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Roche's drug Valcyte recently got itself disentangled from one of the many webs of litigation its Indian patent is currently caught in.

The Chennai Patent Office has dismissed the pre-grant opposition representation that had been filed by two NGOs in June 2006. The Chennai Patent Office had earlier not allowed oral hearing to the two NGOs in relation to their representation and proceeded to grant the patent to Roche. However, Madras High Court directed the Chennai Patent Office to grant hearing to the opponents. The opponents were heard and the opposition was dismissed. Thus, Roche's Valcyte patent continues to remain valid.

A brief chronological history traversing the journey of Valcyte:

Valcyte is the brand name of an antiviral drug with the active ingredient Valganciclovir hydrochloride¹, used to treat cytomegalovirus (CMV) retinitis infection in persons who have acquired immunodeficiency syndrome (AIDS) or for prevention of infection during organ transplant.

This drug was developed by Syntex USA (Inc) in 1994 in the USA. Syntex USA (Inc) is now a subsidiary of Swiss company Roche Holdings Ltd.

The drug was first patented in Switzerland in 1994.

In the USA it is protected under multiple patents, two of which (US6083953 and US5840891) were granted in 1998 and 2001 respectively. These derive priority from their continuation application (Ser. No. 08/281,893) dated July 28, 1994, that was subsequently abandoned in 1996.

Indian prosecution history:

F.Hoffmann-La Roche AG, a subsidiary of Roche Holdings Ltd. ("**Roche/ Applicants**") filed a Patent Application² titled '*2-(2-Amino-1,6-Dihydro-6-oxo-purin-9-yl)-methoxy-1,3-propanediol Derivative*' on July 27, 1995 that was duly published by the Chennai Patent Office ("**Office**") on February 25, 2005.

¹ Chemical IUPAC name: 2-[(2-amino-6-oxo-6,9-dihydro-3H-purin-9-yl)methoxy]-3-hydroxypropyl (2S)-2-amino-3-methylbutanoate

² Application No.959/MAS/1995

On July 12, 2006, two NGOs, Indian Network for People living with HIV/AIDS and Tamil Nadu Networking People with HIV/AIDS (“**Opponents**”) filed a pre-grant opposition representation under Section 25(1) of the Patents Act, 1970 (“**Act**”), accompanied by a specific request for a hearing in the matter. The grounds of opposition raised in the representation were under Section 25(1)(f) and 25(1)(h)³ of the Act.

In November, 2006 the Opponents received a letter from the Office notifying that on the basis of the opposition filed by the Opponents, notice has been given to Applicants in accordance with Rule 55(4) of the Patent Rules, 2003 (“**Rules**”). Thereafter, the Applicants filed a reply within the prescribed time limit. However, the Opponents were not informed of anything about the fate of their objection, nor were they informed of the date of hearing in respect of their objection. On 12th April, 2007, the Patent Office addressed a communication to the Applicants as follows:

“Your above said application for patent has been found in order for grant. However, patent will be granted after disposal of pre-grant opposition by way of third party representation, if any, under Section 25(1) of the Act and found in favour of the application. In this connection, you may note that you can initiate infringement proceedings only after grant.”

Thereafter, the Patent Office granted the patent⁴ to Applicants and the same was published in the Official Journal of the Patent Office on June 29, 2007. On getting information of this, the Opponents issued a letter to the Office dated October 29, 2007 complaining that the Opponents’ right of hearing in respect of their opposition representation was denied and they did not receive any communication from the Patent Office intimating the date of hearing or any intimation that their objections have been rejected. The said letter prayed that the patent granted should be withdrawn or cancelled, failing which proceedings would be initiated.

To this letter, the Patent Office sent a reply on November 12, 2007 informing that the grounds of objections raised by the Opponents in their representation under Section 25(1) of the Act had been carefully considered and it was found that the objections raised were met by the Applicants, and the Office went ahead with the grant in order “to expedite the prosecution of application for patent in question”.

