Intellectual Property
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Lecture - 17
Novartis Case

The Novartis case: the Novartis case is an important case in patent law.

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If you want to understand the case what you would do is; you go to the Supreme Court website and you will find that document like this, what you can see here.

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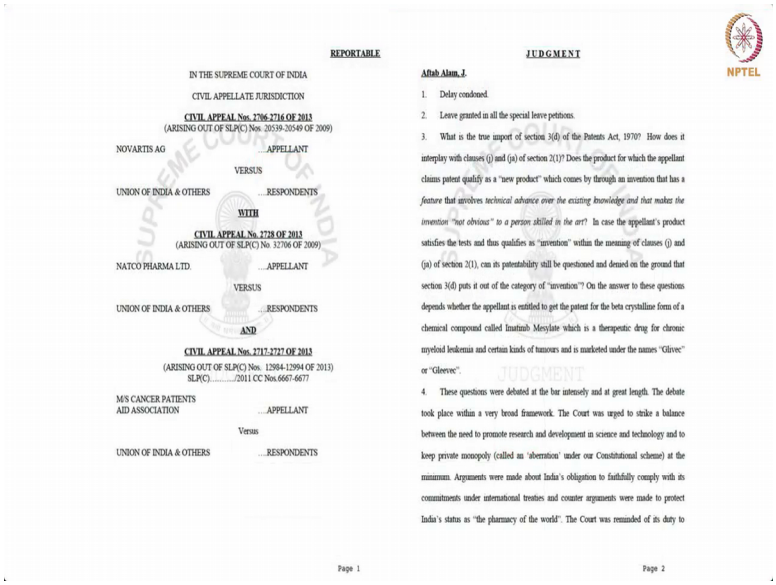

REPORTABLE

IN THE SUPREME COURT OF INDIA

CIVIL APPELLATE JURISDICTION

CIVIL APPEAL Nos. 2706-2716 OF 2013
(ARISING OUT OF SLP(C) Nos. 20539-20549 OF 2009)

NOVARTIS AG ....APPELLANT

VERSUS

UNION OF INDIA & OTHERS ....RESPONDENTS

WITH

CIVIL APPEAL No. 2728 OF 2013
(ARISING OUT OF SLP(C) No. 32706 OF 2009)

NATCO PHARMA LTD. ....APPELLANT

VERSUS

UNION OF INDIA & OTHERS ....RESPONDENTS

AND

CIVIL APPEAL Nos. 2717-2727 OF 2013
(ARISING OUT OF SLP(C) Nos. 12984-12994 OF 2013)
SLP(C).....2011 CC Nos.6667-6677

M/S CANCER PATIENTS
AID ASSOCIATION ....APPELLANT

Versus

UNION OF INDIA & OTHERS ....RESPONDENTS

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JUDGMENT

Aftab Alam, J.

1. Delay condoned.

2. Leave granted in all the special leave petitions.

3. What is the true import of section 3(d) of the Patents Act, 1970? How does it interplay with clauses (j) and (ja) of section 2(1)? Does the product for which the appellant claims patent qualify as a "new product" which comes by through an invention that has a *feature* that involves *technical advance over the existing knowledge and that makes the invention "not obvious" to a person skilled in the art*? In case the appellant's product satisfies the tests and thus qualifies as "invention" within the meaning of clauses (j) and (ja) of section 2(1), can its patentability still be questioned and denied on the ground that section 3(d) puts it out of the category of "invention"? On the answer to these questions depends whether the appellant is entitled to get the patent for the beta crystalline form of a chemical compound called Imatinib Mesylate which is a therapeutic drug for chronic myeloid leukemia and certain kinds of tumours and is marketed under the names "Glivec" or "Gleevec".

4. These questions were debated at the bar intensely and at great length. The debate took place within a very broad framework. The Court was urged to strike a balance between the need to promote research and development in science and technology and to keep private monopoly (called an 'aberration' under our Constitutional scheme) at the minimum. Arguments were made about India's obligation to faithfully comply with its commitments under international treaties and counter arguments were made to protect India's status as "the pharmacy of the world". The Court was reminded of its duty to

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It runs into 112 pages the entire judgment. Novartis case also has a history. If you want something quicker, if you do not have the time to read the 112-page judgment, you would go where we have summarized the entire case for you in a few sentences.

