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REGULATORY

Drug Price Control Order amended vis-à-vis price ceiling exemptions

The Government of India recently amended the Drugs (Prices Control) Order, 2013, ("DPCO 2013") through the Drugs (Prices Control) Amendment Order, 2019 ("DPCO 2019"). DPCO 2019 amends paragraph 32 of DPCO 2013 relating to drug price control exemption.

Prior to DPCO 2019, the scope of price control exemption was limited to only those manufacturers who were producing patented new drugs that were developed through indigenous research and development and not produced elsewhere. DPCO 2019 has the following effect:

a. It has removed the localization requirements for claiming price control exemption. Even importers and marketers of patented new drugs developed and manufactured outside India are now eligible for price control exemption for a period of five years from the start of its commercial marketing.

b. Conversely, domestic manufacturers who manufacture patented new drugs in India and outside India have also become eligible for price control exemption.

c. The drugs covered under DPCO 2019 are those that are covered only by a product patent and not a process patent. For drugs covered by process patents, localization requirements remain.

d. Orphan drugs have also been included in the list of drugs to which the provisions of price control would not be applicable.

CASE LAW UPDATE

PATENT

Delhi High Court asks Patent Office to permit cross examination of expert witness

In February this year, *Onyx Therapeutics, Inc. ("Onyx") vs. Union of India & Ors.*, the Delhi High Court ("DHC") set aside the order of the Controller of Patents, refusing to allow cross-examination of expert witnesses. The patentee, Onyx, was defending a post grant opposition against its granted Indian patent number 255964.

The opponent, a non-government organization, had submitted expert evidence in support of the grounds taken in their post-grant opposition. Onyx on the other hand, had not filed any expert evidence but wished to cross examine the opponent's experts. This request was initially allowed by the Controller and Onyx was asked to submit a formal request. However, the Controller changed his stance without any reasoning and issued a hearing notice for arguments on merits, whilst specifically refusing Onyx's request for cross examining the opponent's experts. Aggrieved by this order, Onyx preferred a constitutional writ before the DHC.

The patent (entitled "*Compounds for enzyme inhibition*") related to therapeutic utilities, including anti-inflammatory properties and inhibition of cell proliferation and was recognized by the Court to be highly technical in nature. The Court observed that in a proceeding wherein the credibility of the witnesses is in question or its statement is in dispute, the denial of an opportunity for cross-examination amounts to violation of principles of natural justice and vitiates the entire proceeding.

The Court also observed that the expert witnesses of the opponent had analysed different prior art documents to opine that the patent was not valid. This does not amount to facts *per se.* The Court, therefore, held that in such cases wherein the request of cross-examination is prayed for, the same ought to be granted.

It was further held that the Controller had conclusively held that cross-examination was required. Thus, in the absence of any change in circumstances, to form a completely opposite *prima facie* view, the *suo moto* act of the Controller to deny cross-examination, was without jurisdiction and a manifest error of law.

The Court thus directed the Controller to allow Onyx to cross examine the opponent's expert witness after filing their own expert affidavit to controvert the opinion of the opponent's experts.

A patentee can sue another patentee, confirms Delhi High Court

In *Hindustan Unilever Ltd. vs. Eureka Forbes Ltd.*, the Delhi High Court ("DHC") recently held that a suit for permanent injunction is maintainable under the provisions of the Patents Act, 1970 by one registered patentee against another.

The case dates back 12 years when Hindustan Unilever Ltd. (HUL) filed a suit for patent infringement against Eureka Forbes for its patent on water purifier. Interestingly, Eureka Forbes also owned a patent on an apparently similar technology. HUL's patent however had been issued prior to that of Eureka Forbes. HUL had filed a pre-grant opposition against Eureka Forbes' patent application, which could not progress due to technical issues.

