CASE STUDIES

LEGAL SYSTEMS IN BUSINESS

Case Study Number	1
Level of Teaching	L2
Program Outcomes Covered	PO1, PO2, PO4, PO5. PO6, PO7
Course Outcome Covered	C201.5

Glivec: Pre-Grant opposition- Novartis case on Indian IPR

The law suit filed by Novartis in the Chennai High Court, challenging the Indian Patent Office for:

1. Denial of its patent application for Glivec
2. Constitutional validity of section 3(d) of Indian Patent Law

Background Information

Glivec (Gleevec in US) (Compound-imatinib mesylate) by Novartis is patented in 35 countries & helpful in Chronic Myeloid Leukemia The corresponding Indian Application for Glivec in India 1602/MAS/1998, titled, "Crystal modification of A N-phenyl-2-Pyrimidineamine derivative, processes for its manufacture and its use" was filed by Novartis on July 17th, 1998. This application is directed to Mesylate salt of Imatinib. Two polymorphs of imatinib mesylate are claimed : Alpha & Beta. [Original molecule imatinib is disclosed in US 5521184 titled "Pyrimidine derivatives and processes for the preparation thereof" in 1993]

Issue: Pre-grant Opposition to Glivec in India

Various interest groups filed a pre-grant opposition to the Indian Application 1602/MAS/1998 under the provision of section 25(1) of the Indian Patent Act. Chennai Patent Office rejected Gleevec patent application in January 2006, on the grounds that the application claimed 'only a new form of a known substance.'

Challenge to the Indian Patent Office

Novartis filed a legal petition in the Chennai High Court by Novartis challenging the Indian Patent Office for:

- Denial of its patent application for Glivec
- Constitutional validity of section 3(d) of Indian Patent Law.

Novartis stated that the Section 3(d) was not compatible to the agreement on Trade Related aspects of Intellectual Property Rights (TRIPS) and that it was vague, illogical and arbitrary. It said the provision conferred "uncanalised" discretionary power on the patent controller, who would apply his own norms that might not be uniform, while deciding the efficacy of the substance submitted for patent. Justice R. Balasubramanian and Justice Prabha Sridevan of the Madras High Court ordered to transfer the case to Appellate Board (2nd April, 2007) Novartis disagreed with the appointment of the former Controller General of the Indian Patent Office to the IPAB. Novartis filed another petition in the High Court in Chennai for a new technical member of the Intellectual Property Appellate Board (IPAB).

Judgment of the High-court

The Madras High Court dismissed two writ petitions filed by Novartis AG and Novartis India Limited.

High Court on the Constitutional validity of 3(d):

Rejecting the contention, a Division Bench, comprising Justices R. Balasubramanian and Prabha Sridevan said: "The argument that the amended Section must be held to be bad in law since, for want of guidelines, it gives

scope to the statutory authority to exercise its power arbitrarily, has to be necessarily rejected. We find that there are inbuilt materials in the amended Section and the Explanation itself, which would control/guide the discretion to be exercised by the statutory authority. In other words, the statutory authority would be definitely guided by the materials placed before it for arriving at a conclusion." If the statutory authority, in exercising his power, misdirects himself, abuses his power in an arbitrary manner and passes an order, then it could be corrected by the hierarchy of forums provided in the Act itself, in addition to the further relief
available before the courts of law. "When that is the position, then we have to necessarily state that the amended Section cannot be invalidated solely on the ground that there is a possibility of
misusing the power," the Judges said. The Right to Equality enshrined in Article 14 of the Constitution could be invoked
only when it was shown that in the exercise of a discretionary power there was a possibility of a real and substantial discrimination, the Bench said. "It is not shown by senior counsel appearing for the petitioners (Novartis) before us that in the exercise of discretionary power by the Patent Controller, any of the petitioner's fundamental rights are violated, namely, to carry on the trade or the petitioner stood singularly discriminated. We find that the amended Section by itself does not discriminate nor does it prohibit the trade being carried on," it said. International treaties and agreements were essentially in the nature of a contract, the Bench said, adding that the TRIPS Agreement provided for a comprehensive dispute settlement mechanism, which was binding on its member-States.

"We see no reason at all as to why the petitioner, which itself is a part of that member-State, should not be directed to have the dispute resolved under the dispute settlement mechanism...We see no reason at all as to why we must disregard it..." Reiterating that there was no ambiguity or vagueness in the provision, the Judges said: "Senior counsel, except arguing that the amended Section must be struck down on the ground of ambiguity, arbitrariness, leading to exercise of uncanalised powers - with which we have not agreed at all - had not shown any other legal ground to invalidate the amended Section." Parliament expressed its object and purpose in general terms while enacting a statute and does not foresee the minute details that were likely to arise in the future and provide a solution. "On the other hand, they would be acting wiser if they make only general expressions, leaving it to the experts/statutory authorities and then courts, to
understand the general expressions used in the statute in the context in which they are used in a case to case basis." The Judges said: "Using general expressions in a statute, leaving the court to
understand its meaning, would not be a ground to declare a Section or an Act ultra vires the Constitution, is the law laid down by the Supreme Court. Interpretation of a statute must be to advance the object which the Act wants to achieve."