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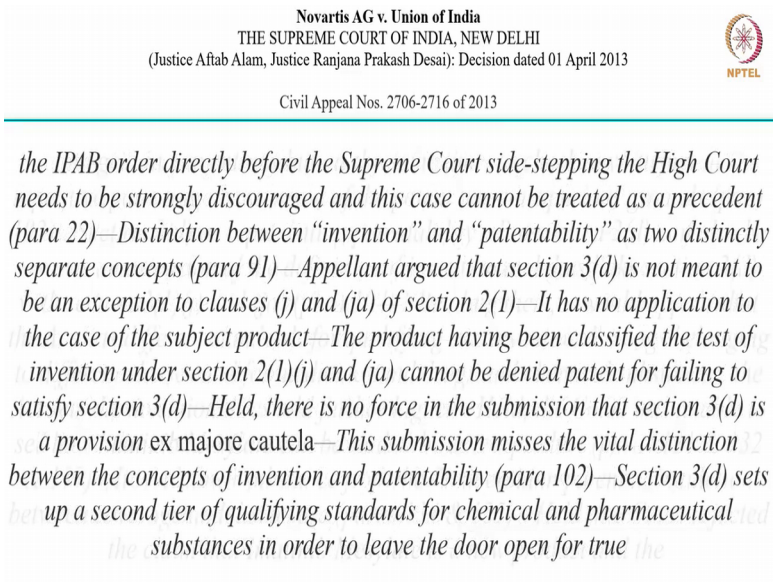

Novartis AG v. Union of India
THE SUPREME COURT OF INDIA, NEW DELHI
(Justice Aftab Alam, Justice Ranjana Prakash Desai): Decision dated 01 April 2013

Civil Appeal Nos. 2706-2716 of 2013

the IPAB order directly before the Supreme Court side-stepping the High Court needs to be strongly discouraged and this case cannot be treated as a precedent (para 22)—Distinction between "invention" and "patentability" as two distinctly separate concepts (para 91)—Appellant argued that section 3(d) is not meant to be an exception to clauses (j) and (ja) of section 2(1)—It has no application to the case of the subject product—The product having been classified the test of invention under section 2(1)(j) and (ja) cannot be denied patent for failing to satisfy section 3(d)—Held, there is no force in the submission that section 3(d) is a provision ex majore cautela*—This submission misses the vital distinction between the concepts of invention and patentability (para 102)—Section 3(d) sets up a second tier of qualifying standards for chemical and pharmaceutical substances in order to leave the door open for true*

Now, let us have a quick look at this case. This case pertain to a patent over the beta crystalline form of Imatinib Mesylate.

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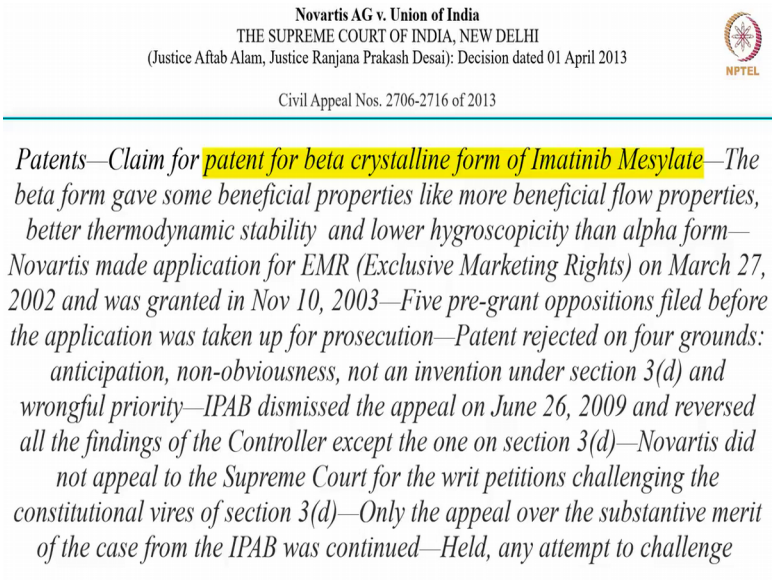

Now, this was a new form of Imatinib Mesylate, which existed before and Novartis patent did, but due to the regime change in India they could not have an earlier pattern which was prior to 1995. So, they filed for a pattern in 1998.

