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# "Kibow case will encourage strong patent protection scenario in India"

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**"Kibow case will encourage strong patent protection scenario in India"**



**About Author:** Prity Khastgir is a Biotech and Pharmaceutical Indian Patent Attorney at Tech Corp Legal LLP, an Indian Intellectual Property law firm based in New Delhi. She also serves as Director at Tech Corp International Consultants Pte. Ltd. (Singapore), wherein she advises clients regarding freedom to operate (FTO) studies for their new product or service and search for possible foreign IP rights that could be infringed. Patent clearance searches are rapidly becoming a necessity for any technology company to enter in India and in any other foreign country. Having multi-jurisdictional experience gives her clients insights in protecting and enforcing their intellectual property rights in several countries.

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From time to time, India has been held responsible by foreign pharmaceutical and biotech companies that India's patent ecosystem is weak and doesn't encourage innovation nor provides adequate patent protection to research and development activities. However, recent judgement of Intellectual Property Appellate Board (IPAB) has been ruled in favour of US-based biotechnology company Kibow, headed by Natarajan Ranganathan upholding its initial patent and affirming that the company's break through probiotic dietary supplement sold under the brand name "Renadyl" capsules is patentable in India.

Renadyl$^{TM}$, a probiotic dietary supplement allows patients with kidney disorders; metabolize nitrogenous waste build up in the blood due to non-proper functioning of the kidney. The nitrogenous wastes are utilized by Renadyl$^{TM}$ as nutrients in the large intestines. Since probiotics grow and multiply, they consume more nitrogenous waste and consequently they are very effective to maintain healthy kidney function in patients. Kibow Biotech was initially granted two patents one on April 3rd, 2007 for the process patent and the other on September 29th, 2008 for the product patent. The product patent was related to the disclosure of dietary supplement capsules and the process patent was related to the disclosure of the process utilized to prepare the capsules.

Factual Background of the Present Case:

La Renon Healthcare has a product under the brand name CUDO with similar composition and has filed for patent registration before the Indian Patent Office, which is still pending approval. However, Kibow had issued a cease and desist notice upon them on October 5th, 2010 to restrain from infringing its two patents. In its reply statement La Renon Healthcare argued that they believed that the composition and process of manufacturing of their product CUDO is unique, superior and first of its kind in India which cannot be disclosed as it is in the process of getting the patent before the Indian Patent Office. La Renon Healthcare did not restrain itself from manufacturing and selling the product CUDO, and subsequently a civil suit was filed in 2011 before the Hon'ble High Court of Madras by Kibow Biotech alleging infringement of patent Nos. 205478 and 224100, a revocation petition against the two Kibow patents was filed by LaRenon Health Care, before the Intellectual Property Appellate Board (IPAB) in India.

**Intellectual Property Appellate Board (IPAB) Analysis On ground of Mere admixture:**

On Analysis, IPAB held that the process patent "claims as granted speak of the process of making the composition by mixing the integers. The five integers are known much prior to the filing of this patent. A mere admixture of such nature does not involve any inventive step. There is no mention of the working of these products so as to having any great result. So, no synergistic effect could be achieved by the combination as a whole and therefore, there is no inventive step in mere combination of known integers."

IPAB held that invention is obvious to a person skilled in the art. Moreover, it was noted that the patent description gives an account of kidney failure and talks of solute removal in the gut in nitro studies which does not describe the process of mixing the pharmaceutical composition as a whole. Subsequently, there was nothing new and no technical advancement was observed in the mixing of the five integers and therefore, not an invention. Consequently, the process patent was revoked by the IPAB.

For the patent No. 224100 granted to Kibow Biotech Inc., for the invention "Compositions for Augmenting Kidney Function", IPAB found that the granted invention is not obvious in view of the prior art documents cited by La Renon Health Care. The inventive composition of the patent comprises at least one probiotics bacteria of a certain kind, in a certain composition and it is not a mere admixture and is patentable under the Indian Patent Act, 1970. As stated by IPAB "the invention covers a new and inventive composition comprising at least one probiotic bacteria of a certain kind, in a certain composition and along with other additives (such as vitamins etc) that confer synergistic impact, enabling the augmentation of kidney function. By no stretch of imagination can this unique composition be labelled as mere admixture."

LaRenon, plans to appeal the IPAB verdict. Currently, LaRenon has been selling Cudo for Rs. 4,500 for a bottle of 30 pills, while Renadyl is expected to sell for Rs. 5,000 for a bottle of 40 pills, a month's dosage.

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**Relevance of Section 3(e) of the Indian Patent Act for Multinational Pharmaceutical Companies**

As per Section 3(e) of the Indian Patent Act "a substance obtained by a mere admixture resulting only in the aggregation of the properties of the components thereof or a process for producing such substance."

The above mentioned section is a major obstacle for new forms (salts, polymorphs, solvates, etc) of pharmaceutical drugs substances, unless until the patentee illustrates improved effectiveness over existing product. For e.g., a composition of two drugs, i.e. Paracetamol and Ibuprofen for curing fever and pain or process of preparation thereof is not patentable for the reason that the composition is a mere admixture of two drug components resulting into aggregation of properties thereof; since Paracetamol is well known for treatment of fever and Ibuprofen for treatment of pain. However, if the mixture of drugs exhibits some unexpected results or synergistic properties in their action, then such composition is considered as patentable subject matter. Moreover, the patent description should be supported with adequate test results to confirm the synergistic properties of the pharmaceutical drug or molecule.

**Factual Effect on Kibow Biotech**

Although IPAB has invalidated the process patent but uphold the product patent, which is much more important for Kibow because it restricts its competitors from making a similar copy of pharmaceutical capsules and other forms and protects the intellectual value of the final pharmaceutical product. IPAB upholding the product patent in favour of Renadyl represents a good sign for Kibow Biotech, which will enter the Indian market with a strong product patent.

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According to the Probiotic Association of India, the India's probiotic market has been growing at an annual growth rate of 22.6% and is expected to reach a turnover of about $8 million by the year 2015. Current major players in the Indian probiotic industry are Amul, Mother Dairy, Yakult Danone and Nestle along with other minor players operating in different regions in their own capacities. Therefore, India is number one market worldwide for dietary supplements, which will provide Kibow bears the fruits of protecting its Intellectual Property Rights in India and subsequently earn a significant amount of capital in the country by manufacturing or by licensing its patented products to third parties in India. Renadyl product is currently sold in the US and Canada, and has met with patent approval in Australia, China, Japan, and Korea and the US, and is pending in the European Union.

**Patent Prosecution Process in India**

The overall process of patent prosecution in India is a bit complicated due to multiple compliances and deadlines to follow by the patent applicants. Moreover, the overall process from the step of patent filing to patent grant is long drawn. Understanding why a research needs patent protection in a particular country, what all processes and drug products can be patented or how to build a strong portfolio of patents is very vital for succuss of biotech ventures. Moreover, section 3 of the Indian Patent Act related to non-patentable inventions is very important section cited by the patent examiners during the patent prosecution stage. Therefore the patent applicant should take proactive steps during the patent prosecution stage and comply with the legal requirements of the Indian patent act.

Conclusion:

The Indian Patent regime has been committed to encourage innovation by providing a strong patent system and thus encouraging strong innovation in research and developmental activities. A strong patent regime in the pharmaceutical industry is very important to foster innovation through the patent system and at the same it is imperative to reject weak patents to prevent patent-extending "evergreening" strategies, which allow the drug manufacturers to create a monopoly and maintain a market share which increases cost of healthcare.