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434C1F – LEGAL SYSTEMS IN BUSINESS

MBA 1ST SEMESTER

CASE STUDY

Prepared by

Dr.S.G.BALAJI, **M.B.A.,M.Phil.,PGDIB., Ph.D., Certificate Course on ESG**
ASSOCIATE PROFESSOR & RESEARCH SUPERVISOR, RESEARCH HEAD.
MEASI Institute of Management
Chennai -14.

Case Study – Sale of goods Act, 1930

Mr. G sold some goods to Mr. H for certain price by issue of an invoice, but payment in respect of the same was not received on that day. The goods were packed and lying in the godown of Mr. G. The goods were inspected by H's agent and were found to be in order. Later on, the dues of the goods were settled in cash. Just after receiving cash, Mr. G asked Mr. H that goods should be taken away from his godown to enable him to store other goods purchased by him. After one day, since Mr. H did not take delivery of the goods, Mr. G kept the goods out of the godown in an open space. Due to rain, some goods were damaged. Referring to the provisions of the Sale of Goods Act, 1930,

Analyse the above situation and decide who will be held responsible for the above damage. Will your answer be different, if the dues were not settled in cash and are still pending?

Case Study - Factories Act, 1948 (Workplace Health and Safety)

Fred has developed a lung infection that appears to have been caused by the fine particles of plastic that escape from the cutting machine he operates at “Ruthless Engineering”. Fred’s boss doesn’t believe him and refuses to advise the workers compensation insurer or the relevant regulatory body. He warns Fred that if he speaks out about his infection, he will be dismissed.

a. Briefly explain the regulations that Ruthless engineering should follow to comply in the state in which you live.
b. Advice “Ruthless Engineering” on how they can stop this happening in the future and avoid potential hazards in their business operation.

Case Study – IPR

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.

(Source- http://www.rkdewan.com)