CLASIS LAW

Newsletter

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Contents

Welcome to the August issue of the newsletter.

This edition brings to our readers a featured article entitled "Indian Patent Office revokes Hoffman-La-Roche's Valganciclovir Patent" which discusses the revocation of patent for drug 'Valganciclovir' and analyses certain interesting developments including the 'locus standi' of person interested who may initiate post grant opposition proceedings in respect of a granted patent.

We continue to highlight certain key judgements passed by the Hon'ble Supreme Court of India as well as changes in corporate and commercial matters, updates in Projects, Energy and Natural Resources and IP sector.

Your inputs and feedback are always welcome and we look forward to our interactions with you.

Indian Patent Office revokes Hoffman-La Roche's 'Valganciclovir' Patent

The Controller of Patents (India) recently revoked the patent granted for the anti-retroviral drug 'Valganciclovir' used for treating active cytomegalovirus retinitis infection (CMV) which if untreated leads to blindness in people with HIV. The said patent was granted by the Patent Office vide Indian Patent No. 207232 to Hoffman-La-Roche for Valganciclovir against the mail-box Application No. 959/MAS/1995 filed on July 27, 1995 under Section 5(2) of the Patents Act, 1970 [*hereinafter referred to as the* '***1970 Act***'].

Snared history of the Vajganciclovir patent up till the recent 1st July, 2015 Order of revocation

The Valganciclovir patent has been entangled in several controversies, judicial and quasi-judicial (if the pre-grant and post-grant oppositions may be described so) proceedings for almost half a decade now. The Patent for 'Valganciclovir' was granted without affording hearing to the pre-grant opponent namely Indian Network for Positive People (INP+) and Tamil Nadu Network of Positive People. INP+ and TNNP+ challenged the grant of patent before the Madras High Court, which set aside the grant of the patent on the ground of violation of natural justice and directed the Assistant Controller to hear the pre-grant oppositions before granting or rejecting the patent. The Assistant Controller after hearing the pre-grant oppositions proceeded to grant the patent in 2009.

Subsequently, INP+ and TNNP+ moved the Apex Court which allowed these organizations to join as intervener, the post grant opposition filed by Delhi Network of Positive People (DNP+), CIPLA, Matrix, Ranbaxy and Bakul Pharma. The Controller, after having considered the post-grant oppositions revoked the patent where after Hoffman-La Roche approached the Intellectual Property Appellate Board (IPAB) in appeal. The IPAB set aside the revocation on technical grounds and remanded the matter back to the Controller for consideration. The Controller, considered the post-grant oppositions afresh and revoked the Valganciclovir patent vide Order dated 1st July, 2015.

Revocation and grounds as per Controller's Order of 1st July, 2015

The patent was revoked by the Controller vide the above stated Order primarily on the following grounds:

Anticipation from prior art

The Valganciclovir patent was anticipated by the prior art US'924 and EP'329. The EP'329 has a Markush type claim and had planted a sign post at the precise destination well before the inventors of the Valganciclovir patent. A skilled person working in the synthetic chemistry field could easily arrive at the present invention without further experimentation;

While the problem in the prior art associated with ganciclovir was the poor oral bioavailability, the Controller held that the solution for improved oral bioavailability provided in the present invention could be undoubtedly derived from the prior art. It was known in the art at the time of filing the application that conversion of hydroxyl group in the side chain of acyclovir and ganciclovir substantially increases the oral bioavailability and suggestion or teaching to esterify the hydroxyl group(s) in the side chain of acyclovir and ganciclovir was clearly indicated in the prior arts US'924 and EP'329.

Therefore, the Controller held that results to be achieved and modification required in the molecule was already disclosed in the prior art and a skilled man in the art can be motivated to esterify one of the free hydroxyl group in the side chain having gone through the teachings in the prior arts US'924 and EP'329.

