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

J U D G M E N T

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".

JUDGMENT

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

uphold the rights granted by the statute, and the Court was also reminded that an error of judgment by it will put life-saving drugs beyond the reach of the multitude of ailing humanity not only in this country but in many developing and under-developed countries, dependent on generic drugs from India. We will advert to these and a number of other arguments at their proper place but we must first take note of the facts that give rise to the above questions and provide the context for the debate.

5. *Jürg Zimmermann* invented a number of derivatives of N-phenyl-2- pyrimidine-amine, one of which is CGP 57148[1] in free base form (later given the International Nonproprietary Name 'Imatinib' by the World Health Organisation). These derivatives, including Imatinib[2], are capable of inhibiting certain protein kinases, especially protein kinase C and PDGF (platelet-derived growth factor)-receptor tyrosine kinase and thus have valuable anti-tumour properties and can be used in the preparation of pharmaceutical compositions for the treatment of warm-blooded animals, for example, as anti-tumoral drugs and as drugs against atherosclerosis. The N-phenyl-2-pyrimidine-amine derivatives, including Imatinib, were submitted for patent in the US. The application was made on April 28, 1994 and patent was granted on May 28, 1996 under US Patent No. 5,521,184 (hereinafter referred to as 'the Zimmermann Patent'). The Zimmermann compounds (i.e., derivatives of N-phenyl-2-pyrimidine-amine) were also granted a European patent under Patent No. EP-A-0 564 409.

6. The appellant claims that beginning with Imatinib[3] in free base form (as the 'e-duct'), in a two-stage invention they first produced its methanesulfonic acid addition salt, Imatinib Mesylate, and then proceeded to develop the beta crystalline form of the salt of

1 4-(4-methylpiperazin-1–ylmethyl)-N-[4-methyl-3-(4-pyridin-3-yl)pyrimidin-2-ylamino)phenyl] benzamide.
2 Ibid
3 Ibid

Imatinib. According to the appellant, starting from Imatinib free base they could reach to the beta crystal form of Imatinib Mesylate in two ways: one "by *digesting* another crystal form, especially the alpha crystal form, or an amorphous starting material of the methanesulfonic acid addition salt of compound of formula I …"; and second "by *dissolving* another crystal form, especially the alpha crystal form, or an amorphous starting material of the methanesulfonic acid addition salt of compound of formula I…". Describing the different processes, step by step, for producing Imatinib Mesylate starting from Imatinib, it is stated that in the first process they would first arrive at Imatinib Mesylate in amorphous form, as the intermediate stage, and thereafter, following further processes, reach the beta crystal form of Imatinib Mesylate. Following the second process, they would reach the beta crystal form of Imatinib Mesylate directly, skipping the intermediate stage in which Imatinib Mesylate first appears in amorphous form. In the third process, they would start with the alpha crystal form of Imatinib Mesylate and arrive at its beta crystal form.

7. It was stated in course of submissions, however, that for practical purposes, the best way to produce the beta form is by proceeding directly from the free base form to the beta form, as in examples 2 and 3 given below, by introducing a specified amount of the beta crystals at the step specified. The three processes are described by the appellant under the following three examples:

EXAMPLE – 1[1]

Step 1- 98.6 gms of Imatinib free base is added to 1.4 liters of ethanol.

Step 2 - To the above, 19.2 gms of methanesulfonic acid is added drop wise for over

1 Examples 1 to 3 stated below are reproduced from the written notes titled "Novartis Document – XIV: Examples in 1602/MAS/1998 (Subject Patent Specification), submitted by Mr. Subramanium, Senior Advocate appearing for the appellant in course of hearing on September 20, 2012.

20 minutes.

Step 3 - Solution obtained in Step 2 is heated under reflux (i.e. boiling). It is heated in a manner to preserve the solution from escaping as a gas, so the gas is captured, condensed and obtained as a liquid. This solution is heated for 20 minutes.

Step 4 - Filtering the solution – the filtrate (which is obtained after filtering the resulting liquid) is evaporated down to 50%. In other words, half of the filtrate is allowed to vaporize.

Step 5 - Residue is again filtered at 25 degrees Celsius.

Step 6 - Mother liquor (the liquid filtrate of step 5) is evaporated to dryness.

Step 7 - Residue obtained after Step 6, and residue obtained after Step 5 are suspended in 2.2 l ethanol.

Step 8 - The suspension obtained after Step 7 is dissolved under reflux and it becomes clear upon heating. Thereafter, 30 ml water is added to it.

Step 9 - Substance is cooled overnight to 25 degrees Celsius, filtered and dried at 65 degrees Celsius, until weight is constant. This results in alpha crystalline form.

Step 10 - Alpha form is stirred in methanol for two days at about 25 degrees Celsius. Then the crystals are isolated by filtration and dried overnight at room temperature. This results in beta crystalline form.

<u>EXAMPLE – 2</u>

Step 1 - 50 gms of Imatinib free base is added to 480 liters (sic milliliters!) of methanol.

Step 2 - To the above, 9.71 gms of methanesulfonic acid and 20 ml methanol is added. This mixture (sic is heated) at 50 degrees Celsius.

Step 3 - To the solution obtained from Step 2, 5 gms of activated carbon is added and the mixture is boiled for 30 minutes under reflux, filtered and evaporated.

Step 4 - The residue obtained from Step 2 (sic 3) is dissolved in 150 ml methanol and inoculated (introduced) with a few mgms (sic mg) of beta form of imatinib mesylate leading to crystallization of the product.

Step 5 - The product is dried at 50 megabars (unit to measure pressure) and at 60 degrees Celsius. This leads to crystallization of beta form of imatinib mesylate.

Step 6 - The retention values (distance traveled by each chemical component in relation to the distance the solution front moves) obtained are as follows;

Methylene chloride: ethyl acetate: Methanol: concentrated aqueous ammonium hydroxide solution = 6:10:30:2 (sic 60:10:30:2)

Step 7 - To the above, High Pressure Chromatography (technique for separation of mixtures) is applied for 10.2 minutes

EXAMPLE – 3

Step 1 - 670 gms of alpha form of imatinib mesylate is heated in 1680 ml of methanol.

Step 2 - The solution obtained from Step 1 is then inoculated at 60 degrees Celsius with 55 (sic mg of) beta form of imatinib mesylate. Upon this, the product starts to crystallize.

Step 3 - Thereafter, the crystals are dried at 50 megabars and at 100 degrees Celsius. This leads to crystallization of beta form of imatinib mesylate.

Step 4 - The retention values (distance traveled by each chemical component in relation to the distance the solution front moves) obtained are as follows;

Methylene chloride: ethyl acetate: Methanol: concentrated aqueous ammonium hydroxide solution = 6:10:30:2 (sic 60:10:30:2)

Step 5 - To the above, High Pressure Chromatography is applied for 10.2 minutes.

[Examples are also given for preparation of 100 mg tablets and 100 mg capsules of Imatinib Mesylate but there is no need to go into that at this stage.]

8. The appellant filed the application (Application No.1602/MAS/1998)[1] for grant of patent for Imatinib Mesylate in beta crystalline form at the Chennai Patent Office on July 17, 1998. In the application it claimed that the invented product, the beta crystal form of Imatinib Mesylate, has (i) more beneficial flow properties: (ii) better thermodynamic stability; and (iii) lower hygroscopicity than the alpha crystal form of Imatinib Mesylate. It further claimed that the aforesaid properties makes the invented product "new" (and superior!) as it "stores better and is easier to process"; has "better processability of the methanesulfonic acid addition salt of a compound of formula I", and has a "further advantage for processing and storing".

9. It is significant to note that the comparison of the aforesaid properties of the beta crystal form of Imatinib Mesylate was made with its alpha crystal form. In the patent application, there is no claim of superiority of the beta crystal form of Imatinib Mesylate in regard to the aforesaid three properties, or any other property, over the starting material Imatinib, or even over Imatinib Mesylate in amorphous form or any form other than the alpha crystal form. On the contrary, insofar as Imatinib in free base form is concerned, it was unambiguously stated in the patent application as under:

> "It goes without saying that **all the indicated inhibitory and pharmacological effects are also found with the free base**, 4-(4-methylpiperazin-1-ylmethyl)-N-[4-methyl-3-(4-pyridin-3-yl) pyrimidin-2-ylamino)phenyl] benzamide, **or other cells thereof**. The present invention relates especially to the β–crystal form of the methanesulfonic acid addition salt of a compound of formula I in the treatment of one of the said diseases or in the preparation of a pharmacological agent for the treatment thereto."
>
> (emphasis added)

10. In fairness to the appellant, however, it should be stated that the application was

1 The initial application that was filed was for "Crystal modification of a N-phenyl-2-pyrimidineamine derivative, processes for its manufacture and its use". This application included both the alpha and beta crystalline forms. Later on during the course of prosecution of the patent application, the claims of the original application were restricted only to the beta form of Imatinib Mesylate and a separate divisional application no. 799/CHE/04 was filed for the alpha form in 2004.

made at the time when there was a different patent regime. After the application was made and before it was taken up for consideration, a number of amendments were introduced in the Indian Patents Act, 1970, which brought about fundamental changes in the patent law of the country. The appellant was, however, fully aware of these changes in the law and, in order to reinforce its claim for patent for the subject product and to bring its claim within the four corners of the changed law, it filed four (4) affidavits of certain experts, two of which stated that the beta crystal form of Imatinib Mesylate has much higher bioavailability as compared to Imatinib in free base form. In due course, we shall examine how far the properties attributed to the subject product in the patent application and the affidavits make it "new" and entitled to grant of patent, but for the moment we may note how the case has come to the present stage.