Conclusion

Novartis could not prove the enhancement in efficacy of the particular polymorphic form of the known moiety as compared to the known efficacy of the compound. Novartis' case suffered as they had produced a bioavailability study conducted on rats while the drug was admittedly in the market for many years and was consumed by humans.

For a new form of a known substance to be patented, it must offer significant advantage over the known substance in terms of efficacy. A patent application in such cases, should clearly furnish the comparative data with regard to efficacies of the known substance and its new forms respectively.

Case Study Number	2
Level of Teaching	L2
Program Outcomes Covered	PO1, PO2, PO4, PO5. PO6, PO7
Course Outcome Covered	C201.5

Merging of Ranbaxy and Diichi Sankyo Ranbaxy Companies Profile

Ranbaxy Pharmaceuticals Inc. (RPI), a wholly owned subsidiary of Ranbaxy Laboratories Limited. (RLL) was established in the U.S. in 1994. RPI began marketing FDA approved generic products in the U.S. in 1998 after receiving its first FDA approval for Cefaclor, a broad spectrum anti-infective agent. Ranbaxy Laboratories Inc. (RLI), also a wholly owned subsidiary of Ranbaxy Laboratories Limited. (RLL) is the branded prescription division in the U.S.RLI has been expanding and growing on the strength of Ranbaxy's R&D efforts, and continuing exploration of novel drug delivery systems (NDDS), licensing activities, mergers and acquisitions. RLI is expanding the visibility and presence of the Ranbaxy name by bringing value-added brand products to the market. Ranbaxy Pharmaceuticals Inc. and RLI have built on RLL's years of successful pharmaceutical experience and expertise. Ranbaxy has positioned itself as a robust and capable player in the U.S. market through the combined commitment of RPI and RLI to developing new and innovative products and a rapidly expanding generic and brand product portfolio. Daiichi Sankyo Companies Profile Daiichi Sankyo Company, Limited was established on September 28, 2005as the joint holding company of two major Japanese pharmaceutical companies - Sankyo Company, Limited and Daiichi Pharmaceutical Co., Ltd. Daiichi Sankyo is a global pharmaceutical innovator,

continuously generating innovative drugs and services and maximizing its corporate value. Sankyo and Daiichi Pharmaceutical have a broad range of major drug products on the Japanese market, including the antihypertensive Benicar(olmesartan medoxomil) and the synthetic antibacterial agent Cravit (levofloxacin). Both companies have used their cumulative knowledge and expertise in the field of cardiovascular disease as a foundation for developing an abundant product lineu and R&D pipeline.

The Merging Deal

Singh is selling his 34.8% stake for around Rs. 10,000 crore ($2.4 billion) at Rs. 737 ($17) per share. Daiichi Sankyo will pick up another 9.4% through a preferential allotment. According to Securities & Exchange Board of India (Sebi) norms, it will have a make an open offer to the shareholders of Ranbaxy for another 20%. There could also be a preferential issue of warrants to take the Daiichi Sankyo stake up by another 4.9%. That will come into play if the ordinary shareholders don't respond to the open offer and Daiichi Sankyo needs another way to raise its stake to 51%.At the end of the exercise, scheduled to be completed by March 2009, Ranbaxy will become a subsidiary of Daiichi Sankyo. Despite all the denials from Ranbaxy leadership, an Indian icon will vanish. (Similar circumstances drove Sunil Mittal of Bharti Airtel to walk out of a deal with MTN of South Africa; he wouldn't compromise the Airtel brand which had become "the pride of India.")What will Singh are doing with his $2.4 billion? He says that major investments are needed in Religare and Fortis, the group's forays into financial services and hospitals. But both are really part of the herd in their sectors while Ranbaxy was number one. Ranbaxy, with $1.6 billion in global sales in 2007, had a profit after tax of $190 million, a gain of 67% over the previous year. It has a footprint in 49countries and manufacturing facilities in 11. It has 12,000 employees, including 1,200 scientists and has been pouring money into R&D, though obviously not on the same scale as the Western majors. Ranbaxy is among the top 10 global generic companies. Its stated vision has been to be among the top five global generic players and to achieve global