Section 3(d) requirement of 'enhancement of known efficacy'

Section 3(d) of the 1970 Act had not been satisfied as the improvement in oral bioavailability of the new form L-monovaline ester of ganciclovir than bis-valine ester of ganciclovir was not supported in the specification pertaining to efficacy.

The Controller further observed that only properties which were directly related to efficacy should be taken into account. The significant improvement in the efficacy of new form of ganciclovir with respect to ganciclovir was not shown in the description and since there was no direct relation shown for the improved bioavailability of new form of ganciclovir in the description with regard to the significant difference in the efficacy, therefore, such a new form shall be considered as a same substance.

Expert evidence does not qualify as prior art

The Controller also looked into the question of whether 'expert evidence' could be relied upon as a prior art document. The Controller observed that 'expert evidence' did provide as analysis of prior art along with the expert's experience in the relevant field. However, at the same time the expert evidence is generally is in favour of the either the applicant or the defendant and accordingly the expert evidence could no longer be deemed an impartial document, unlike the research documents.

The Controller however held that that expert evidence can be used for understanding the prior art documents but and understanding the invention in question. It was held that expert evidences cannot be considered as prior publications/ disclosures and therefore did not qualify as mandatory document to assess the patentability of any given invention under any provision under the 1970 Act.

Locus of NGOs to initiate post grant proceedings affirmed

The instant decision is also noteworthy as it was the first time that the scope of '*persons interested*' (i.e. persons who can file post grant oppositions) under Section 2(1)(t) of the 1970 Act was expanded to include NGOs by IPO when it first revoked the patent in 2010. The above mentioned widening of the definition of 'persons interested' has also been discussed briefly and reaffirmed by the Controller of Patents, Chennai in the latest Order dated 1st July, 2015.

It is pertinent note the difference in *locus standi* in question for initiating a pre-grant opposition and a post-grant opposition under the 1970 Act. While '*any person*' can file a pre-grant opposition since the rationale is to restrict worthless patents to the greatest extent possible. A post-grant opposition, on the other hand, can be filed only by a '*person interested*' and therefore a narrow opening was provided in case of post-grant oppositions.

However, the Controller in the instant matter held that locus standi in the post-grant opposition is to be viewed in broader perspective in order to grant quality patent and that the inventor had to the pass the tests not only in the Patent office but also from the public. The Controller vide the said Order has observed that NGOs have the *locus standi* to file post-grant opposition as they are the end users or persons are directly and severely affected, if the patent is granted and thus may be deemed '***persons interested***' under Section 2(1)(t) of the 1970 Act.

The grant of the said patent itself was particularly significant as the application claimed its earliest priority dated July 28, 1994 (which is prior to 1995) therefore making Valganciclovir the first prior-to-1995 pharmaceutical product to be patented in India while the general assumption has been that only drug molecules post 1995 only are eligible for patent protection in India since India became a party to TRIPS only in 1995.

Having said that, the revocation of the Valganciclovir patent is a landmark decision and a significant relief for patients as it has now opened the gates for cheaper generic versions of the same, thus making the treatment more affordable.

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Legal alert

Recent Judgements

Essar Oil Limited versus Hindustan Shipyard Limited and Others

Civil Appeal Nos. 3353 and 3344 of 2005
Decided on 2 July 2015

Oil and Natural Gas Commission ("ONGC") had given a contract to Hindustan Shipyard Ltd. ("HSL") to carry out certain works in coastal areas of India. HSL further entered into a contract containing an arbitration agreement with M/S Essar Oil Ltd ("Essar") and entrusted Essar with certain work. Dispute arose between HSL and Essar and the matter was referred to arbitration.

The Arbitral Tribunal held that since there was no privity of contract between Essar and ONGC, the liability to make payment to Essar was that of HSL.

Aggrieved from the said award, HSL filed a petition under section 34 of the Arbitration and Conciliation Act, 1996 before the District Court wherein the arbitral award was confirmed. HSL thereafter filed an appeal against the said order before the High Court wherein the appeal was allowed and set aside the arbitral award passed by the arbitral tribunal and the order passed by the District Court.