11. As noted above the patent application was made on July 17, 1998, giving July 18, 1997, the date on which the appellant had applied for grant of patent for the subject product in Switzerland, as the "priority date". On July 18, 1997, Switzerland was not one of the "Convention Countries" as defined under section 2 (1)(d) read with section 133 of the Act and it was notified as a convention country as per section 133 of the Act on November 30, 1998.

12. In 1997, when the appellant filed its application for patent, the law in India with regard to product patent was in a transitional stage and the appellant's application lay dormant under an arrangement called "the mailbox procedure". Before the application for patent was taken up for consideration, the appellant made an application (Application No. EMR/01/2002) on March 27, 2002, for grant of exclusive marketing rights (EMR) for the subject product under section 24A of the Act, which was at that time on the statute book

and which now stands deleted. The Patent Office granted EMR to the appellant by order dated November 10, 2003.

13. The appellant's application for patent was taken out of the "mailbox" for consideration only after amendments were made in the Patents Act, with effect from January 1, 2005. But before it was taken up for consideration, the patent application had attracted five (5) pre-grant oppositions[1] in terms of section 25(1) of the Act. And it was in response to the pre-grant oppositions that the appellant had filed the affidavits on the issue of bioavailability of Imatinib Mesylate in beta crystalline form.

14. The Assistant Controller of Patents and Designs heard all the parties on December 15, 2005, as provided under rule 55 of the Patent Rules, 2003, and rejected the appellant's application for grant of patent to the subject product by 5 (five) separate, though similar, orders passed on January 25, 2006 on the 5 (five) opposition petitions. The Assistant Controller held that the invention claimed by the appellant was anticipated by prior publication, i.e., the Zimmermann patent; that the invention claimed by the appellant was obvious to a person skilled in the art in view of the disclosure provided in the Zimmermann patent specifications; and further that the patentability of the alleged invention was disallowed by section 3(d) of the Act; and also that July 18, 1997, the Swiss priority date, was wrongly claimed as the priority date for the application in India and hence, the alleged invention was also anticipated by the specification made in the application submitted in Switzerland.

15. At that time, the appellate authority under the Act had yet to become functional. The appellant, therefore, challenged the orders passed by the Assistant Controller in writ

1 The oppositions were made by M/s. Cancer Patients Aid Association (Respondent No. 4), NATCO Pharma Ltd. (Respondent No. 5), CIPLA Ltd. (Respondent No. 6), Ranbaxy Laboratories Ltd. (Respondent No. 7), Hetro Drugs Ltd. (Respondent No. 8).

petitions filed directly before the Madras High Court. Apart from challenging the orders of the Assistant Controller, the appellant also filed two writ petitions (one by the appellant and the other by its Indian power of attorney holder) seeking a declaration that section 3(d) of the Act is unconstitutional because it not only violates Article 14 of the Constitution of India but is also not in compliance with "TRIPS". After the formation of the Intellectual Property Appellate Board, the five writ petitions challenging the five orders of the Assistant Controller were transferred from the High Court to IPAB by order dated April 4, 2007, where these cases were registered as appeals and were numbered as TA/1 to 5/2007/PT/CH. The other two writ petitions assailing section 3(d) of the Act were finally heard by a Division Bench of the High Court and dismissed by the judgment and order dated August 6, 2007. The appellant did not take that matter any further.

16. The appellant's appeals against the orders passed by the Assistant Controller were finally heard and dismissed by the IPAB by a long and detailed judgment dated June 26, 2009.

17. The IPAB reversed the findings of the Assistant Controller on the issues of anticipation and obviousness. It held that the appellant's invention satisfied the tests of novelty and non-obviousness, and further that in view of the amended section 133, the appellant was fully entitled to get July 18, 1997, the date on which the patent application was made in Switzerland, as the priority date for his application in India. The IPAB, however, held that the patentability of the subject product was hit by section 3(d) of the Act. Referring to section 3(d) the IPAB observed:

> "Since India is having a requirement of higher standard of inventive step by introducing the amended section 3(d) of the Act, what is patentable in other countries will not be patentable in India. As we see, the object of amended section 3(d) of the Act is nothing but a requirement of higher standard of

inventive step in the law particularly for the drug/pharmaceutical substances."

18. The IPAB also referred to the judgment of the Madras High Court, dismissing the appellant's writ petitions challenging the constitutional validity of section 3(d) where the High Court had observed:

> "We have borne in mind the object which the amending Act wanted to achieve namely, to prevent evergreening; to provide easy access to the citizens of the country to life saving drugs and to discharge their constitutional obligation of providing good health care to its citizens."

19. In light of the High Court's observation, the IPAB also referred to the pricing of the drug Gleevec by the appellant while it enjoyed EMR over it, and held that the patentability of the subject product would also be barred by section 3(b) of the Act and in this regard observed as follows:

> "We are fully conscious of the Appellant's benevolent GIPAP program for free distribution of GLEEVEC to certain cancer patients. But as per information furnished in its written counter–argument by R 3 that when the Appellant was holding the right as EMR on GLEEVEC it used to charge Rs.1,20,000/- per month for a required dose of the drug from a cancer patient, not disputed by the Appellant, which in our view is too unaffordable to the poor cancer patients in India. Thus, we also observe that a grant of product patent on this application can create a havoc to the lives of poor people and their families affected with the cancer for which this drug is effective. This will have disastrous effect on the society as well. Considering all the circumstances of the appeals before us, we observe that the Appellant's alleged invention won't be worthy of a reward of any product patent on the basis of its impugned application for not only for not satisfying the requirement of section 3(d) of the Act, but also for its possible disastrous consequences on such grant as stated above, which also is being attracted by the provisions of section 3(b) of the Act which prohibits grant of patent on inventions, exploitation of which could create public disorder among other things (Sic .) We, therefore, uphold the decision of R 8 on section 3(d) of the Act to the extent that product patent cannot be made available to the Appellant…"

20. Though agreeing with the Assistant Controller that no product patent for the subject patent could be allowed in favour of the appellant, the IPAB held that the appellant could

not be denied the process patent for preparation of Imatinib Mesylate in beta crystal form. The IPAB ordered accordingly.

21. Against the order of the IPAB the appellant came directly to this Court in a petition under Article 136 of the Constitution. When the matter was first taken up before this Bench, we first thought of dismissing the SLPs at the threshold as the appellant had an alternative remedy to challenge the judgment and order of the IPAB before the Madras High Court. However, Mr. Gopal Subramanium, the senior advocate appearing for the appellant, submitted that the SLPs were filed on August 11, 2009, and the Court issued notice to the respondents on September 11, 2009. Further, before coming to this Bench, the matter was listed before another Bench, where it was heard on merits on different dates from August 9, 2011 to September 6, 2011. Mr. Subramanium further submitted that relegating the appellant to the High Court might render the matter infructuous in as much as the period for the patent applied for would come to end after 20 years from the date of the application, i.e. in July 2018. He submitted that the High Court would take at least 2 – 3 years before a final decision would be rendered and then, whatever be the High Court's decision, the matter was bound to come to this Court. In this to and fro whatever remains of the patent period would also lapse. Mr. Subramanium further submitted that the case involved a number of seminal issues and it was in the larger interest that an authoritative pronouncement on those issues be made by this Court.

22. Initially some of the respondents strongly opposed the maintainability of the petitions made directly to this Court by-passing the High Court, but in the end all agreed that given the importance of the matter, this Court may itself decide the appeals instead of directing the appellant to move the High Court. It is in such circumstances that we agreed

to hear the parties and decide the appeals on merits. However, we, wish to make it clear that any attempt to challenge the IPAB order directly before this Court, side-stepping the High Court, needs to be strongly discouraged and this case is certainly not to be treated as a precedent in that regard.

23. As this Court now proceeds to decide the case on merits, it needs to be noted that after notice was issued in the SLPs filed by Novartis AG, all the five parties who had filed pre-grant oppositions before the Controller (hereinafter referred to as the Objectors) filed their respective counter-affidavits. Two of the Objectors, namely NATCO Pharma Ltd. and M/s Cancer Patients Aid Association, additionally filed Special Leave Petition, challenging the findings recorded by the IPAB in favour of Novartis AG. Leave to appeal has also been granted in all those SLPs, and hence, all the issues are open before this Court and this Court is deciding the case unbound by any findings of the authority or the tribunal below.