Thereafter, the Opponents sent a further letter on November 28, 2007 to the Office praying for furnishing them with documents leading to the grant of the patent including a “copy of the

³ Section 25 (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—*
(f) That the subject matter of any claim of the complete specification is not an invention within the meaning of this Act, or is not patentable under this Act
(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

⁴ The patent is numbered as IN207232.

decision disposing of the representation by way of opposition". The Patent Office did not reply to this letter. Consequently the Opponents filed a Writ Petition on October 15, 2008 before the Madras High Court under Article 226 of the Constitution of India praying for the issue of a Writ of Mandamus to quash the said patent and consequently direct the Patent Office to consider the patent application only after hearing the Opponents as per provisions of the Act and Rules and award costs.

The ruling of the Madras High Court on December 12, 2008:

The Hon'ble Chief Justice of the High Court took into consideration the above facts and allowed the writ petition.

It held that the grant of said patent without hearing the Opponents' representation was "in blatant violation of statutory procedure by the statutory authority, which is acting in a quasi-judicial capacity." It held that such a grant was "not legally sustainable".

While setting aside the grant of the patent, it directed the Patent Office to assign the consideration of the Opponents' pre-grant opposition to any officer in the rank of Assistant Controller of Patents, Designs & Trade Marks, other than the Examiner who had granted the Patent.

Accordingly, the Chennai Patent Office heard the Opponents and Applicants in a hearing conducted in January 2009.

The hearing before the Assistant Controller at Chennai Patent Office

The High Court had issued clear instructions in its judgement, that this hearing should be restricted to only those contentions that were submitted by the Opponents before the grant of the patent and no fresh grounds or documents should be considered. Hence the Assistant Controller gave his decision based on the two grounds raised by the Opponents.

1. Arguments under Section 25(1)(f):

- (a) The Opponents under this ground would have to prove that the subject matter claimed is not an invention within the meaning of the Act, or is not patentable under the Act. The Opponents argued that this being an omnibus provision, it includes the patentability criteria of 'novelty' and 'inventive step' under Section 2(1)(j) in addition to Sections 3 and 4 falling under the heading "*Inventions Not Patentable*".

However, the Assistant Controller held that Section 25(1)(f) included only the criteria laid down under Sections 3 and 4 of the Act, and was not relevant for 'novelty' and 'inventive step'. The Controller pointed out that Section 25(1) had specific grounds under other clauses if the Opponents wished to argue on 'novelty' and 'inventive step'.

(b) The Opponents also argued that a patent ought not to be granted for the Applicants' invention because it claimed priority from a pre-1995 Convention country application, a time when India did not grant product patents.

What is the significance of "pre-1995"?

The Indian Patents Act, 1970 specifically excluded grant of product patents in relation to chemicals (and hence drug molecules) till it became TRIPS⁵ compliant in 2005. Being under the category of "developing country", India was given a ten year transition period from January 1, 1995 to allow product patents for drugs. However, legislation allowing the same was not immediately enacted. Hence, in the period between January 1, 1995 and January 1, 2005, in accordance with the 'mailbox' provisions in Article 70.8 of TRIPS, India started to allow filing for the said product patent applications and thereby establish their filing dates, while at the same time permitting India to defer the granting of the patent for pharmaceutical products. Hence, a chemical product disclosed by any means, before 1995, for which a patent application was not filed in India within the time prescribed by the Paris Convention, would consequently lose Novelty (since India did not permit product patent).

Why the Opponents' "pre-1995" argument failed:

The Applicants, claiming priority from US patent application number 08/281,893, filed on July 28, 1994, had filed the Indian application on July 27, 1995 i.e. within 12 months, as is prescribed under Paris Convention. The Assistant Controller stated that the claimed invention was not in public domain on the date of filing the application in India, and rejected the Opponents' contention.

It is pertinent to observe that on the contrary, pre-1995 chemical products were not eligible for grant of Exclusive Marketing Rights (EMR)⁶ under the Section 24B (deleted under the 2005 Amendment of the Act). Only those applications filed on or after "the first day of January, 1995" in any country under the Paris Convention were considered for grant of EMRs.

2. Argument under Section 25(1)(h):

The Controller stated that the ground of opposition under section 25(1)(h) is only limited to:

(a) *the applicant has failed to disclose to the Controller the information required by Section 8,*

⁵ TRIPS stands for: Agreement on Trade-Related Aspects Of Intellectual Property Rights

⁶ Exclusive rights to market within India those chemical products claimed by a patent applicant between 1995 and 2005 i.e. in the transition period. These rights were granted to an applicant upon satisfaction of certain conditions, in accordance with Article 70.9 of TRIPS.

