Intellectual Property
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Lecture - 18
The Novartis Standard

The Novartis case which was decided by the Supreme Court set what is called the Novartis Standard. In cases involving in interpretation of section 3 d of the Patent Act; which was a subject matter which was decided by the Supreme Court in that case; the court evolved a standard for applying section 3 d.

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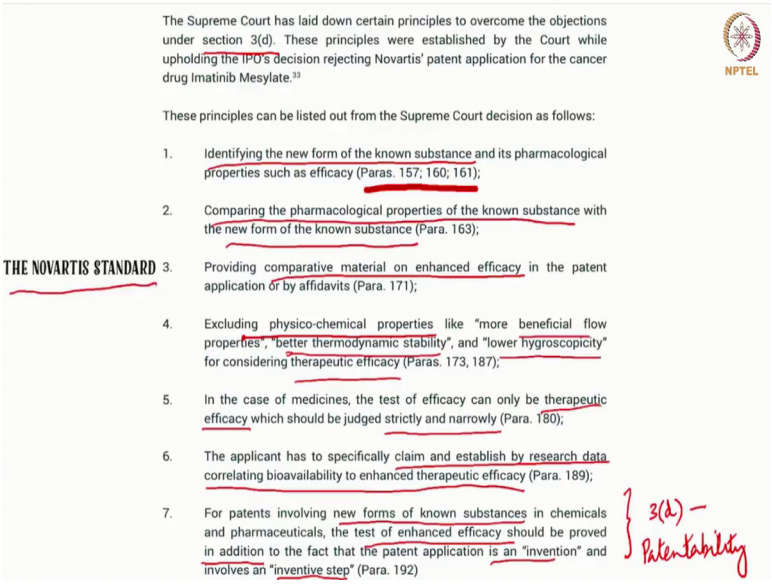

Now, let us look at the standard. Section 3 d is a provision of the Indian Patent Act, which prevents patents for new forms of known substances. The only instance where a new form of a known substance will be granted a patent is where it demonstrate enhanced efficacy.

Now the principles that were laid, now the Supreme Court upheld the decision of the patent office rejecting the patent application for Novartis which went to the Intellectual Property Appellate Board. The Intellectual Property Appellate Board also upheld the decision of the patent office rejecting the patent for Novartis. So, this was the final culmination of the case before the Supreme Court. The principles that the court evolved pertained to; we can classify them in 7 broad steps.

So, the Novartis standard pertains to identifying the new form of the known substance. So, you have to first identify the new form of known substance. We have given the paragraphs from the judgment in brackets; then, comparing the pharmacological properties of the known substance with the new form of the known substance. So, the first step is to identify the known substance, the new form of the known substance and comparing the properties of the known substance with the new form of the known substance.

3, providing comparative material on enhanced efficacy, comparative material to show and this is an obligation on the patent applicant. The applicant has to show comparative material on enhanced efficacy. So, it is the applicant claims that the new forms has an enhanced efficacy, the applicant has to demonstrate that by producing material. Now, the fourth step would involve excluding physic chemical properties like beneficial flow, better thermodynamic stability, lower hygroscopicity from the consideration of therapeutic efficacy. Now, the Madras high court earlier had interpreted efficacy as therapeutic efficacy which was also followed by the Supreme Court.

In cases of medicine, the test of efficacy can only be therapeutic. Now this is reiteration of a decision of the Madras high court which happened some time ago and it should be judged strictly and narrowly. 6th, the applicant has to specifically claim and establish by research data correlating bioavailability to therapeutic efficacy. Now one of the arguments in this case was that demonstration of bioavailability amounts to enhanced therapeutic efficacy. So, the court said that mere demonstration is not enough, you have to establish by research data that the bioavailability correlates to enhanced therapeutic efficacy.

And the 7th point is that for patents involving new forms of known substances, the test of enhanced efficacy should be proved in addition to the fact that the patent application is an invention and involves an inventive step. Now, this reiterates that section 3 d is an additional layer over the tests of patentability. So, this was the standard that was developed by the Supreme Court. Now, this was critical because in 2013, Novartis case has been pending for quite some time and the Supreme Court came up with this announcement. But what we notice in a research that I and some of my colleagues conducted was that post 2013 patent office has not been adhering to the 7 principles laid down in the Novartis case.

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Now, this is the report. The report is titled pharmaceutical patent grants in India, how our safeguard against ever greening have failed and why the system must be reformed.