24. In connection with the case of the appellant, the first and foremost thing that needs to be kept in mind is that it falls in the transitional period between two fundamentally different patent regimes. In 1998, when the application was made on behalf of the appellant, the Patents Act, 1970, had a provision in section 5 with the marginal heading, "*Inventions where only methods or processes of manufacture patentable*" that barred grant of patent to **substances** intended for use, or capable of being used, as food or medicine or drug, or prepared or produced by chemical processes. The application was then put in the "mailbox" and was taken out for consideration when many changes had been made in the Patents Act, 1970, with effect from January 1, 2005, to make the patent law in the country compliant with the terms of an international agreement entered into by the Government of India. Following the international agreement, the Patents Act, 1970, was subjected to large

scale changes in three stages; and finally, by the Patents (Amendment) Act, 2005, section 5 was altogether deleted from the Parent Act (Patents Act, 1970). Between January 1, 1995 and January 1, 2005, the Patents Act, 1970, underwent wide ranging changes, but if we are asked to identify the single most important change brought about in the law of patent in India as a result of the country's obligations under the international agreement, we would unhesitatingly say the deletion of section 5 from the Patents Act, which opened the doors to product patents in the country. It is, however, important to note that the removal of section 5 from the statute book was accompanied by amendments in clauses (j) and (ja) of section 2(1), apart from some other ancillary clauses of section 2(1), as well as amendments in section 3, which redefined the concepts of invention and patentability.

25. Some important provisions of the Patents Act, 1970, as they stand after the amendment of the Act in 2005, and with which we are especially concerned in this case, indeed present a problem of interpretation. Why was section 5, which, in one sense, was the distinctive feature of the patent law in India, taken off the statute book? What does the legislature wish to say through clauses (j) and (ja) of section 2(1), section 3 and several other sections? How is it that some of the provisions of the Act apparently seem to be of no use or purpose, e.g., sections 2(1)(l) and 2(1)(ta)? Why is it that some of the crucial provisions in the Act appear to be wanting in precision and clarity?

26. It is easy to know why section 5 was deleted but to understand the import of the amendments in clauses (j) and (ja) of section 2(1) and the amendments in section 3 it is necessary to find out the concerns of Parliament, based on the history of the patent law in the country, when it made such basic changes in the Patents Act. What were the issues the legislature was trying to address? What was the mischief Parliament wanted to check and

what were the objects it intended to achieve through these amendments?

27. The best way to understand a law is to know the reason for it. In *Utkal Contractors and Joinery Pvt. Ltd. and others v. State of Orissa and others*[1], Justice Chinnappa Reddy, speaking for the Court, said:

> "9. … **A statute is best understood if we know the reason for it. The reason for a statute is the safest guide to its interpretation.** The words of a statute take their colour from the reason for it. How do we discover the reason for a statute? There are external and internal aids. The external aids are statement of Objects and Reasons when the Bill is presented to Parliament, the reports of committees which preceded the Bill and the reports of Parliamentary Committees. Occasional excursions into the debates of Parliament are permitted. Internal aids are the preamble, the scheme and the provisions of the Act. Having discovered the reason for the statute and so having set the sail to the wind, the interpreter may proceed ahead…"
>
> (emphasis added)

28. Again in *Reserve Bank of India v. Peerless General Finance and Investment Co. Ltd. and others*[2] Justice Reddy said:

> "33. Interpretation must depend on the text and the context. They are the bases of interpretation. One may well say if the text is the texture, context is what gives the colour. Neither can be ignored. Both are important. That interpretation is best which makes the textual interpretation match the contextual. **A statute is best interpreted when we know why it was enacted.** With this knowledge, the statute must be read, first as a whole and then section by section, clause by clause, phrase by phrase and word by word. **If a statute is looked at, in the context of its enactment, with the glasses of the statute-maker, provided by such context, its scheme, the sections, clauses, phrases and words may take colour and appear different than when the statute is looked at without the glasses provided by the context**. With these glasses we must look at the Act as a whole and discover what each section, each clause, each phrase and each word is meant and designed to say as to fit into the scheme of the entire Act. No part of a statute and no word of a statute can be construed in isolation. Statutes have to be construed so that every word has a place and everything is in its place. It is by looking at the definition as a whole in the setting of the entire Act and by reference to what preceded the enactment and the reasons for it that the Court construed the expression 'Prize Chit' in *Srinivasa* and we find no reason to depart from the

1 (1987) 3 SCC 279
2 (1987) 1 SCC 424

Court's construction."

(emphasis added)

29. In order to understand what the law really is, it is essential to know the "why" and "how" of the law. Why the law is what it is and how it came to its present form? The adage is more true in case of the law of patents in India than perhaps any other law.

30. Therefore, in order to correctly understand the present law it would be necessary to briefly delve into the legislative history of the law of patents in the country.

31. At the time of Independence, India's patent regime was governed by the Patents and Designs Act, 1911, which had provisions both for product and process patents[1]. It was, however, generally felt that the patent law had done little good to the people of the country. The way the Act was designed benefited foreigners far more than Indians. It did not help at all in the promotion of scientific research and industrialization in the country, and it curbed the innovativeness and inventiveness of Indians.

32. Shortly after Independence, therefore, in 1949, a committee was constituted under the chairmanship of Justice (Dr.) Bakshi Tek Chand, a retired judge of the Lahore High Court, to undertake a comprehensive review of the working of the 1911 Act.

33. The Committee submitted its interim report on August 4, 1949 and the final report in 1950 making recommendations for prevention of misuse or abuse of patent rights in India. It also observed that the Patent Act should contain a clear indication that food and medicine and surgical and curative devices were to be made available to the public at the cheapest price commensurate with giving reasonable compensation to the patentee. Based

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1 **Section 2(8) "Invention"** means any manner of new manufacture and includes an improvement and an alleged invention

Section 2(10) "Manufacture" includes any art, process or manner of producing, preparing or making an article, ***and also any article*** prepared or produced by manufacture.

Section 14- Term of Patent. (1)The term limited in every patent for the duration thereof shall, save as otherwise expressly provided by this Act, be sixteen years from its date.

on the committee's recommendations, the 1911 Act was amended in 1950 (by Act XXXII of 1950) in relation to working of inventions, including compulsory licensing and revocation of patents. In 1952, a further amendment was made (by Act LXX of 1952) to provide for compulsory license in respect of food and medicines, insecticide, germicide or fungicide, and a process for producing substance or any invention relating to surgical or curative devices. The committee's recommendation prompted the Government to introduce a bill (Bill no. 59 of 1953) in Parliament, but the bill was not pressed and it was allowed to lapse.

34. In 1957, another committee came to be appointed under the chairmanship of Justice N. Rajagopala Ayyangar to take a fresh look at the law of patent and to completely revamp and recast it to best sub-serve the (contemporary) needs of the country[1].

35. Justice Ayyangar painstakingly collected valuable data (taking the figures for the years 1930 to 1939 from the Bakshi Tek Chand report) and, compiling them into a number of tables,[2] showed the share of Indians in the field of patents. He analyzed the figures in the tables and pointed out that during the period 1930-37, the grant of patents to Indians and foreigners was roughly in the ratio of 1:9. Even after Independence, though a number of institutions for post-graduate training were set up and several national laboratories were established to encourage a rapid growth of scientific education, the proportion of Indian and the foreign patents remained substantially the same, at roughly 1:9. Justice Ayyangar further pointed out that this ratio does not take into account the economic or industrial or scientific importance of the inventions. If these factors are taken into account, Indians would appear to be lagging even further behind. Further, taking into reckoning the number

1 The Bakshi Tek Chand Committee's (also called Patents Enquiry Committee I) report and the Ayyangar Committee's report are important milestones in the development of the patent law in the country.

2 The different tables compiled in the Justice Ayyangar's report are put together at one place at the end of this judgment in Appendix I.

of inventions for which renewal fees were paid beyond the 6th year, which would give a rough idea of the value attached to the invention by the patentee, the patents taken by Indians would appear to be of little worth as compared with patents held by foreign nationals.

36. Justice Ayyangar examined the nature of the patent right and considered the arguments advanced as justifications/rationalizations for grant of patents. He described the patent law, in his report, as an instrument for managing the political economy of the country. He observed:

> "It would not be an exaggeration to say that the industrial progress of a country is considerably stimulated or retarded by its patent system according as to whether the system is suited to it or not." (p. 9, para 16)

He also quoted from Michel[1] with approval as under:

> "* * * Patent systems are not created in the interest of the inventor but in the interest of national economy. The rules and regulations of the patent systems are not governed by civil or common law but by political economy."