Eureka Forbes contested the suit and applied for rejection of plaint, among others, on the ground that no suit for infringement of the patent lies against a registered patentee. The Court dismissed this contention in a detailed judgement in 2007. Eureka Forbes appealed before the Division Bench (DB) of the Delhi High Court which ruled in favour of HUL while keeping the question of law open. Later, the Supreme Court also upheld the Division Bench's order stating that the aforesaid question of law be made a preliminary issue, which was finally decided in the recent order.

Agreeing with the reasoning of the previous Judgment (dated August 10, 2007), the Judge pointed out that in its earlier position, Eureka Forbes drew parallels with the interpretation of Designs Act, 2000 in *Tobu Enterprises Vs. Megha Enterprises* and *SS Products of India Vs. Star Class*. It had contended that an infringement suit by one registered holder of design against another was not maintainable. However, when HUL relied upon the more recent judgement in *Mohan Lal, Proprietor of Mourya Industries Vs. Sona Paint & Hardwares* which established that a registered holder of a design can sue another registered design holder, Eureka Forbes changed its stance to state that patent and design law are different.

The Court held that Eureka Forbes has not cited any provisions which bar a suit for infringement by one patentee against another. Absent any such bar, the suit for injunction cannot be said to be in contravention of any statutory rules. Thus, the Court decided the preliminary issue of maintainability of the suit in favour of HUL.

Pendency of revocation petition at IPAB not a ground for staying infringement suit

The Gujarat High Court recently dismissed an application seeking stay of an infringement suit in the matter of *Galatea Ltd. and Ors. Vs. Diyora and Bhanderi Corporation and*

Ors. One of the defendants had sought a stay of the suit till the disposal of its revocation pending before the Intellectual Property Appellate Board ('IPAB'). The other two defendants had preferred a counter claim and not filed any revocation petition before the IPAB.

The defendant contended that before the suit for infringement of patent was filed by the patentee (Galatea), it had filed the revocation petition before the IPAB and that there is likelihood that the suit patent would be revoked. The defendant further argued that if the suit is not stayed, it may suffer irreparable loss which could not be compensated in terms of money and will suffer serious prejudice.

Galatea argued that the said revocation petition was not even registered with the IPAB since they were not served a copy of the same by the IPAB. Mere filing of a revocation petition and its pendency before the IPAB could not be a ground for staying the infringement proceedings.

Relying on the judgment of the Supreme Court in *Alloys Wobben vs. Yogesh Mehra*, the Court opined that there is no provision in the Patents Act, 1970 which calls for stay of infringement proceedings in the manner it exists in the Trade Marks Act, 1999 or in other enactments. The Court noted that prior to the Patents Act, 1970, the remedy for revocation of the patent, was available only before a High Court by way of a revocation petition or on a counterclaim in the patent infringement suit. However, Section 64 of the amended Patents Act (of 2005) provides two remedies to a defendant in a suit: a revocation petition before the IPAB or a counterclaim in the suit before the High Court.

In Alloys Wobben (supra), it was held that if a defendant in an infringement suit raises a counterclaim seeking revocation of a patent, the validity of such a challenge can be determined only by the High Court. The IPAB would thereafter cease to have the jurisdiction to adjudicate upon the validity of the patent. Applying the same principle, the Judge rejected the application for stay in the infringement proceedings. Further, the defendant's plea to invoke inherent powers of the Court under the Civil Procedure Code to pass orders in the interest of justice, was also rejected.

Supreme Court of India restores Monsanto's Bt-Cotton patent and remands the matter for trial

On January 8, 2019, the Supreme Court of India in *Monsanto Technology vs. Nuziveedu Seeds Ltd* restored Monsanto's patent and remanded the case to the Delhi High Court (DHC) for trial. Monsanto had appealed the order of a two-judge Bench of the DHC in early 2018 that had revoked Monsanto's Indian patent covering the Bt-Cotton technology. The DHC had summarily adjudicated the validity of the patent, without calling for evidence at trial. Elaborate submissions on issues of fact, law and technical processes involved in the patent in question, were made before the Supreme Court. However, the Court limited its order to the question whether or not the patent was invalidated by the DHC as per the law. All the other issues of facts and law were kept open to be urged for consideration in appropriate proceedings.
Brief facts involved in the case are as below:

