure access to relevant expertise for examination. In consultation with stakeholders, guidelines have been established to address complex examination questions arising in specific technology fields, including traditional knowledge and biological material, biotechnology, pharmaceuticals and computer-related inventions. The Government's aim is to ensure that India's IP services are on a par with the best in the world.

Contributed by **Mohit Kumar Choudhary**

THE LALL & SETHI TEAM

Dr. Anju Khanna, Partner at Lall & Sethi, heads the Patent Department of the firm. She is a Ph.D. and a post doctorate from the Indian Institute of Technology (IIT), Delhi. She is a registered Patent Agent and has more than 15 years of experience in handling patent matters. She works on various technology areas including chemistry, pharmaceuticals, polymers, medical devices, mechanical, electrical and electronics and computer software. She is actively involved in advising clients in relation to their prosecution and litigation strategies for procurement and enforcement of patents rights in India. She also actively participates in policy making in relation to the procurement and enforcement of patent rights in India.

Anju is a member of International Trade Marks Association (INTA), Intellectual Property Attorneys Association (IPAA), Asian Patent Attorneys Association (APAA), AIPPI and the IPO Annual Meeting. She is a member of the Designs Committee at INTA and the Patent Committee at APAA.

Mohit Kumar Choudhary

Manika Arora

Abhinav Agarwal

Aditya Kochhar

Harshad Kharadbhajne

Rohin Koolwal

Abhimanyu Chauhan

Sweta Sharma

Raghav Malik (Managing Partner), is an advocate registered with the Bar Council of India since 2006. With an experience of around 11 years, his practice focuses on overall IP prosecution and enforcement for both domestic and international clients. He specializes in strategy building, enforcement strategies, anti-counterfeiting actions and other legal issues arising thereto. He represents clients in the field of pharmaceuticals, apparel, banking & financial services and FMCGs. He also heads the Nepal branch office. He is a member of International Trade Marks Association (INTA) and is actively involved in INTA Committees. He is also a member of Intellectual Property Attorneys Association (IPAA).

Ali Areeb Zaidi

Pranav Taneja

Nireeti Gupta

Ananya Singh

Jyotideep Kaur - Partner is an advocate registered with the Bar Council of India since 2006. With an experience of around 11 years, her practice focuses on overall IP prosecution and enforcement for both domestic and international clients. She specializes in portfolio management and enforcement strategies, anti-counterfeiting actions and other legal issues arising thereto. She serves as a counsel for a wide range of clients ranging from alcoholic beverages major, leading confectionery companies, FMCGs, pharmaceutical giants etc. She is a member of International Trade Marks Association (INTA) and Intellectual Property Attorneys Association (IPAA).

Rahul Govind

Radhika Arora

Sanat Bathla

Tia Malik – Partner Tia is an advocate registered with the bar council of India since 2007. With an experience of around 10 years, her practice focuses on overall IP prosecution and enforcement for both domestic and international clients. She specializes in strategy building, enforcement strategies, anti-counterfeiting actions and other legal issues arising thereto. Her clients include giants from the industry of media & telecommunications, fashion, pharmaceuticals, banking & financial services, confectionery and information technology. She also heads the Sri Lanka branch office. She is a member of International Trade Marks Association (INTA) and Intellectual Property Attorneys Association (IPAA).

Karan Bajaj

Manas Upmanyu

Saachi Shante

Litigation:

Kripa Pandit

Kangan Roda

Dhruv Nayar

Shreya Sethi

Anirudh Bhatia

Samridhi Sarang