37. Observing that industrial countries and under-developed countries had different demands and requirements, Justice Ayyangar pointed out that the same patent law would operate differently in two countries at two different levels of technological and economic development, and hence the need to regulate the patent law in accordance with the need of the country. Commenting upon the Patents and Designs Act, 1911, (even after its post–Independence amendments) Justice Ayyangar said:

> "It is further obvious however that the system would not yield the same results when applied to under-developed countries. I entirely agree with the views of the Patents Enquiry Committee that "the Indian Patent system has failed in its main purpose, namely, to stimulate invention among Indians and to encourage the development and exploitation of new inventions for industrial purposes in the country so as to secure the benefits thereof to the

1 Michel on Principal National Patent Systems, Vol. I, P.15

largest section of the public." (Interim Report, p. 165).

38. Justice Ayyangar observed that the provisions of the Patent law have to be designed, with special reference to the economic conditions of the country, the state of its scientific and technological advancement, its future needs and other relevant factors, and *so as to minimize, if not to eliminate, the abuses to which a system of patent monopoly is capable of being put.* Bearing in view the matters set above, he recommended retaining the patent system, but with a number of improvements.

39. One of the improvements suggested was to define, with precision, those inventions which should be patentable *and equally clearly identify certain inventions, the grant of patents to which would retard research, or industrial progress, or be detrimental to the national health or well-being, and to make those inventions non-patentable.*

40. Justice Ayyangar's report specially discussed (a) patents for chemical inventions; and (b) patents for inventions relating to food and medicine.

41. In regard to patents for chemical substances, he examined the history of the law in other countries and pointed out that Germany was the first to adopt the system of confining the patentability of inventions relating to chemical products or substances to process claims. The law was then followed in many other countries in the world, for instance Austria, Brazil, Czechoslovakia, Holland, Hungary, Japan, Mexico, Norway, Poland and the U.S.S.R. Products produced by chemical process were not patentable though processes for making such products were patentable, if, of course, they satisfied the other tests of patentability, *e.g.* novelty, subject matter, etc. In light of the experience of the other countries, Justice Ayyangar recommended:

> "I have considered the matter with the utmost care and have reached the conclusion that the chemical and pharmaceutical industry of this country

would be advanced and the tempo of research in that field would be promoted if the German system of permitting only process claims were adopted."

42. Coming next to the patents for inventions relating to food and medicine, Justice Ayyangar pointed out that barring the US, there was hardly any country that allowed unrestricted grant of patents in respect of articles of food and medicines, or as to the licensing and working of patents in this class. In none of the countries of Europe were patents granted for product claims for articles of food or medicine, and in a few (Denmark for articles of food; and Italy, under the law of 1957, for medicinal products) even claims for processes for producing them were non-patentable. He explained that the reason for this state of law is stated to be that the denial of product claims is necessary in order that important articles of daily use such as medicine or food, which are vital to the health of the community, should be made available to everyone at reasonable prices and that no monopoly should be granted in respect of such articles. It is considered that the refusal of product patents would enlarge the area of competition and thus result in the production of these articles in sufficient quantity and at the lowest possible cost to the public.

43. Justice Ayyangar submitted a comprehensive Report on Patent Law Revision in September 1959 and the new law of patent, namely, the Patents Act, 1970, came to be enacted mainly based on the recommendations of the report, and came into force on April 20, 1972, replacing the Patents and Designs Act, 1911.

44. Section 1 of the new Act gave it its name and territorial extent and provided that it would come into effect on such date as the Central Government may appoint, by notification in the official gazette. Section 2 contained the definition and interpretation clauses; it defined the terms "invention" and "medicine" in clauses (j) and (l) respectively

as under[1]:

"**Section 2(1)(j) "invention" means any new and useful** –

(i) art, process, method or manner of manufacture;

(ii) machine, apparatus or other article;

(iii) substance produced by manufacture,

and includes any new and useful improvement of any of them, and an alleged invention.

Section 2(1)(l) "medicine or drug" includes –

(i) all medicines for internal or external use of human beings or animals,

(ii) all substances intended to be used for or in the diagnosis, treatment, mitigation or prevention of diseases in human beings or animals,

(iii) all substances intended to be used for or in the maintenance of public health, or the prevention or control of any epidemic disease among human beings or animals,

(iv) insecticides, germicides, fungicides, weedicides and all other substances intended to be used for the protection or preservation of plants;

(v) all chemical substances which are ordinarily used as intermediates in the preparation or manufacture of any of the medicines or substances above referred to."

45. Sections 1 and 2 comprised Chapter I, following which Chapter II was headed "Inventions not patentable". Chapter II had three sections which, as originally framed, are as under:

"**Section 3. What are not inventions.**– The following are not inventions within the meaning of this Act,–

(a) an invention which is frivolous or which claims anything obviously contrary to well established natural laws;

(b) an invention the primary or intended use of which would be contrary to law or morality or injurious to public health;

(c) the mere discovery of a scientific principle or the formulation of an abstract theory;

(d) the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant;

1 The provisions quoted here are as those were enacted in the 1970 Act and before those provisions underwent the amendments with effect from January 1, 2005.

(e) 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;

(f) the mere arrangement or re-arrangement or duplication of known devices each functioning independently of one another in a known way;

(g) a method or process of testing applicable during the process of manufacture for rendering the machine, apparatus or other equipment more efficient or for the improvement or restoration of the existing machine, apparatus or other equipment or for the improvement or control of manufacture;

(h) a method of agriculture or horticulture;

(i) any process for the medicinal, surgical, curative, prophylactic or other treatment of human beings or any process for a similar treatment of animals or plants to render them free of disease or to increase their economic value or that of their products.

Section 4. Inventions relating to atomic energy not patentable.– No patent shall be granted in respect of an invention relating to atomic energy falling within sub-section (1) of section 20 of the Atomic Energy Act, 1962 (33 of 1962).

Section 5. Inventions where only methods or processes of manufacture patentable.– In the case of inventions–

(a) claiming substances intended for the use, or capable of being used, as food or as medicine or drug, or

(b) relating to substances prepared or produced by chemical processes (including alloys, optical glass, semi-conductors and inter-metallic compounds), no patent shall be granted in respect of claims for the substances themselves, but claims for the methods of processes of manufacture shall be patentable."

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46. It is significant to note that section 5 in chapter II of the Act expressly excluded product patents for substances intended for use and capable of being used as food or as medicine or drug, and substances prepared or produced by chemical process, and made these substances non-patentable. Section 4 similarly prohibited grant of patent in respect of an invention relating to atomic energy. The Act thus clearly recognized and maintained the distinction between invention and patentability.

47. We have briefly examined some aspects of the legislative history of the patent law in

India. We may now take a look at how the Patent and Designs Act, 1911, and the Patents Act, 1970, impacted the pharmaceutical industry and the availability of drugs in the country.

48. Sudip Chaudhuri in his book titled, *The WTO and India's Pharmaceuticals Industry*[1] describes the market shares of multi-national companies and Indian companies in India by means of a table as under:

Market Shares of MNCs & Indian Companies in the Pharmaceutical Industry in India

Year	MNCs (%)	Indian Companies
1952	38	62
1970	68	32
1978	60	40
1980	50	50
1991	40	60
1998	32	68
2004	23	77

Sources: For 1952, Pharmaceutical Enquiry Committee 1954, pp. 20 – 1, 61 – 6;
For 1970, Ministry of Petroleum & Chemicals 1971, p. 1;
For 1978, Chaudhuri 1984, p. 176 (based on ORG 1978);
For 1980, 1991, and 1998, Kalsekar 2003;

49. The fall and rise of the Indian pharmaceutical industry is explained as the result of certain factors, not the least important of which was the change in the patent law in the country, which made medicines and drugs and chemical substances non-patentable. Chaudhuri explains that before the introduction of sulfa drugs (1930s) and penicillin (1940) that brought about the therapeutic revolution, drugs of natural origin were more important than synthetic ones. Also, medicinal plants (that is, raw materials) for about three-fourths of the drugs mentioned in British and other pharmacopoeias actually grew in India.

50. By the time the Second World War started (1939), several indigenous firms were

1 Chaudhuri, Sudip, *The WTO and India's Pharmaceuticals Industry (Patent Protection, TRIPS, and Developing Countries)* (Oxford University Press, 2005).

engaged in manufacturing drugs, and indigenous producers met 13 per cent of the medicinal requirements of the country. They still had a long way to go to attain self-sufficiency but in terms of the range of operations they were already manufacturing all types of drugs. By the early 1950s, because of the spread of manufacturing activities, the indigenous sector dominated the pharmaceutical industry in India. It accounted for about 62 per cent of the market in 1952 (the table above). However, the rise and growth of multinational corporations (MNCs) worldwide in the post-Second World War period, as well as the therapeutic revolution changed these dynamics. The MNCs started research for developing new drugs in the 1930s-40s. As a result, in the late 1940s and during the 1950s and even after that at a slower rate, new drugs discovered by the MNCs began to be available for medical use. The indigenous sector was not equipped for research for developing new drugs, that is, for developing a new chemical entity. With the introduction of new drug at a rapid rate by the MNCs, the role of patents became important. Because of the patent regime under the 1911 Act and the unsupportive industrial policy, the indigenous sector lost its status in the 1950s and the 1960s. In contrast to 62 per cent of the market in the early 1950s, the market share of the indigenous sector declined to 32 per cent by 1970. In contrast, the market share of the MNCs increased from 38 per cent in 1952 to 68 per cent in 1970 (the table above).

