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## CASE COMMENT: ASTRAZENECA AB & ANR. VS. INTAS PHARMACEUTICALS LIMITED

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### ABSTRACT

In the recent times, pharma based companies have occupied the limelight all around. Within that very limelight, it is very easy to undertake the prohibited practice of ever-greening and ensure that the drug under consideration can be patented for a period extending more than the prescribed 20 years. The concept was again brought to the forefront in the recent judgment of the Delhi High Court in the Astrazeneca v. Intas Pharmaceuticals case. Indian courts have not shied away from intervening in the practices of ever-greening. The case concerned double patenting and time and again it has been reassured that a product cannot be covered by more than one patent. The case further goes on to distinguish between the two patents and due notice of the criterion for the grant of patents was taken. There has to be a difference between two patents and this is why we have entered into the protection of intellectual property at the first place. Though with respect to the drug under consideration, the issue of disclosure and the reported manufacture and sale of the drug was not dealt with in detail by the court, the parties relied heavily on the patenting provisions in other countries to prove the difference. We have been growing vigilant about our rights and the various statutes are there for the protection of the sake but at the same time, the rampant misuse of the provisions has been causing a lot of trouble. Though this judgment gave a clear outlook onto the various twists and turns which the pharma IP in India is expected to have in the coming times, it is imperative that a friendly atmosphere be created so as to give a due effect to the national policies on the same.

**Keywords:** Double-patenting, Ever-greening, pharma, intellectual property

## Introduction

Intellectual Property Rights are very dynamic in nature. Conventionally, a person can acquire only one patent for a particular invention. Had this principle been not in place, the same would have led to obtaining of monopoly for a single invention. However the intent any intellectual property right is to vest the author, creator or the inventor with a bundle of rights for a specified period of time and the invention gets released in the public domain after the expiry of the period.

The public consideration of a patent is deprived when a patent is granted twice, or rather, more than once. Hence in such a case, the free use after the expiry of the period is not taken into account. This might give a rise to manifold proceedings of infringement of patents. The same was made explicitly clear in the case of *United States of America v. American Bell Telephone Company*<sup>1</sup>. It was very categorically stated by the court that monopoly in a patent gets over after the time limit gets exhausted and the public is free to use the same since they pay in for the same. Hence it is imperative that multiplicity of infringement proceedings is avoided.

When it comes to double patenting, it is used to prevent any kind of unjust extension of a patent beyond the prescribed term of a patent under consideration. The apt justification behind this doctrine is that the public is under the impression that after the term of patent gets over, it will be released in the public domain. This is not solely related to the use of the invention but also any kinds of upgrades, modifications or new variants which could have been imperative given the fact of the skill used in the invention and the other prior skills other than those used in the patent could be called to use.<sup>2</sup>

In other words, when the right to exclude anyone else from using the patent is unjustly extended by the grant of any later patent, the same is referred to as double patenting.<sup>3</sup>

This issue came to the fore front once again when it was raised in the case of *Astrazeneca Ab & Another v. Intas Pharmaceuticals Limited*<sup>4</sup> before the Hon'ble High Court of Delhi and some findings were made on the issue of double patenting. In this case, Astrazeneca had two patents

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<sup>1</sup> *United States of America v American Bell Telephone Company*, (167 US 224)

<sup>2</sup> The United States Patent & Trademark Office, Definition of Double Patenting [R-10.2019]

<sup>3</sup> *Zickendraht*, 319 F.2d 225, 232, 138 USPQ 22, 27 (CCPA 1963)

<sup>4</sup> 2020 SCC Online Del 1446

covering the product compound, 'Dapagliflozen'. The same were called into question and observations were made.

### **Facts of the case**

The two plaintiffs in this case were AstraZeneca AB Sweden and AstraZeneca Pharma India Ltd. The two patents were originally granted to Bristol Myers Squibb Company. Later on, both of them were acquired and were registered in the name of the Plaintiff No. 1. The validity of both the patents stood till October 4, 2020 & May 15, 2023 respectively.

Now since the term of the first patent was on the verge of expiry, suits for infringement in relation to both Patents were filed against Micro Labs Ltd, Ajanta Pharma Ltd, Intas Pharmaceuticals Ltd, Torrent Pharmaceuticals Ltd and Alkem Laboratories Ltd. Post the expiry of the term, an infringement suit against the second patent was filed against MSN Laboratories, USV Pvt Ltd, Zydus Healthcare Ltd, Zydus Medica and Eris Lifescience.