The main issues involved in the appeal before the Supreme Court were about ascertainment of a person, who would be liable to make payment to Essar since there was a sub-contract made by the HSL with Essar in addition to the contract with ONGC.

The Supreme Court vide its order dated 2 July 2015 set aside the order passed by the High Court and upheld the award passed by the arbitral tribunal. The Court held that in the absence of privity of contract between ONGC and Essar, merely because some payments were made by ONGC to Essar, does not make ONGC liable towards Essar. The Supreme Court further observed that ONGC was neither a party to the arbitration agreement nor a party to the sub-contract between HSL and Essar and hence cannot be held liable.

Nandkishore Lalbhai Mehta vs. New Era Fabrics Private Limited and Others

Civil Appeal Nos. 1131-1132 and 1148 of 2010
Decided on 8 July 2015

HIn the present case, Nandkishore Lalbhai Mehta and New Era Fabrics Private Limited ("NEFPL") entered into an agreement for sale of a property in favour of Nandkishore. Pursuant to the said agreement, Nandkishore paid certain amount as part of earnest money. The sale was subject to the permission that was required to be obtained from the concerned authority to convert the said property from industrial use to residential use. Accordingly, NEFPL intimated Labour Union about the Agreement and requested to give their consent to the same. At the same time, it approached the Arbitrator, Town Planning Scheme to have the said property converted into residential zone from industrial zone.

Labour Union however informed that they were not agreeable to the sale of stipulated property. Consequently, NEFPL informed this fact to Nandkishore stating that the agreement stood cancelled and they would return the amount of Rs 11,50,000/- with interest and also withdrew the application made to the Arbitrator, Town Planning Scheme for conversion of the property from industrial to residential zone. The Single Bench of jurisdictional High Court decreed the suit for specific agreement in favour of Nandkishore. On further appeal, the Division Bench set aside the decree of specific performance granted by single Judge of the High Court.

The Supreme Court has observed that once a contract has been terminated, either on the breach of the terms of the contract by one party and subsequent repudiation by the other or by frustration of the contract due to circumstances beyond the control of either of the parties, the contract legally comes to an end between the parties.

The Supreme Court further held that then there is no question of any contract/agreement subsisting between the parties, what follows is only the legal consequences which may have been contemplated in the terms of the contract e.g. liquidated damages, etc. However, the parties are at liberty to mutually novate the contract by bringing into existence a new contract altogether which would replace the old contract between the parties and the terms of the new contract take the place of the old contractual terms.

Corporate and commercial

Reserve Bank allows export factoring on non-recourse basis

The Reserve Bank of India vide its A.P. (DIR Series) Circular No. 5 dated 16th July, 2015 has permitted AD category-I banks to factor the export receivables on a 'non-recourse basis' so as to enable the exporters to improve their cash flow and meet their working capital requirements subject to conditions as under:

- AD banks may take their own business decision to enter into export factoring arrangement on non-recourse basis
- In case the export financing has not been done by the Export Factor, the Export Factor may pass on the net value to the financing bank/ Institution after realising the export proceeds
- AD bank, being the Export Factor, should have an arrangement with the Import Factor for credit evaluation & collection of payment
- Notation should be made on the invoice that importer has to make payment to the Import Factor
- After factoring, the Export Factor may close the export bills and report the same in the Export Data Processing and Monitoring System (EDPMS) of the RBI
- In case of single factor, not involving Import Factor overseas, the Export Factor may obtain credit evaluation details from the correspondent bank abroad
- KYC and due diligence on the exporter shall be ensured by the Export Factor

MCA clarification with regard to circulation of financial statements

The MCA as per General Circular No. 11/2015 dated 21st July, 2015 has clarified that a company holding a general meeting after giving a shorter notice under section 101 of the Companies Act may also circulate the financial statements at such shorter notice.