51. However, according to Chaudhuri, the situation changed in the 1970s. Several official initiatives were taken in the 1970s, of which the most important one was the enactment of the Patents Act, 1970, which changed the environment in favour of the indigenous sector.

52. In regard to the Patents Act, 1970, Chaudhuri maintains that Patent "reforms"

contributed directly to the transformation of the pharmaceutical industry. He points out that under the Patents Act, 1970, articles of food, medicines and drugs and chemical substances could be patented only for a new method or process of manufacture, not for the products as such (section 5 of the 1970 Act). Further, unlike in the previous patent regime, for each particular drug only one method or process – the best known to the applicant - could be patented (sections 5 and 10 of the 1970 Act). Also, even in case of a process patent for an article of food, medicine or drug, the term of the patent was brought down from fourteen (14) years to five (5) years from the date of sealing of the patent, or seven (7) years from the date of patent whichever was earlier.

53. He then examines the growth of the Indian pharmaceutical industry driven by the new patent regime in three phases:

- Till the early 1970s;
- The late 1970s and the 1980s; and
- Since the 1990s

54. Till the early 1970s the industry was dominated by MNCs who commanded 68% of the market share. India was dependent on imports for many essential bulk drugs. This import dependence constricted consumption in a country deficient in foreign exchange, and inhibited the growth of the industry. Drug prices in India were very high.

55. In the late 1970s and 1980s, Indian companies started large-scale production of bulk drugs. The development of the bulk drugs sector is actually the most important achievement of the pharmaceutical industry in India. This led to the transformation of the industry.

56. The most rapid growth of the Indian pharmaceutical industry took place from the 1990s onwards. Both production and exports grew remarkably fast. The production of both

bulk drugs and formulations started increasing sharply and steadily. From Rs.6,400 million in 1989-90, bulk drugs production increased to Rs.77,790 million in 2003-04; and from Rs.34,200 million in 1989-90, formulation productions increased to Rs.276,920 million in 2003-04. The growth was most remarkable from 2000 to 2005, when production increased much more than it had in the last two decades. Indian companies further consolidated their domination in the domestic market. Their market share increased from 60 per cent in 1991 to 68 per cent in 1998 and 77 per cent in 2003.

57. The growth was also very fast in the export markets. India became a net exporter by 1988-89, and since then there has only been an increase in the Indian exports. As a result, net exports as a percentage of exports have increased from 4.4 per cent in 1988-9 to about 50 per cent in the early 1990s and more than 75 per cent in the early 2000s. More than three-fourths of bulk drug production and almost one-fourth of the formulations production are exported. The USA, which has the toughest regulatory requirements, has emerged as India's largest export partner in pharmaceuticals.

58. Dealing with the growth of the Indian pharmaceutical industry after the change in the patent law, Chaudhuri writes:

> "Because of the rapid growth and structural transformation in the last three decades or so, India now occupies an important position in the international pharmaceutical industry… India has received worldwide recognition as a low cost producer of high quality bulk drugs and formulations. India produces about 350 bulk drugs ranging from simple pain killers to sophisticated antibiotics and complex cardiac products. Most of the bulk drugs are produced from basic stages, involving complex multi-stage synthesis, fermentation and extractions. For more than 25 bulk drugs, India accounts for more than 50 per cent of the international trade. India is a major force to reckon with in the western markets for such drugs as ibuprofen, sulphamethoxasole…"

59. Even as the country's pharmaceutical industry, helped by the basic changes made in the patent system by the Patent Act, 1970, was going from strength to strength, certain

developments were taking place at the international level that would deeply impact the Patent system in the country. Following the Uruguay round of multilateral negotiations under the General Agreement on Tariffs and Trade (GATT), the Agreement on Trade-Related Aspects of Intellectual Property Rights (The TRIPS) was arrived at and it came into force on January I, 1995. The TRIPS Agreement is the most comprehensive multilateral agreement to set detailed minimum standards for the protection and enforcement of intellectual property rights, and aims at harmonizing national intellectual property systems. All members of the World Trade Organisation (WTO) are bound by the obligations under the TRIPS Agreement. India is one of the founding members of the GATT and thus a member of the WTO from its inception from January 1, 1995, and is bound by the obligations under TRIPS Agreement like all other members of the WTO. Some of the Articles of the Agreement, which have a bearing on our discussion, are reproduced below.

"**Article 1**

Nature and Scope of Obligations

1. Members shall give effect to the provisions of this Agreement. Members may, but shall not be obliged to, implement in their law more extensive protection than is required by this Agreement, provided that such protection does not contravene the provisions of this Agreement. Members shall be free to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice.

2. For the purposes of this Agreement, the term "intellectual property" refers to all categories of intellectual property that are the subject of Sections 1 through 7 of Part II.

3. xxx

Article 3

National Treatment

1. Each Member shall accord to the nationals of other Members treatment

no less favourable than that it accords to its own nationals with regard to the protection[1] of intellectual property, subject to the exceptions already provided in, respectively, the Paris Convention (1967), the Berne Convention (1971), the Rome Convention or the Treaty on Intellectual Property in Respect of Integrated Circuits. In respect of performers, producers of phonograms and broadcasting organizations, this obligation only applies in respect of the rights provided under this Agreement. Any Member availing itself of the possibilities provided in Article 6 of the Berne Convention (1971) or paragraph 1(b) of Article 16 of the Rome Convention shall make a notification as foreseen in those provisions to the Council for TRIPS.

2. Members may avail themselves of the exceptions permitted under paragraph 1 in relation to judicial and administrative procedures, including the designation of an address for service or the appointment of an agent within the jurisdiction of a Member, only where such exceptions are necessary to secure compliance with laws and regulations which are not inconsistent with the provisions of this Agreement and where such practices are not applied in a manner which would constitute a disguised restriction on trade.

Article 7

Objectives

The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.

Article 8

Principles

1. Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement.

2. Appropriate measures, provided that they are consistent with the provisions of this Agreement, may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology.

PART II

1 For the purposes of Articles 3 and 4, "protection" shall include matters affecting the availability, acquisition, scope, maintenance and enforcement of intellectual property rights as well as those matters affecting the use of intellectual property rights specifically addressed in this Agreement.

Section 5: Patents

Article 27

Patentable Subject Matter

1. Subject to the provisions of paragraphs 2 and 3, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application.[1] Subject to paragraph 4 of Article 65, paragraph 8 of Article 70 and paragraph 3 of this Article, patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.

2. Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.

3. Members may also exclude from patentability:

(a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals;

(b) plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof. The provisions of this subparagraph shall be reviewed four years after the date of entry into force of the WTO Agreement.

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Article 28

Rights Conferred

1. A patent shall confer on its owner the following exclusive rights:

(a) where the subject matter of a patent is a product, to prevent third parties not having the owner's consent from the acts of: making, using, offering for sale, selling, or importing[2] for these purposes that product;

(b) where the subject matter of a patent is a process, to prevent third parties not having the owner's consent from the act of using the process, and from the acts of: using, offering for sale, selling, or importing for these purposes at least the product obtained directly by that process.

1 For the purposes of this Article, the terms "inventive step" and "capable of industrial application" may be deemed by a Member to be synonymous with the terms "non-obvious" and "useful" respectively.

2 This right, like all other rights conferred under this Agreement in respect of the use, sale, importation or other distribution of goods, is subject to the provisions of Article 6.

2. Patent owners shall also have the right to assign, or transfer by succession, the patent and to conclude licensing contracts.

PART V

Dispute Prevention and Settlement

Article 63

Transparency

1. Laws and regulations, and final judicial decisions and administrative rulings of general application, made effective by a Member pertaining to the subject matter of this Agreement (the availability, scope, acquisition, enforcement and prevention of the abuse of intellectual property rights) shall be published, or where such publication is not practicable made publicly available, in a national language, in such a manner as to enable governments and right holders to become acquainted with them. Agreements concerning the subject matter of this Agreement which are in force between the government or a governmental agency of a Member and the government or a governmental agency of another Member shall also be published.

2. Members shall notify the laws and regulations referred to in paragraph 1 to the Council for TRIPS in order to assist that Council in its review of the operation of this Agreement. The Council shall attempt to minimize the burden on Members in carrying out this obligation and may decide to waive the obligation to notify such laws and regulations directly to the Council if consultations with WIPO on the establishment of a common register containing these laws and regulations are successful. The Council shall also consider in this connection any action required regarding notifications pursuant to the obligations under this Agreement stemming from the provisions of Article 6*ter* of the Paris Convention (1967).