1. Pursuant to a patent being granted for their Bt-Cotton technology (Patent number 214436), Monsanto entered into a sub-licence agreement in 2004 with the defendants (collectively, "Nuziveedu") for an initial period of ten years, further extended by a year. The agreement entitled the defendants to develop and commercialize "Genetically Modified Hybrid Cotton Planting Seeds" with the help of Monsanto's technology. In return, Monsanto were to receive licence fee/trait value.
2. Disputes arose regarding payment of licence fee/trait value in view of subsequent price control regime introduced by the Government, which Nuziveedu wanted Monsanto to adhere to. The agreement was ultimately terminated by Monsanto in November 2015. In view of the termination, Monsanto approached the DHC for an injunction to restrain Nuziveedu from using their registered trade mark and selling the Bt-Cotton seeds in violation of their patent.
3. Nuziveedu, denying any infringement, filed a counter claim for invalidation of the patent as being in violation of Section 3(j) of the Patents Act in respect of plants and seeds that contained DNA sequences.
4. In March 2017, a Single Judge of the DHC held that the issues arising in the suit necessarily required formal proof, particularly expert opinion, which in complicated matters like that of patent infringement

were crucial for ascertaining the breadth of the monopoly granted by the specifications of a patent claim.

5. The Court held that pending the suit, the parties would remain bound by their respective obligations under the sub-licence agreement and that the licence fee/trait value payable by Nuziveedu would be governed by the laws in force.
6. Aggrieved, both the parties preferred appeals. The two-judge Bench of the DHC dismissed Monsanto's appeal and directed them to agree to payment of licence fee/trait value by Nuziveedu in accordance with the law and restore their obligations under the sub-licence agreement.
7. Going a step further, the Court also revoked Monsanto's patent suggesting that they take recourse to the Protection of Plant Varieties and Farmers' Rights Act, 2001 (PPVFRA).
8. Monsanto approached the Supreme Court by way of a Special Leave Petition (SLP) against the two-judge Bench order. The Court held that, given the complexity of the suit and in the absence of any expert evidence, the Appellate Bench of the DHC was wrong to have disposed it in a summary manner. The Court also stated that complicated issues such as whether or not the nucleic acid sequence trait once inserted could be removed from that variety and whether the patented DNA sequence was a plant or a part of a plant etc., are all matters which were required to be considered at the final hearing of the suit, i.e., after trial.

The judgment has provided much-awaited relief to the biotech industry in general as the Supreme Court nullified the adverse opinion of the two-judge Bench of DHC with regard to patentability of biotech-based inventions in India.

TRADEMARKS

Delhi High Court on descriptive marks

The issue for determination in *Bigtree Entertainment Pvt. Ltd. v. D Sharma & Anr.*, before the Delhi High Court was whether the plaintiff could assert rights in a descriptive mark. Bigtree Entertainment (Bigtree), the plaintiff, is a very popular and successful online ticketing venture operating under the mark "BOOKMYSHOW". Bigtree was aggrieved by the use of the mark "BOOKMYEVENT" by the defendant, Bookmyevent.in Private Limited (BPL) for similar services. Bigtree sought an injunction against BPL and argued that the prefix "BOOKMY" was an essential part of its registered mark "BOOKMYSHOW" and that it had come to be exclusively associated with it due to open, continuous and extensive use over the years.

BPL defended the suit and argued that "BOOKMY" is a descriptive term in the industry relating to booking of shows, events, films etc. That being so, BPL contended that it cannot be monopolized. Agreeing with BPL and denying any interim relief to Bigtree, the Court noted that the expression "BOOKMY" is not an invented word and is in fact, an apt description of a business that is involved in booking of tickets for shows, events, films, etc. The Court further pointed out that whether the expression "BOOKMY" has acquired secondary meaning or distinctiveness and has come to be associated exclusively with Bigtree can only be established at trial after the parties have led evidence. The Court also observed that the rival marks were visually different from each other in terms of their colour scheme and the font, thereby reducing the chances of confusion and deception among public.