Further, clarification has also been issued in relation to:

- Clause (a) of fourth proviso to section 136(1) of the Companies Act, which require every company having a subsidiary or subsidiaries to place on its website, if any, separate audited accounts in respect of each of its subsidiary
- Fourth proviso to section 137(1) of the Companies Act, which requires that a company shall attach along with its financial statements to be filed with the ROC, the accounts of its subsidiaries which have been incorporated outside India and which have not established their place of business in India

Subject to such conditions, the MCA in consultation with ICAI has clarified that in case of a foreign subsidiary, which is not required to get its accounts audited as per legal requirements prevalent in the country of incorporation and which does not get such accounts audited, the holding/parent Indian may place/file such unaudited accounts to comply with requirements of Section 136(1) and 137(1) as applicable.

Introduction of composite caps for simplification of FDI Policy to attract foreign investments

The Government of India has issued Press Note 8 on FDI policy, 2015 inter-alia notifying following amendments in the FDI Policy:

- It is clarified that unless provided otherwise, the maximum amount which can be invested in an entity by foreign investors, is composite and includes all types of foreign investments, direct and indirect, regardless of whether the said investments have been made under Schedule 1 (FDI), 2 (FII), 2A (FPI), 3 (NRI), 6 (FVCI), 8 (QFI), 9 (LLPs) and 10 (DRs) of FEMA (Transfer or Issue of Security by Person Resident Outside India) Regulations
- The aggregate FII/FPI/QFI investment, individually or in conjunction with other kinds of foreign investment, will not exceed the sectoral/statutory cap
- Foreign investment in sectors under Government route resulting in transfer of ownership and/or control of Indian entities from resident Indian citizens to non-resident entities will be subject to Government approval
- Foreign investment in sectors under automatic route but with conditionalities, resulting in transfer of ownership and/or control of Indian entities from resident Indian citizens to non-resident entities will be subject to compliance of such conditionalities and no Government approval will be required

- Portfolio investment, up to aggregate foreign investment level of 49% or sectoral/statutory cap, whichever is lower, will not be subject to either Government approval or compliance of sectoral conditions, if such investment does not result in transfer of ownership and/or control of Indian entities from resident Indian citizens to non-resident entities
- Any existing foreign investment already made in accordance with the policy in existence would not require any modification to conform to these amendments
- The onus of compliance with the above conditions/ provisions will be on the investee company

Sector specific clarifications

- It is clarified that there are no sub-limits of portfolio investment and other kinds of foreign investments in commodity exchanges, credit information companies, infrastructure companies in the securities market and power exchanges
- In Defence sector where sectoral cap of 49% is prescribed, portfolio investment by FPI/FIIs/NRIs/QFIs and investments by FVCIs together will continue to be restricted to 24% of the total equity of the investee/joint venture company. Portfolio investments will be under automatic route
- In Banking – Private sector, where sectoral cap is 74%, FII/ FPI/QFI investment limits will continue to be within 49% of the total paid up capital of the company

Projects, energy and natural resources

Government clears 16 defence licence proposals worth Rs 6.13 billion

Giving a boost to the private participation in the defence sector the Department of Industrial Policy and Promotion, which has been undertaking major reforms to promote defence manufacturing under 'Make in India' initiative, has cleared 16 proposals with potential investment of over Rs 6.13 Billion pertaining to defence sector manufacturing. The proposals for industrial licences, including those of Pipavav Defence, the Tatas and the Samtel Thales, that were stuck for last several years, have been cleared in the latest meeting of the Licensing Committee, which was chaired by DIPP secretary Mr. Amitabh Kant.