3. Each Member shall be prepared to supply, in response to a written request from another Member, information of the sort referred to in paragraph 1. A Member, having reason to believe that a specific judicial decision or administrative ruling or bilateral agreement in the area of intellectual property rights affects its rights under this Agreement, may also request in writing to be given access to or be informed in sufficient detail of such specific judicial decisions or administrative rulings or bilateral agreements.

4. Nothing in paragraphs 1, 2 and 3 shall require Members to disclose confidential information which would impede law enforcement or otherwise be contrary to the public interest or would prejudice the legitimate commercial interests of particular enterprises, public or private.

Article 64

Dispute Settlement

1. The provisions of Articles XXII and XXIII of GATT 1994 as elaborated and

applied by the Dispute Settlement Understanding shall apply to consultations and the settlement of disputes under this Agreement except as otherwise specifically provided herein.

2. Subparagraphs 1(b) and 1(c) of Article XXIII of GATT 1994 shall not apply to the settlement of disputes under this Agreement for a period of five years from the date of entry into force of the WTO Agreement.

3. During the time period referred to in paragraph 2, the Council for TRIPS shall examine the scope and modalities for complaints of the type provided for under subparagraphs 1(b) and 1(c) of Article XXIII of GATT 1994 made pursuant to this Agreement, and submit its recommendations to the Ministerial Conference for approval. Any decision of the Ministerial Conference to approve such recommendations or to extend the period in paragraph 2 shall be made only by consensus, and approved recommendations shall be effective for all Members without further formal acceptance process.

Article 65

Transitional Arrangements

1. Subject to the provisions of paragraphs 2, 3 and 4, no Member shall be obliged to apply the provisions of this Agreement before the expiry of a general period of one year following the date of entry into force of the WTO Agreement.

2. A developing country Member is entitled to delay for a further period of four years the date of application, as defined in paragraph 1, of the provisions of this Agreement other than Articles 3, 4 and 5.

3. Any other Member which is in the process of transformation from a centrally-planned into a market, free-enterprise economy and which is undertaking structural reform of its intellectual property system and facing special problems in the preparation and implementation of intellectual property laws and regulations, may also benefit from a period of delay as foreseen in paragraph 2.

4. To the extent that a developing country Member is obliged by this Agreement to extend product patent protection to areas of technology not so protectable in its territory on the general date of application of this Agreement for that Member, as defined in paragraph 2, it may delay the application of the provisions on product patents of Section 5 of Part II to such areas of technology for an additional period of five years.

5. A Member availing itself of a transitional period under paragraphs 1, 2, 3 or 4 shall ensure that any changes in its laws, regulations and practice made during that period do not result in a lesser degree of consistency with the provisions of this Agreement.

Article 70

Protection of Existing Subject Matter

1 to 6 xxx

7. In the case of intellectual property rights for which protection is conditional upon registration, applications for protection which are pending on the date of application of this Agreement for the Member in question shall be permitted to be amended to claim any enhanced protection provided under the provisions of this Agreement. Such amendments shall not include new matter.

8. Where a Member does not make available as of the date of entry into force of the WTO Agreement patent protection for pharmaceutical and agricultural chemical products commensurate with its obligations under Article 27, that Member shall:

(a) notwithstanding the provisions of Part VI, provide as from the date of entry into force of the WTO Agreement a means by which applications for patents for such inventions can be filed;

(b) apply to these applications, as of the date of application of this Agreement, the criteria for patentability as laid down in this Agreement as if those criteria were being applied on the date of filing in that Member or, where priority is available and claimed, the priority date of the application; and

(c) provide patent protection in accordance with this Agreement as from the grant of the patent and for the remainder of the patent term, counted from the filing date in accordance with Article 33 of this Agreement, for those of these applications that meet the criteria for protection referred to in subparagraph (b).

9. Where a product is the subject of a patent application in a Member in accordance with paragraph 8(a), exclusive marketing rights shall be granted, notwithstanding the provisions of Part VI, for a period of five years after obtaining marketing approval in that Member or until a product patent is granted or rejected in that Member, whichever period is shorter, provided that, subsequent to the entry into force of the WTO Agreement, a patent application has been filed and a patent granted for that product in another Member and marketing approval obtained in such other Member."

60. The Agreement (vide. Part V: Article 64) provides for a mechanism for resolution of disputes between the members of the WTO. In case of a dispute, a panel of specially appointed trade experts interprets the provisions of the Agreement and issues a report. The panel's decision may be subjected to appeal before the WTO Appellate Body. If a party to the decision fails to abide by a decision, the other party can impose trade sanctions on the member in breach, upon authorization by the Dispute Settlement Body. The dispute

resolution mechanism in the TRIPS is strong and effective as was proved in the case of India herself.

61. Article 65 (sub-articles 1and 2) allowed India to delay the application of the provisions of the Agreement for a period of 5 years, that is, till January 1, 2000; sub-Article 4 allowed India to delay for a further period of five years, that is, till January 1, 2005, the application of the provision relating to product patent, in respect of all articles excluded by the Patent Act, 1970[1], which included pharmaceuticals and agricultural chemical products. But, Article 70 (sub-articles 8 and 9) enjoined that in the meanwhile it should provide for a means by which applications for patents for inventions in respect of pharmaceutical and agricultural chemical products could be filed and also for the grant of "exclusive marketing rights" for such products. In discharge of its obligations under the Agreement, the Government of India promulgated the Patents (Amendment) Ordinance, 1994 (Ordinance No. 13 of 1994), on December 31, 1994, amending the Patents Act, 1970. The Ordinance provided for making "a claim for patent of an invention for **a substance itself intended for use, or capable of being used, as medicine or drug**" (as required by sub-paragraph (a) of Article 70.8 of the TRIPS Agreement) and for the grant of exclusive marketing rights with respect to the product that is the subject matter of such a patent claim (as required by Article 70.9 of the Agreement). The Ordinance, however, lapsed on March 26, 1995, on expiration of six weeks from the commencement of the next session of the Parliament, without being replaced by any corresponding Act[2]. The Patents (Amendment) Bill, 1995, which was intended to give permanent legislative effect to the provisions of the

1 Section 5 of the Act as before it was amended:
Section 5. Inventions where only methods or processes of manufacture patentable.– In the case of inventions –
(a) claiming substances intended for the use, or capable of being used, as food or as medicine or drug, or
(b) relating to substances prepared or produced by chemical processes (including alloys, optical glass, semi-conductors and inter-metallic compounds), no patent shall be granted in respect of claims for the substances themselves, but claims for the methods of processes of manufacture shall be patentable.

2 During this brief period, 125 applications for product patents were received and filed.

Ordinance, was introduced in the Lok Sabha in March 1995. The Bill was passed by the Lok Sabha and it was then introduced in the Rajya Sabha where it was referred to a Select Committee of the House for examination and report. The Select Committee was unable to give its report before the dissolution of the Lok Sabha on May 10, 1996. The Patents (Amendment) Bill, 1995, lapsed with the dissolution of the 10th Lok Sabha.

62. In this state of the patent law in the country, India was twice taken to the WTO panel, first on a complaint by the USA (WT/DS50/AB/R, dated December 19, 1997) and the second time on a complaint filed by the European Communities (WT/DS79/R, dated August 24, 1998). The complaint by the USA was in regard to the absence, in India, of either patent protection for pharmaceutical and agricultural chemical products under Article 27 of the TRIPS Agreement, or of a means for the filing of patent applications for pharmaceutical and agricultural chemical products pursuant to Article 70.8 of the TRIPS Agreement and of the legal authority for the grant of exclusive marketing rights for such products pursuant to Article 70.9 of the TRIPS Agreement. The WTO panel returned the finding that India had not complied with its obligations under Article 70.8 (a) and, in the alternative, paragraphs 1 and 2 of Article 63 and also 70.9 of the TRIPS Agreement. India took the matter in appeal. By a decision dated December 19, 1997, the Appellate Body affirmed the panel's findings that India had not complied with its obligations under Article 70.8(a) and Article 70.9 of the TRIPS Agreement, but set aside the panel's finding relating to the alternative claim by the United States under Article 63 of TRIPS Agreement. In conclusion, the Appellate Body recommended "that the Dispute Settlement Body request India to bring its legal regime for patent protection of pharmaceutical and agricultural chemical products into conformity with India's obligations under Article 70.8 and 70.9 of

the TRIPS Agreement".

63. In the proceedings arising from the complaint filed by the United States, the European Communities were added as the Third Party before the panel and as the Third Participant before the Appellate Body. Nonetheless, the European Communities and their members filed a similar but separate complaint against India (WT/DS79/R, dated August 24, 1998). The WTO panel, accepting the complainant's request, extended the findings in the earlier dispute (WT/DS50), as modified by the Appellate Body, to the complaint filed by the European Communities and their member States as well. This matter did not go to the WTO Appellate Body.