Delhi High Court awards "aggravated" punitive damages

What do you do with a habitual infringer who has been at it for over 25 years? In *Whatman International Ltd. v. P. Mehta & Ors*, the Delhi High Court was dealing with a deliberate, willful, and undeterred infringer habituated to perjury, who needed to be dealt with a heavy hand. The infringed mark was WHATMAN owned by the plaintiff, Whatman International ("WI"), in respect of filter papers. The defendants (collectively, "Mehtas"), a group of individuals, apparently related to each other, were manufacturing and selling Whatman filter paper and were also using an identical colour combination (white and blue) for other filter papers sold by them under various trademarks such as HIRAL, ACHME, LABSMAN, U-CHEM, SUN etc.

WI's Product

Mehtas' products

The Mehtas had a long history of manufacturing and selling counterfeit Whatman filter paper, going back to 1992. Despite giving several undertakings to WI prior to the institution of this suit, Mehtas continued to sell the infringing goods, leading to WI filing the present suit.

Taking note of the fact that Mehtas had deliberately, consciously and willfully impinged on WI's rights for a period spanning over 25 years, the Court observed that this was a fit case for award of "aggravated", punitive damages. The punitive damages awarded by the High Court was to the tune of INR 38.5 million (~US$ 550,000) in favour of WI. The Court also went on to award WI the actual costs incurred in the case. The Court also observed that not only Mehtas had caused damage to WI, they had also caused damage to the customers who had purchased these products presuming the same to be genuine WHATMAN filter paper.

The quantum of punitive damages awarded herein is amongst the highest in India in cases pertaining to trademark infringement and passing-off and highlights the Court's resolve to deal with habitual infringers with a heavy hand.

No similarity between "Officer's Choice" and "Fauji"

In *Allied Benders & Distillers Private Limited v. Govind Yadav & Anr.*, the question that arose for consideration was whether the marks "Officer's Choice" and "Fauji" were similar? The plaintiff, Allied Blenders & Distillers Private Limited ("AB") owned the mark "Officer's Choice" and had been using the same in relation to whisky since 1988. The defendant, Gwalior Distilleries Limited ("GDL"), was using the mark "Fauji" in respect of an identical product. "Fauji" in Hindi language means a 'soldier'. It was AB's case that GDL's mark "Fauji", depicting a similar idea, was conceptually and deceptively similar to the mark "Officer's Choice". AB argued that "Fauji" was a commonly used Hindi language phrase that refers to a "Military Officer" and that since AB and GDL were in the same trade/business, the likelihood of the confusion amongst the consumers was very high. AB also alleged similarity in the labels of the rival products, which are reproduced below:

AB's labels

GDL's label

However, the Court rejected the arguments advanced by AB and held that there was no resemblance or similarity between the rival marks. It was observed that while the word "Officer" refers to "a person in power", the expression "Fauji" means a "soldier" who is not a military officer. Reference was made to Section 2(zy) of the Cantonments Act, 2006 which defines the expression "soldier" to mean any person who is a soldier or sailor or an airman subject to the Army Act, 1950, the Navy Act, 1957 or the Air Force Act, 1950, as the case may be, and who is not a "military officer". The Court also rejected AB's claim vis-à-vis the similarity in labels stating that GDL had used a different font and epaulette in their label.

Non-use of plaintiff's mark is no defense to infringement action

In *New Balance Athletic Inc v. Apex Shoe Company Pvt Ltd*, the registered trademark 'NEW BALANCE' of the plaintiff New Balance Athletic Inc ("NB") in class 25 was filed based on proposed use. NB had filed a suit for trademark infringement against the defendant, Apex Shoe Company Pvt Ltd ("AS"). AS had a pending application for the mark APEX NEW BALANCE in class 25, with a user claim since 1999. AS argued that NB's registration disentitled it from an injunction, as it was on 'proposed use' basis. The Court, however, noted that, till the institution of the suit, AS did not take any steps for having NB's mark removed from the register for non-use and granted an interim injunction in favour of NB.