Govt. of Kerala awards Rs 40.89 billion port project to Adani Ports and Special Economic Zone Limited

The Govt. of Kerala has issued the Letter of Award to Adani Ports and Special Economic Zone Limited for construction and operation of the Vizhinjam International Seaport on PPP mode. The total project cost estimated by the Kerala government is Rs 40.89 Billion and the time-frame for commissioning of the project is 4 years. Once developed it will be Kerala's first deep water multi cargo port and India's first deep water trans-shipment port which has been missing till date. Currently approximately 1 million TEUs of Indian cargo gets trans-shipped through foreign ports like Colombo.

Indian Oil awards EPC contract for LNG Terminal at Ennore port to Black & Veatch Consortium

Indian Oil Corporation Limited (IOCL) has awarded a turn-key contract for a new LNG Terminal at Ennore, Tamil Nadu to the consortium of Black & Veatch - a global engineering, procurement and construction (EPC) company and KSS Petron Pvt Ltd of India. Black & Veatch will lead the engineering, procurement, construction (EPC) and commissioning work on a turnkey basis and the plant is scheduled to be completed by 2018. India currently has four LNG terminals, all of them being on the west coast. IOCL's Ennore terminal will be the first-of-its-kind on India's east coast. The Ennore EPC project entails designing and building a facility to regasify five million metric tonne per annum (MMTPA) of tanker-borne LNG imported by IOCL.

Japan International Co-operation Agency submits the Draft feasibility report for the Mumbai-Ahmedabad High Speed Corridor

The Japan International Cooperation Agency (JICA), which had undertaken the feasibility study for a high-speed railway system on the Mumbai-Ahmedabad route, has submitted the draft report to the joint monitoring committee. The Joint Monitoring Committee has representations from the Railways Ministry, Finance Ministry and External Affairs Ministry and NITI Ayog from India with their counterparts from Japan. Under a Memorandum of Understanding (MoU) signed between India and Japan, the study is being jointly funded by both the countries. JICA is likely to submit the Final Report next month.

Government launches Digital India Initiative

The Central Govt. launched the Digital India Initiative under which it has attracted investment commitments worth Rs 4.5 Trillion from leading technology giants. The programme aims to foster e-governance initiative and promote inclusive growth in the areas of electronic services, products, devices and manufacturing.

IP update

Supreme Court upholds unconstitutionality of certain qualifications and selection procedure to members of IPAB

A Division Bench of the Hon'ble Supreme Court has affirmed the findings of the Madras High Court with respect to unconstitutionality of certain qualifications and the selection procedure to members of IPAB. The Madras High Court had declared unconstitutional Section 85(2) (b) and Section 85(3) (a) of the Trade Marks Act, 1999 which dealt with qualification and selection of Vice – Chairman and Judicial Member of the Intellectual Property Appellate Board (IPAB) on the ground that the same were contrary to the principle of separation of powers and the basic structure of the Constitution. The Apex Court, while dismissing the SLP preferred by the Union of India, observed that that there were no legal and valid grounds for interference with the Madras High Court's Order.

Uncertainty over 'Confidential discussion' in a dispute between Film Writer and Director continues

Adding to the jurisprudence of 'Breach of Confidence' cases in India, the Bombay High Court recently passed an ad-interim injunction in the case of ***Jyoti Kapoor & Anr. v. Kunal Kohli & Ors.*** *(Notice of Motion No. 490 of 2015 in Suit (L) No. 176 of 2015 decided on 19th May, 2015)* on the release of the film 'Phir Se', which was the centre of controversy between a film writer, Jyoti Kapoor and film director & producer, Kunal Kohli. The Plaintiff contended that the film was based on her script titled 'RSVP' and that the Defendant, Mr. Kunal Kohli had discussed with her the possibility of making a film on the aforesaid script.