Novartis had an exclusive marketing right granted to it is patent in 2002 and this was preliminary right it was not actually a right granted on complete scrutiny of the patent application. Soon 5 pre grant oppositions were filed by competitors and some NGOs, because drug involved an anti cancer drug in which some public health groups where interested. Now the opposition proceeded and the patent was eventually rejected by the patent office.

Now it was rejected on 4 grounds, you can see the 4 grounds here anticipation non obviousness, not an invention under section 3 d, and wrongful priority. This or was appeal by Novartis to the intellectual property applet board, the intellectual property applet board also dismissed the appeal and finally, the matter ended up in the Supreme Court.

Now, there is a small detail here Novartis initially filed writ petitions before the Madras high court challenging the constitutionality or section 3 d of the patter site. They had also appealed to the high court, because when the order of rejection team from the patent office the IPAB the intellectual property applet board was not in force, it has not being constituted the yet. So, there were 2 writ petitions, 2 batches filed: one questioning the

constitutionality and the other raising the substantial merits of the decision of the Indian patent office.

The high court decided the constitutionality up holding the constitutionality of section 3 d, but it transfer the case soon to the intellectual property applied board, when the applied board was constituted this was constituted when RIT petitions where pending before the Madras high court. Now so that decision of the Madras high court up holding the constitutional was not questioned by Novartis before the Supreme Court. What eventually came to the Supreme Court was the decision of the IPAB on merits over the decision of the controller.

Now when this came up the Supreme Court very clearly mentioned that; it is not the right way to challenge decision of the IPAB directly in the Supreme Court they said that side-stepping the high court needs to be strongly discouraged and they will not allow this to be treated as a precedence. So, if you need to agitate any order of intellectual property applet board both the case has to go to the high court first.

Now the Novartis case did discuss various other things the distinction between invention and patentability, it also had a look at what are the major qualifying standards for pharmaceutical and chemical substances.

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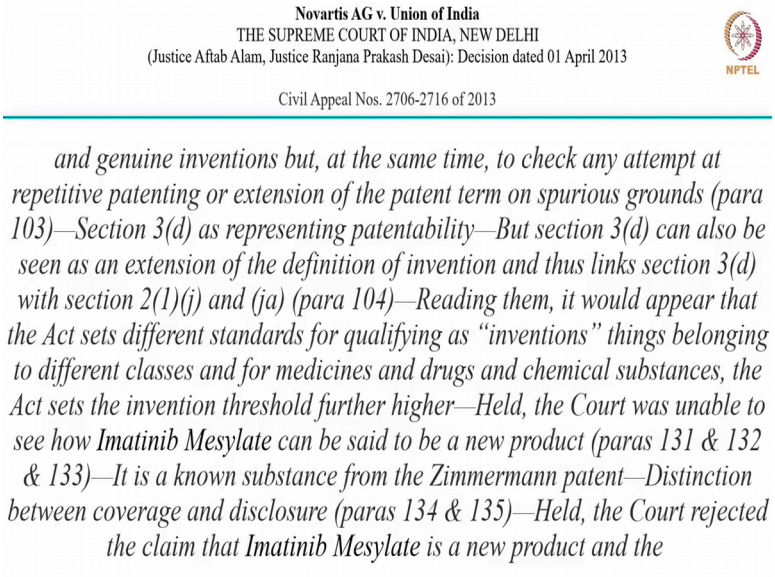

And the case eventually was decided by the court by holding that the court was unable to see that Imatinib Mesylate is a new product. Now that is paragraph 131, 32 and 33. Now the court also held that it that it rejected the claim that Imatinib Mesylate is a new product and outcome of an invention.