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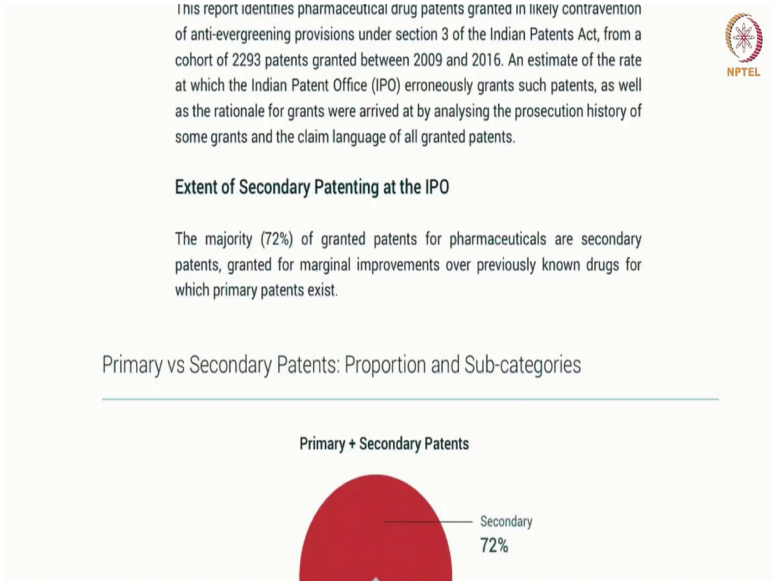

Now, here we show that extent of secondary patenting at the IPO is much higher than what was anticipated. 72 percent of the granted patents pertain to secondary patent. Secondary patents presume that the there is an primary patent before it and only a small improvement or a modification is now being covered what we call marginal improvements are covered by secondary patents.

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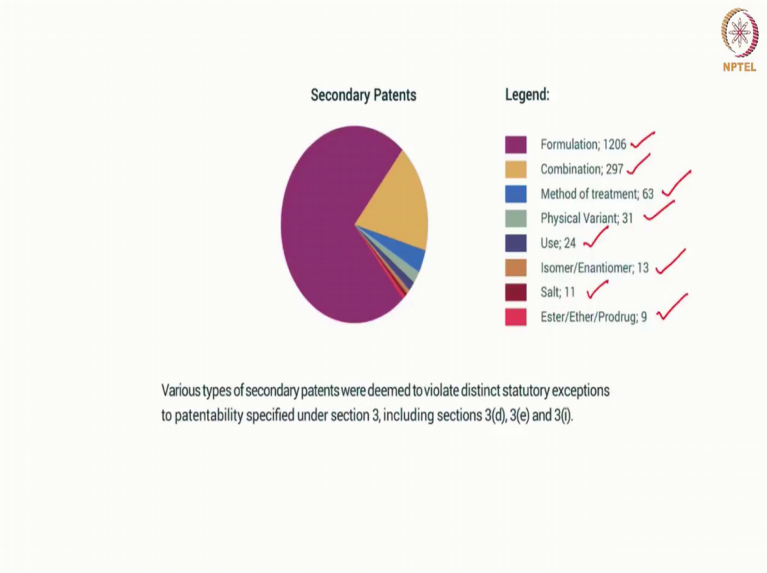

Now, we also give the splitter for the secondary patenting in pharmaceutical it could be Formulation, it could be for Combination, it could be for Method of Treatment, Physical Variant, New Uses, Isomers Salt, Ether, Ester and Prodrug.

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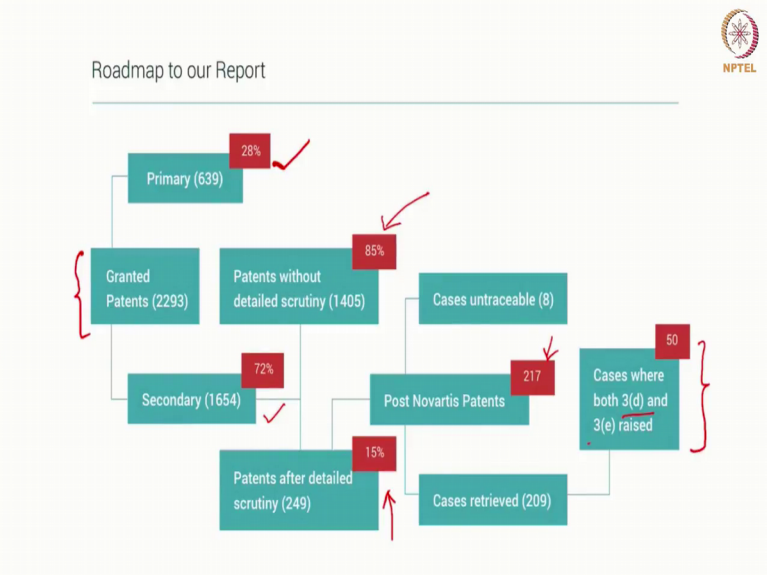

And this is the roadmap of our report. We found that 28 percent pertain to primary of the number that we analyze that is 2293 and 1654 that is 72 percent pertain to secondary patents of which 85 percent which is substantial was granted without detail scrutiny. Only 15 percent went through a detail scrutiny. The detail scrutiny is an order by the

IPO, a written order which a third person can scrutinize, a detail written order. Now and then, we looked at post Novartis they were 217 patents and we were able to retrieve out of that 209 and of the 209, 50 were the cases were 3 d and 3 e objections were raised initially, but the applicants got over it. So, of the 50, we found that all of them did not follow this standard lay down by the Supreme Court. The Novartis standard was not followed; either one of those 7 steps were not followed in granting these patents.