A Single Judge Bench of the Bombay High Court, in what was being hailed as a landmark decision from the perspective of film writers and authors, recognized 'Breach of Confidentiality' in favour of the author and in doing so observed that in such a case, the idea or plot itself, if sufficiently developed, is entitled to protection from unauthorized use. The Single Judge Bench relied on the famed precedents in *Beyond Dreams Entertainment v. Zee Entertainment Enterprises Limited [2003 (27) PTC 457 (Bom)] and Zee Telefilms v Sundial Communications [2015 (62) PTC 241 (Bom)]* in concluding that known or commonplace individual components, when uniquely combined by design, organization or execution, lend 'novelty' or 'uniqueness' to the material. The Single Judge Bench further laid down that use of material need not be dishonest or deliberate but rather even an unintentional unauthorized use of such material leads to breach of trust or confidence. The Hon'ble Court further noted that the defendants had used the kernel of the plot and that the story contained confidential information used as a springboard to work around that information and coming up with the film 'Phir Se'.

However, the Division Bench of the Bombay High Court set aside the Single Judge Bench's Order by stating that the precedents didn't state anything about the combination of commonplace/known elements attaining novelty or uniqueness. Further, the Division Bench found that the balance of convenience in favour of the defendants as the film had been completed and was about to be released. It also observed that the plaintiffs, though had knowledge of the impugned film made by the defendants in October 2014 itself, chose to approach the courts for an interim relief against the defendants only at the last moment when all arrangements for the release of the film has been made by the Defendants. Therefore, the Division Bench found no prima facie case in favour of the Plaintiff nor the Plaintiffs were able to establish any irreparable injury which may entitled them for an injunction at this stage.

While the matter was taken in appeal before the Supreme Court by the Plaintiff - Ms. Jyoti Kapoor, wherein the parties resolved the matter by way of settlement.

BIFR / SICA scheme cannot be used to shield an injunction for infringement of trade marks

The Delhi High Court has in the case of ***Ferrero Spa and Ors. v. V M Siddique & Anr.*** *(I.A. No. 579/2014 in C.S.(O.S.) 2627/2013 decided on 24th March, 2015)* held that BIFR Scheme cannot be used as a 'shield' to carry out illegal/infringing activities and granted an interim injunction restraining the defendants from infringing the plaintiffs' trade marks.

In the instant matter, the plaintiffs were the proprietor of and had been using the trade mark "Tic Tac" since 1969 for fresh breath mints and introduced the same in India in 1999. The plaintiffs had brought a suit for injunction restraining the defendants from using a deceptively similar trade mark 'Tits Bits' in respect of the identical goods.

The defendant contended that plaintiffs demand for temporary injunction qualified as an action amounting to "Distress" and, if granted, would adversely impact the implementation of the rehabilitation scheme and would amount to an act of "execution" against the defendants, as understood under Section 22(1) of the Sick Industrial Companies (Special Provisions) Act, 1985 [hereinafter referred to as 'SICA Act'] and that the injunction would defeat the purpose of the SICA Act as if would be a failure to protect the assets of the company. The defendant contended that as a condition precedent, prior permission had to be sought from BIFR and it was only when the BIFR concluded that the relief for injunction would not impact the scheme, should the present proceedings for injunction refraining trade mark infringement be considered by the Court.

The Hon'ble Court rejected the contention put forth by the Defendant/Applicants and held that the same if accepted would be unfair and would lead to a state of affairs that would enable 'sick industrial companies' to evade liabilities for their wrongful acts and such a construction is not only against the spirit of the law but also against the very spirit of the statute invoked. The injunction would not act as distress under the SICA Act. The Hon'ble Court further observed that if the property/design in question does not belong to the defendants, then the provision of Section 22(1) of the SICA Act cannot be invoked as the said Section does not protect theft and/or piracy and/or imitation.

Recent events

Bunkering in Asia

29-30 July 2015, Singapore

Mustafa Motiwala, Partner attended the two days conference on 7th Annual Bunkering in Asia which was held on 29-30 July 2015 at Suntec, Singapore International Convention & Exhibition Centre, Singapore. The bunkering conference brought together around 200 participants. Regional and international leaders convened and addressed commercial, regulatory, supply-demand, price and global market issues.

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