(b) has furnished the information which in any material particular was false to his knowledge.

Under (a) the Opponents contended that there was delay on the part of the Applicants in filing information regarding corresponding foreign filings, and the Office had rejected Applicants' petition under Rule 138 for extension of time on one occasion. It had finally accepted the information after a petition under Rule 137 was accepted by the Controller. The Opponents claimed that any order of the Office in this regard under Rule 137 was null and void. The Assistant Controller held that a Controller of the Office had the power to correct any irregularity in procedure, and hence contention under (a) was rejected.

Under (b) the Opponent neither argued nor submitted any evidence regarding the Applicant not disclosing the information or giving wrong information to the Controller.

Hence, the ground of opposition under Section 25(1)(h) was struck down.

Other litigations Valcyte is embroiled in:

- **Post grant oppositions:**

There are reportedly five post grant oppositions against Roche's 'Valcyte' patent (number IN207232) filed by Indian generic companies: Cipla Ltd. ("**Cipla**"), Ranbaxy Ltd. and Matrix Laboratories, all of which have launched the generic versions of Valcyte in the market already, and two by NGOs.

- **Roche's infringement suit against Cipla:**

Roche has reportedly proceeded against Cipla in the Bombay High Court on September 27, 2008 alleging that:

1. Cipla's drug Valcept- the generic version of Valcyte, violated Roche's rights in its patent and
2. The name Valcept was phonetically similar to Valcyte and hence violated trademark rights in relation to Valcyte.

In December 2008, Roche got an interim order in its favour under which Cipla was enjoined from using the trademark Valcept for its drug as it was found to be "deceptively and confusingly similar" with Roche's trademark Valcyte. Cipla was given three weeks to comply with the order. However, the Court adjourned the patent infringement matter for eight weeks because Roche's Valcyte patent was then yet under judicial scrutiny.

Valcyte is the fifth Roche drug that has been granted a patent in India since 2006. In February 2007, Roche got a patent for its drug Erlotinib used for treating patients of small cell lung cancer, branded as 'Tarceva'. Cipla launched its generic version in December, 2007 called 'Erlocip', post

which, Roche filed a suit for patent infringement against Cipla in Delhi High Court. The Court in its interim order dated March 19, 2008, refused injunction against Cipla on the grounds that the price of Erlocip was one-third the cost of Roche's Tarceva. On the point of "balance of convenience", the Court stated that between two competing public interests, that is, the public interest in granting an injunction to affirm a patent during the pendency of an infringement action, as opposed to the public interest in access for the people to a life saving drug, the balance has to be tilted in favour of the latter." The matter is expected to come for final hearing in a few months.

In the present case of Valganciclovir, in the domestic market, Roche's branded Valcyte costs INR 1000 per tablet, while Cipla's generic Valcept is sold at a price of INR 245 for a tablet. A treatment course of approximately four months for CMV retinitis using Roche's drug in India reportedly costs over INR 2,50,000.

It remains to be seen how the patent infringement suit in the Valcyte-Valcept Bombay High Court matter proceeds now that the grant of the patent has been upheld by the Chennai Patent Office by its January 30, 2009 order.

Sources - Times of India, Business Standard, Mint, Madras High Court order dated December 2, 2008 and Chennai Patent Office order dated January 30, 2009.

This analysis should not be construed as a legal opinion. Although every effort has been made to provide accurate information in this analysis, we cannot represent or guarantee that the content of this analysis is appropriate for your situation and hence this information is not a substitute for professional advice. The facts and figures mentioned in this analysis have been obtained from publically available sources and Nishith Desai Associates does not vouch the accuracy of the same. It may not be relied upon by any person for any other purpose, nor is it to be quoted or referred to in any public document or shown to, or filed with any government authority, agency or other official body without our consent. We are relying upon relevant provisions of the Indian laws, and the regulations thereunder, and the judicial and administrative interpretations thereof, which are subject to change or modification by subsequent legislative, regulatory, administrative, or judicial decisions. Any such changes could have an effect on our interpretation of the relevant provisions contained in this analysis.