### **Arguments**

The arguments put forth by the plaintiffs were two fold. Firstly, the claim for the product compound has been made in the second patent and not the first. It was further stated that the first patent is the genus which covers the core structure, while the second one is the species which specifically claims the compound. Secondly, the compound came into existence in 2001 and has specifically been protected under the second patent, which happens to be the genus.

Countering the plaintiffs, it was argued by the defendants that the infringement claim does not stand valid at the very first place. The first argument put forth was that the second patent itself was invalid. It was also mentioned that the product compound under consideration has been covered under the first patent itself and the second patent for the same should not have been granted. Hence the injunction claimed by the plaintiffs did not subsist. Further, the term for the first patent had also expired and hence injunction in the same respect could not be claimed as well.

### **Issue involved**

Whether subject matter of species patent held by Astrazeneca was disclosed in the genus patent held by the same person, thereby invalidating the species patent for lack of inventive step and being obvious to person skilled in art?

## **Decision**

Separate benches of Single Judges denied any kind of injunction in both the suits and the defendants were asked to present the documents requisite to settle their claim. The decisions were appealed against by the plaintiffs.

The Division Bench refused to reverse the decisions of the Single Judge and also stated the reasons for such rejection. Firstly, it was stated that the both these patents could not cover the same compound. It was clearly mentioned that if the defendants invented and got patented the compound and was not disclosed when the patent was sought, hence the first patent could not be infringed by the same. With respect to one subject matter, there has got to be only one patent.

Further, it was mentioned that for the grant of a subsequent patent, there has to be an inventive step in reference to a new product. The technical advancement so made should have been evidently described in the efficacy of the other patent. It was noted by the Hon'ble Court that the complete specification provided forth in the description of the second patent did not disclose any such technological advancement. Interestingly, the field of invention was totally identical, and so was the inventor. No new inventive step was found out in the description.

Since reliance was also placed on the similar cases going on in the United States of America and the reference to the United States Patent and Trademark Office was also made, because of the fact that one of the plaintiffs was based from in there, the ground mentioned therein was prior claiming i.e., obviousness-type double patenting. The plaintiffs did not accept the term and they correspondingly agreed for the term to be coterminous with the term of the first patent itself. It was made clear by the court that if the plaintiffs had agreed to the term of both the patents to end on the same day, given the equivalence of the United States Patent and Trademark Office norms, the plaintiffs could not claim two different validity periods for the two different patents.

Three tests were also referred to by the Court which were the tests of "obvious to a person skilled in the art", "anticipation by publication" and "use before the date of filing of patent application with complete specification". This was in reference to a patent and its specifications being different when the inventor is the same. The tests had to be in the context of the "person in the know", and not of a "person ordinarily skilled in the art". The inquiry, in such a situation, has to be guided by whether the inventor, while writing the first patent application, knew of the invention claimed in the subsequent patent.

## **Comments**

First and foremost, it has not been made clear by the court whether selection patents are allowed or not in India. In the initial judgment of a single bench, it was mentioned that even if a selection patent has not been disclosed clearly or has pretty ambiguous in nature, the same can also be granted a valid patent provided that such a selection patent shows substantial advantage or avoidance of disadvantage over the genus patent, by use of the selected members of the species patent. This finding was not dealt with properly when the matter came before the Division Bench. Hence the possibility of the grant of a selection patents still persists. Technical advancement seems to be the only criteria which is a pre-requisite so as for a selection patent to be granted,

Next, if the same detailing of a particular invention has been put forth in the description of two distinct patents, care has to be undertaken while the details of the same are sought. When it comes to a drug, it is largely possible to claim the working on the basis of same drug but the process undertaken has to be starkly different. But if the same product is claimed in two patents, it might lead to an adverse finding regarding the validity of the patents.

Further, when it comes to the application of tests over deciding the issue of patentability, the Court clearly mentioned that the 'higher threshold' of the 'person in the know' shall be considered to be the inventor. But an ambiguity has been left by the court in determining the extent of the threshold, usage of such threshold by the patent office or the extent of the same.

Next, heavy reliance was placed on International Provisions like the USPTO but the matter is about jurisdiction and whether the same law shall be applied in India or not that is again a question.

So, the law concerning double patenting and ever greening of patents is not clear in India and that is why the courts have to intervene in one way or the other. However, if the same gets codified, it has been made clear that the legislative intent of limiting the life of a patent and making it available for the public will largely be hampered. So the rights concerning the same shall keep on vesting with the inventor himself. But the domain of intellectual property rights in India is largely unpredictable and more twists and turns may be expected. Efficacy of medicines and drugs has to be maintained and this is possible only after a robust legal policy.