PLANT VARIETY

Computation of renewal fee for plant varieties clarified by the Delhi High Court

Clarifying the controversy revolving around computing of renewal fee in respect of registration of plant varieties, the Delhi High Court ("DHC") has recently allowed a writ petition filed by Maharashtra Hybrid Seed Co. Pvt. Ltd. ("Mahyco") against an order passed in October 2016 by the Registrar of Protection of Plant Varieties and Farmers' Rights Authority (PPV&FRA).

Rule 39 of the PPV&FR Rules ("Rules") provides for the renewal fee to be computed based on the average annual fee levied during the last two years of the initial period of registration. Seemingly inconsistent with this, Entry 5 of the Second Schedule to the said Rules provides for a flat rate of payment of renewal fee (INR 80,000).

Mahyco had paid the annual fee in respect of two wheat varieties registered under the Act in its favour, and also remitted a renewal fee in accordance with Rule 39 of the PPV&FR Rules, 2003. The Registrar of PPV&FRA in response called upon Mahyco to pay the renewal fee in accordance with the Second Schedule.

Though Mahyco contested the aforesaid demand, the Registrar of PPV&FRA rejected the contentions after a hearing. The Registrar in his order construed Mahyco's contention as one asserting that "if average of annual fees of the last two years of the initial period of registration is paid, it would suffice for both annual fee and renewal fee for the remaining period of registration".

Aggrieved by this, Mahyco challenged the order before the DHC. The DHC in its judgement pointed out that the impugned order had misinterpreted the contention of Mahyco. It further held that the Second Schedule would not override the provisions of Rule 39 essentially for two reasons:

- Rule 39 is a special rule relating to the renewal of registration and by applying the maxim of *generalia specialibus non derogant*, that is, "a special provision shall override the general", Rule 39 would override the Second Schedule.
- The Second Schedule is an adjunct to Rule 8 and provides the Schedule of fees as payable under said Rule. Although the Second Schedule provides for the renewal fee, there appears to be no such provision under Rule 8.

Setting aside the Registrar's order, the Court clarified that Rule 39 is a special rule for the computation of renewal fee. Thus, it directed the PPV&FRA to accept the renewal fee for Mahyco's registered plant varieties, as computed under said Rule.

Plant Variety Authority of India issues directions on seed production and price regulation

Earlier this year, the Protection of Plant Varieties and Farmers' Rights Authority (PPV&FRA) issued directions to the departments of the Central and State Governments, and the public and private sector organizations regarding seed production and price regulation. The directions include suitable revision of the procedures in place for such matters including, among others, sale price fixation of seed, trait value fixation per variety, etc., of varieties registered under PPV&FR Act, 2001 during the period of their protection.

The notice further states that the exclusive intellectual property rights conferred by Section 28 of the PPV&FR Act, 2001 to plant breeders and farmers on the new and extant plant varieties cannot be abrogated. Accordingly, the sale and sale price fixation, trait value fixation etc., of a registered variety must be done in accordance with the PPV&FR Act. This can only be done with the authorisation of registered breeder or his assignee or his agent, and as per the mutual terms and conditions between the right holder and others concerned.

The notice carrying these directions also recognises the obligation of registered breeder/agent/licensee to provide the seeds to farmers in time for planting to satisfy their requirements at a reasonable market price. It further affirms that in case the conditions of requirements and reasonable market price are not met, the aggrieved parties may opt for compulsory licensing option.

While the actual impact and implementation of this notice remains to be seen, it does seem to be a step towards accomplishing the fundamental intent of the PPV&FR Act, i.e., to protect the rights of farmers and plant breeders while encouraging the development of new varieties of plants.

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