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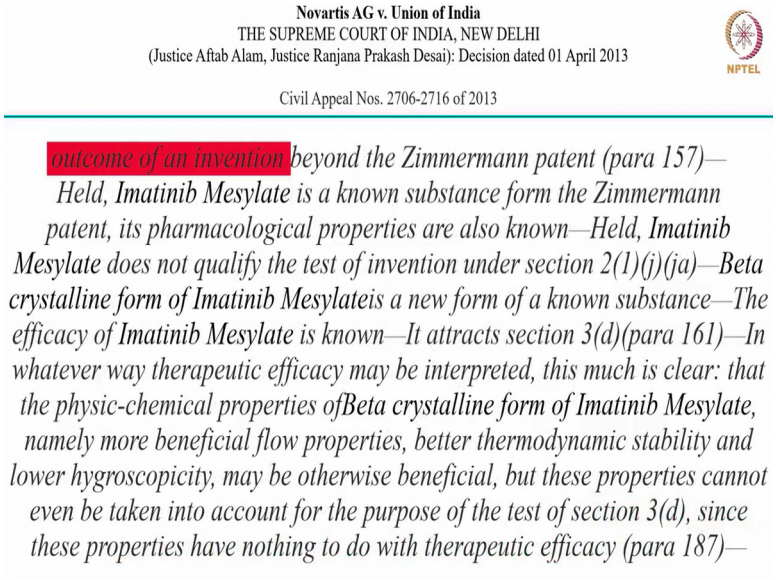

That is in paragraph 157 the efficacy of Imatinib Mesylate, efficacy is something the applicants needs to prove if he comes with a pattern for a new form of a know substance under section 3 d.

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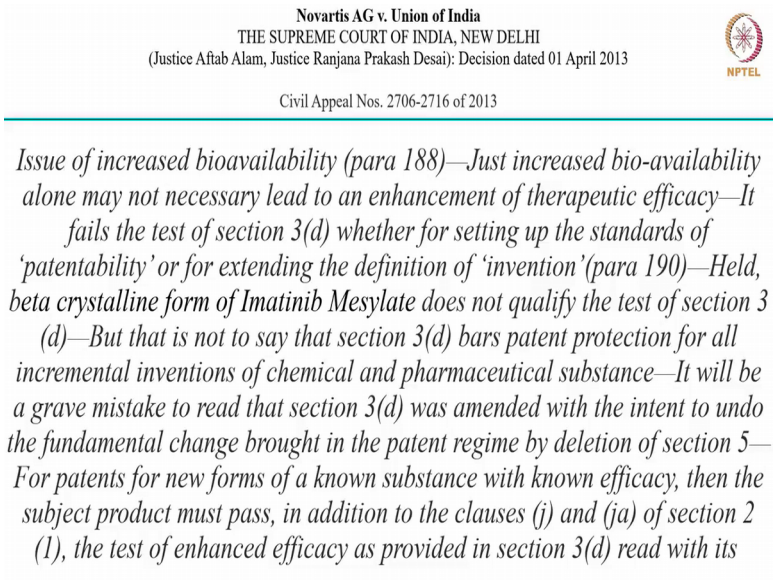

The court held that the efficacy criteria that Novartis had put forward was not sufficient to demonstrate enhanced efficacy.

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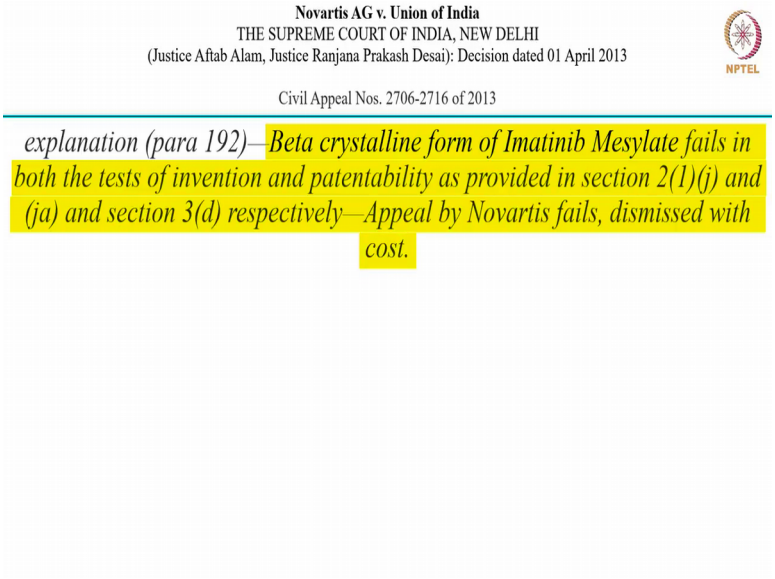

And ultimately the patent was rejected. Beta crystalline form of Imatinib Mesylate fails in both the tests of invention and patentability as provided in section 2 1 j and ja, and section 3 d respectively. The appeal failed dismissed with cost.