sales of $5 billion by 2012. How much of that survives the Daiichi Sankyo regime remains to be seen. Indeed, there is a question over whether Singh himself will survive. He said that Ranbaxy is in his genes and there is no question he will remain CEO and, now, chairman. But will he be able to make the transition from a promoter to a professional CEO? He may have delivered Ranbaxy to Daiichi Sankyo, but now he has to deliver the goods. Daiichi Sankyo is the product of a 2005 merger between Sankyo and Daiichi. In the financial year ended March 2008, it had net sales of $8.2 billion and a profit after tax of $915 million. It has a presence in 21 countries and employs 18,000 people. It is the second largest pharmaceutical company in Japan. The company can trace its roots back to 1899, though the formal entity today is relatively new. Daiichi Sankyo makes prescription drugs, diagnostics, radiopharmaceuticals and over-the-counter drugs. The combined company will be worth about $30 billion. The acquisition will help Daiichi Sankyo to jump from number 22 in the global pharmaceutical sector to number 15. "The deal will complement our strong presence in innovation with a new, strong presence in thefast-growing business of non-proprietary pharmaceuticals," according to Shoda. The combination has other benefits for the Japanese company. It gets as take in a major player in generics, an area that is becoming increasingly important in Japan. According to the 2008 Japanese Pharmaceuticals &Healthcare Report (2nd quarter), the country's pharmaceutical market is currently valued at $74.4 billion and is the most mature in the Asia-Pacific region. By 2012, the market will grow to $82 billion. The country's generics sector is one of the most promising. "In an effort to control ballooning healthcare costs, the ministry of health plans to raise the volume share of generics within the total prescription market to at least 30% by 2012," says the report. "The current value of the sector is $5.5 billion, which equates to7.3% of total medicines sales. Changes to prescribing procedures and the influx of foreign firms with low-cost goods will provide a stimulus to the generic drug sector." The comparative figures of volume share of generics for the U.S. and the UK are 13% and 26%, so there is some way to go.

Getting into Japan

As much smaller companies than Ranbaxy have gone to Japan, shopping bag in hand, why didn't Singh try to purchase Daiichi Sankyo instead of selling? Domestic laws make Japanese companies difficult to take over. But there surely could have been an equivalent in Europe or the US. The Tata's and the Birla's have successfully targeted foreign companies several times their size. Why did Ranbaxy follow a different prescription? The answer may be in the fact that that Ranbaxy was on a much weaker wicket. The official version talks of synergies. Says a joint company statement: "Daiichi Sankyo and Ranbaxy believe this transaction will create significant long-term value for all stakeholders through:

•A complementary business combination that provides sustainable growth by diversification that spans the full spectrum of the pharmaceutical business.

•An expanded global reach that enables leading market positions in both mature and emerging markets with proprietary and non-proprietary products.

•Strong growth potential by effectively managing opportunities across the full pharmaceutical life-cycle.

•Cost competitiveness by optimizing usage of R&D and manufacturing facilities of both companies, especially in India."

Post-acquisition Objectives

In light of the above analyses, Daiichi Sankyo's focus is to develop new drugs to fill the gaps and take advantage of Ranbaxy's strong areas. To overcome its current challenges in cost structure and supply chain,

Daiichi Sankyo's primary aim is to establish a management framework that will expedite synergies. Having done that, the company seeks to reduce its exposure to branded drugs in a way that it can cover the impact of margin pressures on the business, especially in Japan. In a global pharmaceutical industry making a shift towards generics and emerging market opportunities, Daiichi Sankyo's acquisition of Ranbaxy signals a move on the lines of its global counterparts Novartis and local competitors Astellas Pharma, Eesei and Takeda Pharmaceutical. Post acquisition challenges include managing the different working and business cultures of the two organizations, undertaking minimal and essential integration and retaining the management independence of Ranbaxy without hampering synergies. Ranbaxy and Daiichi Sankyo will also need to consolidate their intellectual capital and acquire an edge over their foreign counterparts.

Conclusion

In summary, Daiichi Sankyo's move to acquire Ranbaxy will enable the company to gain the best of both worlds without investing heavily into the generic business. The patent perspective of the merger clearly indicates the intentions of both companies in filling the respective void spaces of the other and emerge as a global leader in the pharmaceutical industry. Furthermore, Daiichi Sankyo's portfolio will be broadened to include steroids and other technologies such as sieving methods, and a host of therapeutic segments such as anti-asthmatics, anti-retroviral, and impotency and antimalarial drugs, to name a few. Above all, Daiichi Sankyo will now have access to Ranbaxy's entire range of 153 therapeutic drugs across 17 diverse therapeutic indications. Additional NDAs from the US FDA on anti-histaminic and anti-diabetics is an added advantage. (Source - http://www.scribd.com)