64. The TRIPS Agreement also provides for a built-in mechanism for review through the biennial Ministerial Conference (vide Article 71). The Ministerial Conference is the highest decision-making body of the WTO and it can make decisions on all matters under any of the WTO agreements, including the TRIPS Agreement. The fourth WTO Ministerial Conference in Doha on November 14, 2001, adopted the Doha Declaration on the TRIPS and Public Health. The Doha Declaration is as follows:

> "1. We recognize the gravity of the public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics.
>
> 2. We stress the need for the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) to be part of the wider national and international action to address these problems.
>
> 3. We recognize that intellectual property protection is important for the development of new medicines. We also recognize the concerns about its effects on prices.
>
> 4. We agree that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all.

In this connection, we reaffirm the right of WTO members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose.

5. Accordingly and in the light of paragraph 4 above, while maintaining our commitments in the TRIPS Agreement, we recognize that these flexibilities include:

a. In applying the customary rules of interpretation of public international law, each provision of the TRIPS Agreement shall be read in the light of the object and purpose of the Agreement as expressed, in particular, in its objectives and principles.

b. Each member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted.

c. Each member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency.

d. The effect of the provisions in the TRIPS Agreement that are relevant to the exhaustion of intellectual property rights is to leave each member free to establish its own regime for such exhaustion without challenge, subject to the MFN and national treatment provisions of Articles 3 and 4.

6. We recognize that WTO members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement. We instruct the Council for TRIPS to find an expeditious solution to this problem and to report to the General Council before the end of 2002.

7. We reaffirm the commitment of developed-country members to provide incentives to their enterprises and institutions to promote and encourage technology transfer to least-developed country members pursuant to Article 66.2. We also agree that the least-developed country members will not be obliged, with respect to pharmaceutical products, to implement or apply Sections 5 and 7 of Part II of the TRIPS Agreement or to enforce rights provided for under these Sections until 1 January 2016, without prejudice to the right of least-developed country members to seek other extensions of the transition periods as provided for in Article 66.1 of the TRIPS Agreement. We instruct the Council for TRIPS to take the necessary action to give effect to this pursuant to Article 66.1 of the TRIPS Agreement."

65. In the course of the hearing, we were told that the Doha Declaration effectively reflected and addressed the deep disquiet of the developing and the least-developed countries regarding their obligation under TRIPS to grant patent protection for

pharmaceutical and agricultural chemical products and the likelihood of its highly adverse consequence on public-health. Dr. Dhawan, appearing for Cipla (one of the Objectors), was particularly severe in his criticism of the TRIPS Agreement and called it a "predatory and coercive" agreement. The other counsel, though, appearing for the different Objectors, were more muted in their criticism of the TRIPS Agreement. Mr. Kuhad, the learned Additional Solicitor General appearing for the Union of India, and Mr. Grover, Senior Advocate, appearing on behalf of the M/s. Cancer Patients Aid Association (one of the Objectors), especially adapted their submissions, taking the TRIPS Agreement as a fact that cannot be simply wished away. However, all the counsel representing the Union of India and the different Objectors unanimously took the stand that the TRIPS Agreement has sufficient flexibility (vide Articles 7, 8 and 27), which was further reaffirmed by the Doha Declaration (in paragraphs 4 to 6), to enable the member States to control the patent rights in a manner as to avoid any adverse impact on public-health. It was contended on behalf of the Union of India and the Objectors that the TRIPS Agreement coupled with the Doha Declaration leaves it open to the member States to adjust their respective patent systems by regulating the grant of patents and to set up higher standards for patent protection for pharmaceutical and agricultural chemical products. The Union of India and all the Objectors maintained that the patent law in India, as it stands to-day after major changes were brought about in the Patents Act, 1970 in 2005, is fully TRIPS compliant. But they insisted that the Indian law must be judged and interpreted on its own terms, and not on the basis of standards of patentability prescribed in some countries of the western world.

66. We have referred to the TRIPS Agreement and certain developments arising from it

not to comment upon the fairness or otherwise of the Agreement nor to examine the correctness and wisdom of the decision of the Government of India to subscribe to the Agreement. That is farthest from our mind. We have referred to the Agreement as being the main reason behind the basic changes brought about in the patent law of the country by legislative action. We have also referred to the Agreement as being the cause of a good deal of concern not only in this country but also (as we shall see presently) in other parts of the world; the concern being that patent protection to pharmaceutical and agricultural chemical products might have the effect of putting life-saving medicines beyond the reach of a very large section of people. In the following lines we shall see how the Indian legislature addressed this concern and, while harmonizing the patent law in the country with the provisions of the TRIPS Agreement, strove to balance its obligations under the international treaty and its commitment to protect and promote public health considerations, not only of its own people but in many other parts of the world (particularly in the Developing Countries and the Least Developed Countries).

67. We have seen above that, simultaneously with the TRIPS coming into force, the Government of India had brought an Ordinance to comply with the provisions of Article 70 (8) and (9), but the Ordinance lapsed without being replaced by any enactment. Complaints were then filed on which pronouncements were made against India. On the complaint filed by the USA, the decision of the Appellate Body was rendered on December 19, 1997; and on the complaint filed by the European Communities, the report of the Panel came on August 24, 1998. Thus faced with the threat of trade sanctions, Parliament passed the Patents (Amendment) Act 1999 (Act No. 17 of 1999) on March 26, 1999, which amended the provisions of the Patents Act 1970 retrospectively, with effect from January 1, 1995,

the date when the TRIPS Agreement came into force. By the Amendment Act of 1999, section 5 of the Parent Act was amended to provide for making "a claim for patent of an invention for **a substance itself intended for use or capable of being used, as medicine or drug**"[1]. The Amendment Act further incorporated in the Parent Act, Chapter IVA, which contained provisions for grant of exclusive marketing rights in respect of pharmaceutical substances for which a claim for patent was made under section 5 of the Act. The Amendment Act of 1999 thus complied with Article 70(8) and (9) of the TRIPS Agreement.

68. Three years later the Patents (Amendment) Act, 2002 (Act No. 38 of 2002) came to be enacted on June 25, 2002. It brought large scale amendments in the Patents Act, 1970. The Statement of Objects and Reasons for the Amendment Act of 2002 is stated as under:

> "Amendment Act 38 of 2002 – Statement of Objects and Reasons.– The law relating to patents is contained in the Patents Act, 1970 which came into force on the 20th April, 1972. **The Act was last amended in March, 1999 to meet India's obligations under the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS)** which forms part of the Agreement establishing the World Trade Organisation (WTO). …….. Development of technological capability in India, coupled with the need for integrating the intellectual property system with international practices and intellectual property regimes, requires that the Act be modified into a modern, harmonised and user-friendly legislation to **adequately protect national and public interests while simultaneously meeting India's international obligations under the TRIPS Agreement which are to be fulfilled by 31st December, 1999.**
>
> 2. xxx
>
> 3. While considering amendment to the Act, **efforts have been made to make the law not only TRIPS complaint (sic) but also to provide therein necessary and adequate safeguards for protection of public interest, national security, bio-diversity, traditional knowledge, etc.** Opportunity is also proposed to be availed of for harmonising the procedure for grant of patents in accordance with international practices and to make the system more user friendly.

1 Excepting all chemical substances which are ordinarily used as intermediates in the preparation or manufacture of any of the medicines or substances referred to in sub-clauses (i) to (iv) of section 2 (1) (l) of the Parent Act.

4. Some of the salient features of the Bill are as under:–

(a) to define the term "invention" in consonance with international practices and consistent with TRIPS Agreement;

(b) to modify section 3 of the present Act **to include exclusions permitted by TRIPS Agreement** and also subject-matters like discovery of any living or non-living substances occurring in nature in the list of exclusions which in general do not constitute patentable invention;

(c) to align rights of patentee as per article 28 of the TRIPS Agreement;

(d) to (k) xxx;

(l) to amend several provisions of the Act with a view to simplifying and rationalising the procedures aimed at benefiting users.

(emphasis added)

69. The Amendment Act of 2002 greatly expanded the definition clause in section 2 of the Parent Act by including a number of new expressions and terms and redefining some earlier terms.

70. "Invention" was defined in the Parent Act as under:

"**Section 2(1)(j) "Invention" means any new and useful-**

(i) art, process, method or manner of manufacture;
(ii) machine, apparatus or other article;
(iii) substance produced by manufacture,

and includes any new and useful improvement of any of them, and an alleged invention."

JUDGMENT

71. "Invention" was re-defined by the Amendment Act of 2002 as under:

"**Section 2(1)(j) "invention"** means a new product or process involving an inventive step and capable of industrial application."

