



Indian Patent Office Rejects Abraxane Patent Application for the Second Time

IPpro Services (India) Pvt. Ltd

© IPpro Inc., 2014



IPpro Services (India) Pvt. Ltd.

Indian Patent Office Rejects Abraxane Patent Application for the Second Time

On June 24, 2014, the Indian Patent Office (IPO) refused to grant a patent for Abraxane®, the anti-cancer drug developed by the US firm Abraxis Biosciences (hereinafter referred as Abraxis), for the second time. The IPO had rejected the patent for Abraxane earlier on 28th April, 2009. Thereafter, Abraxis appealed at Intellectual Property Appellate Board (IPAB). The IPAB had passed a remand order on 20th January, 2014 to consider the patent application for Abraxane as afresh. The patent application for Abraxane was considered as afresh in April, 2014 by the IPO and was rejected again. The rejection was based on lack of inventive step. The IPO was also of the opinion that the patent application for Abraxane does not constitute an invention on consideration of the claims and a pre-grant opposition filed by Natco Pharma Ltd.

History of the Abraxane case:

Abraxis, a fully integrated biotech firm, developed a proprietary tumor targeting system known as nanoparticle albumin-bound nab® technology platform which was used to develop Abraxane. Abraxane is used in the treatment of breast cancer, lung cancer and pancreatic cancer. Abraxis filed a patent application 2899/DELNP/2005, titled "Composition and method for delivery of pharmacological agents" for the anti-cancer drug Abraxane. Natco Pharma Ltd. challenged the validity of the patent application for Abraxane by filing a pre-grant opposition under section 25(1) on various grounds. One of the grounds in the pre-grant opposition was lack of inventive step. The challenge of Natco was on the basis of its anti-cancer drug that had already been launched as Albupax in 2008. Albupax was the first nanotech-based cancer drug developed indigenously by Natco. Around 4 years ago, Abraxis had complained to the Drug Controller General of India (DCGI) about safety and efficacy issues with Albupax. Upon investigation, DCGI concluded that Albupax contained excessively high amounts of endotoxins and chloroform and Natco's license to manufacture the Albupax was revoked. Till date, Natco is yet to launch the drug again.

In view of the pre-grant opposition, the IPO rejected the patent application for Abraxane. The IPO refused to grant the patent based on lack of inventive step in claims, not being patentable under section 3(d) and insufficient disclosure. The



IPpro Services (India) Pvt. Ltd.

main ground of rejection was under section 3 (d), the provision under which Novartis lost protection on a blockbuster drug Glivec last year.

Abraxis contesting the IPO's decision filed an appeal at the IPAB. The appellant was Abraxis and the respondents were Natco Pharma Ltd., Union of Indian, Controller and Assistant Controller General of Patents, Design.

- The appellant argued on denial of opportunity to be heard, which is mandatory as per section 14 and 15 of the Act, to clarify objections raised by IPO.
- The appellant also raised an appeal against the order passed under section 25(1) for which IPAB denied the opportunity for the appellant to appeal the ruling, stating that the order passed under section 25(1) is not appealable in accordance with the existing rules.
- The appellant informed that the order passed by the Delhi High Court order states that the pre-grant opposition is appealable. Thus, the appellant was allowed to file an appeal with the IPAB.
- The denial was on the ground of appellant not responding to the FER within the prescribed time period, though in reality, they had filed a response to the FER within the prescribed time period as per the appellant.
- The appellant also pointed out that the IPO took the decision suo moto on the ground of insufficient disclosure which was not raised by Natco.
- The appellant also argued that during the proceeding in the IPO, on March 10, 2009 Natco Pharma filed additional documents. The appellant objected taking the additional documents into consideration through an interlocutory petition. Without looking into the petition from the appellant, the controller had proceeded to hear the matter.
- Natco argued that the order does not cause any violation of principles of natural justice and the IPO was right in refusing patent for the drug.

On 20th January 2014, the IPAB set aside the order of the IPO, stating that there was "flagrant violation of principles of natural justice", since it stems from the fact that the IPO failed to accord Abraxis an opportunity to be heard u/s 14 of the patents act 1970 before giving an order u/s 25(1) which was not appealable at that time. Therefore, the order passed on 28th April, 2009 was set aside and the IPO was asked to consider the patent application as afresh. The IPAB also directed that the proceedings should be completed within three months from the date of the IPAB order.



IPpro Services (India) Pvt. Ltd.

The matter was heard afresh in April 2014 by the IPO and another order was passed, rejecting the patent application again. The Assistant controller of Patents and Design Nilanjana Mukherjee ordered, "The amended claims of Abraxis Boisciences lack inventive step and do not constitute an invention under the Patents Act, 1970." Therefore, it is concluded that amended claims lack inventive step and do not constitute an invention u/s 2(1) (j). Also, the amended claims fall u/s 3(d) and 3(e) and the specification is also insufficient u/s 10 of the Patents Act, 1970.

Analysis:

Abraxis's loss is likely to encourage generic drug manufacturers to fearlessly market low cost versions of Abraxane. The loss is may be viewed as similar to the loss of Novartis for Glivec. The loss of Abraxis is another blow to the western pharmaceutical companies who are looking to improve sales in India and elsewhere. Abraxis might either appeal the order in front of the IPAB again or file a writ petition. If the order of the IPO is upheld, then the generic drug manufacturers will be the winners once again.



IPpro Services (India) Pvt. Ltd.

References:

1. <http://www.indiawrites.org/india-and-the-world/why-patent-for-anti-cancer-drug-was-denied/>
2. <http://www.lifesciencesipreview.com/news/indian-patent-office-rejects-anti-cancer-drug-patent-543>
3. [http://www.smartinvestor.in/market/story-222583-storydet-IPAB remands Natcos pre grant opposition on anti cancer drug Abraxane to patent office.htm#.U60K1LFNF6Y](http://www.smartinvestor.in/market/story-222583-storydet-IPAB%20remands%20Natcos%20pre%20grant%20opposition%20on%20anti%20cancer%20drug%20Abraxane%20to%20patent%20office.htm#.U60K1LFNF6Y)
4. <http://www.pharmabiz.com/ArticleDetails.aspx?aid=82608&sid=1>
5. <http://www.bananaip.com/sinapse-blog/2014/06/rejection-ipo-anti-cancer-drug-abraxane.html>
6. <http://www.samachar.com/ipab-refers-opposition-to-anti-cancer-drug-to-patent-office-obwaligajda.html>
7. <http://www.jagranjosh.com/current-affairs/indian-patent-office-refused-to-grant-patent-on-anticancer-drug-abraxane-of-us-firm-1403701157-1>
8. http://www.business-standard.com/article/companies/ipab-refuses-patent-for-anti-cancer-drug-abraxane-114062200461_1.html



IPpro Services (India) Pvt. Ltd.

Disclaimer

The content of this article is intended as a research article and provides general information existing at the time of preparation. This article is written for educational purposes only and should not be construed as legal opinion. IPpro Services (India) Pvt. Ltd. neither assumes nor accepts any responsibility for any loss arising to any person acting or refraining from acting as a result of any material contained in this article. The information provided in the article is to the best of our knowledge; however, we do not guarantee about the quality, accuracy, reliability, adequacy or completeness of any of such information and material, and expressly disclaim any liability for errors or omissions in such information and material. It is recommended that professional advice be taken based on the specific facts and circumstances. This article does not substitute the need to refer to the original pronouncements.



IPpro Services (India) Pvt. Ltd.

About IPpro Services (India) Pvt. Ltd.

IPpro is a knowledge based research driven firm that provides customized cost effective patent and litigation support services. With four office location worldwide in Bangalore, Bombay, Singapore and the Silicon Valley, we deliver high quality work and round-the-clock connectivity to ensure high-speed delivery and full coordination with client companies and patent attorneys. We provide a unique value proposition through a disciplined project methodology, in which we customize each assignment as per client requirements, while taking advantage of our integrated team of highly-skilled and motivated professionals and overall low cost structure through economies of scale and scope. For maintaining confidentiality, we follow a detailed internal policy in which all employees are required to enter into confidentiality agreements, which include detailed steps on the use and disclosure of confidential information. We also use technology to maintain the highest level of security in our computer systems, thereby preventing leakage and unauthorized access of confidential information.

For more information about IPpro, please visit our website: www.ipproinc.com

BANGALORE

G-02, Prestige Loka, 7/1, Brunton Road,
Bangalore - 560 025, India.
Phone: + 91 - 80 6693 5000
Fax: + 91 - 80 6693 5001

MUMBAI

93-B Mittal Court, Nariman Point,
Mumbai - 400 021, India.
Phone: + 91 - 22 6669 5000
Fax: + 91 - 22 6669 5001

SILICON VALLEY

220 California Ave, Suite 201, Palo Alto,
CA - 94306, USA.
Phone: + 1 - 650 325 7100
Fax: + 1 - 650 325 7300

SINGAPORE

Level 30, Six Battery Road
Singapore - 049909
Tel: + 65 - 6550 9855
Fax: + 65 - 6550 9856