72. The expressions "capable of industrial application" and "inventive step" were separately defined in clauses (ac) and (ja) respectively which are as under:

"**Section 2(1)(ac) "capable of industrial application"**, in relation to an invention, means that the invention is capable of being made or used in an industry.
Section 2(1)(ja) "inventive step" means a feature that makes the invention not

obvious to a person skilled in the art."

73. Section 3 of the Parent Act, which provided for exclusions from patentability, was recast. In section 5 of the Parent Act, an Explanation was added after sub-section (2). Chapter XVI was substituted with the Chapter Heading "Working of Patents, Compulsory Licenses and Revocation". Section 83 in this Chapter laid down the general principles applicable to working of patented inventions; section 84 provided for compulsory licenses; and section 85 for revocation of patents for non-working. Here, it may not be out of place to take note of section 83 which provided as under:

> "**Section 83: General principles applicable to working of patented inventions.–** Without prejudice to the other provisions contained in this Act, in exercising the powers conferred by this Chapter, regard shall be had to the following general considerations, namely: -
>
> (a) that patents are granted to encourage inventions and to secure that the inventions are worked in India on a commercial scale and to the fullest extent that is reasonably practicable without undue delay;
>
> (b) that they are not granted merely to enable patentees to enjoy a monopoly for the importation of the patented article;
>
> (c) that the protection and enforcement of patent rights contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations;
>
> (d) that patents granted do not impede protection of public health and nutrition and should act as instrument to promote public interest specially in sectors of vital importance for socio- economic and technological development of India;
>
> (e) that patents granted do not in any way prohibit Central Government in taking measures to protect public health;
>
> (f) that the patent right is not abused by the patentee or person deriving title or interest on patent from the patentee, and the patentee or a person deriving title or interest on patent from the patentee does not resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology; and
>
> (g) that patents are granted to make the benefit of the patented invention available at reasonably affordable prices to the public."

74. The many amendments to and enlargement of the Parent Act by the Amendment Act of 2002 laid most of the ground-work, but India was yet to take the one final step to make its patent law compliant with the mandate of TRIPS. And that was to amend the Act to allow for grant of product patents for pharmaceutical and agricultural chemical substances. Steps were taken to finally amend the Patents Act, 1970, but the draft Bill lapsed in February 2004. Further efforts were made but the legislature was unable to bring an enactment to make that final amendment in the Act by December 2004; thus, the Government of India had no option but to amend the law through an Ordinance. Therefore, in order not to default on its obligations under the TRIPS Agreement, the Government brought the Patents (Amendment) Ordinance, 2004 (Ordinance No. 7 of 2004) with effect from January 1, 2005. By this Ordinance, section 5 of the Patents Act, 1970, which barred the grant of patent for substances intended for use or capable of being used as food or as medicine or drugs or substances prepared or produced by chemical processes was done away with, opening the doors for grant of patents to, amongst others, pharmaceutical products.

75. But the troubles were far from over, because the Ordinance was to lapse on March 31, 2005. Hence, it was imperative for Parliament to pass an enactment, replacing the Ordinance before it lapsed on March 31, 2005. The pressure of time under which Parliament was obliged to deal with the matter and pass the Act, replacing Ordinance No. 7 of 2004 and amending the Patents Act, 1970, is best stated in the *Statement of Objects and Reasons* for the Patents (Amendment) Act, 2005 (Act 15 of 2005). In paragraph 5 of the *Statement of Objects and reasons* it is stated as under:

> "Amendment Act 15 of 2005 – Statement of Objects and Reasons.–
> 5. The time-frame for this set of amendments was most crucial as any slippage

> in meeting the January 01, 2005 deadline had the potential of inviting retaliatory action under the WTO disputes mechanism. Having availed of the entire ten-year transition period provided under the TRIPS Agreement, India had no legal basis to defend its default on the deadline. The past record of delayed implementation would also not have helped the Indian case. This default would also have created a legal vacuum for the "mailbox" applications, as there would not be any mechanism to deal with them from January 01, 2005. This would have amounted to a specific default on the international commitment to examine and dispose of these cases, and might have again provided an opportunity to WTO member countries to raise a dispute against India in the WTO. There would also have been a legal vacuum in respect of fresh applications after January 01, 2005, as the law was salient on whether the "mailbox" provision would subsist or whether it would have ceased. Finally, there would have been an erosion of India's credibility in the international field. In the circumstances it was considered necessary to bring in the required amendments in time and as Parliament was not in session, the President promulgated the Patents (Amendment) Ordinance, 2005 (Ord. 7 of 2004) on the 26th December, 2004."

76. Parliament had an absolutely unenviable task on its hands. It was required to forge, within a very limited time, an Act that would be TRIPS compliant without, in any way, compromising on public health considerations. It is seen above that the TRIPS Agreement had aroused grave concerns about its impact on public health. India had learnt from experience the inverse relationship between product patents and the indigenous pharmaceutical industry, and its effects on the availability of essential drugs at affordable prices. It is also seen above that after the patent system in India barred the grant of patents for pharmaceutical and chemical substances, the pharmaceutical industry in the country scaled great heights and became the major supplier of drugs at cheap prices to a number of developing and under developed countries. Hence, the reintroduction of product patents in the Indian patent system through the TRIPS Agreement became a cause of alarm not only in this country but also for some international agencies. Our attention was invited to a letter of the HIV/AIDS Director of the WHO, dated December 17, 2004, to the Minister of Health and Family Welfare, Government of India. The letter deserves to be noted in full.

“17 December 2004

Dr. A Ramadoss
Minister of Health and Family Welfare
Government of India
Nirman Bhawan, Maulana Azad Road
New Delhi-110 001
India

Dear Dr. Ramadoss,

We would like to bring to your attention that several of our Member States have expressed their concern that in the future, generic antiretroviral drugs from India may no longer be available to them. Among other places, these concerns were expressed by the delegations of Ghana, Lesotho, Malawi, and Namibia at our recent Procurement & Supply Management (PSM) Workshop in Nairobi, Kenya (2-9 December, 2004), and by Bangladesh, Cambodia, China, Indonesia, Korea, Laos, Thailand, Papua New Guinea, and Vietnam at the Asian Regional Workshop on the WTO/TRIPS Agreement and Access to Medicines held in Kuala Lumpur, Malaysia (28-30 November 2004).

As you are aware, WHO has been actively monitoring the implications of trade agreements on public health. One key issue is the impact of the end of the transition period at 1 January 2005 allowed under the TRIPS Agreement, which delayed the application of product patents, on the local production and supply of generic antiretroviral agents.

The WTO Ministerial Declaration on the TRIPS Agreement and Public Health adopted in Doha, 2001 affirmed that "the TRIPS Agreement can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all." In line with this, recent resolutions of the World health Assembly have also urged that national legislation should be adapted in order to use to the full the flexibilities contained in the TRIPS Agreement (WHA 56.27, May 2003 and 57.14, May 2004). In accordance with its mandate, WHO will therefore seek to provide technical assistance and support to Member States to promote implementation of the TRIPS Agreement consistent with the public health objective of ensuring access to medicines.

As India is the leader in the global supply of affordable antiretroviral drugs and other essential medicines, we hope that the Indian government will take the necessary steps to continue to account for the needs of the poorest nations that urgently need access to antiretrovirals, without adopting unnecessary restrictions that are not required under the TRIPS Agreement and that would impede access to medicines.

We thank you for your attention to this issue and send our best regards.

Sincerely,

Dr. Jim Yong Kim

Director
Department of HIV/AIDS"

(emphasis added)

77. We were also shown another letter dated February 23, 2005, from the Director of Advocacy, Communication and Leadership for UNAIDS, to the Minister of Commerce and Industry, Government of India. This letter is also useful as reflecting the concern of the international community over the impending change in the patent system in India. This letter is as under:

"Honourable Minister
Mr Kamal Nath
Ministry of Commerce and Industry
Udyog Bahavan
New Delhi 110001
India

23 February 2005

Reference: ACL/AD/lp

Excellency,

I have the honour to refer to India's leadership in promoting access to and supplying affordable essential generic HIV medicines to those most in need in developing countries, which has long been recognized and applauded by the international community. India can rightly take pride in the fact that it has significantly supported the response to the global AIDS emergency through helping to ensure AIDS medicines are more affordable and accessible.

Affordable HIV medications from India have so far saved thousands of lives yet more than 8,000 people around the world continue to die every day because they have no access to treatment. Despite concerted efforts across the world, only about one in ten people in urgent need of HIV antiretroviral treatment in low- and middle-income countries has access to existing medicines.

Current legislative proposals intended to take the 1970 Indian Patents Act beyond the commitments agreed in the World Trade Organization's Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) threaten to undermine India's leadership in providing affordable medicines. For example, the requirement that countries wishing to import from India under the WTO 30 August 2003 Decision must issue a compulsory license in every case goes far beyond the WTO Decision. This requirement in the Indian Ordinance places a cumbersome and often unnecessary administrative burden on the importing country. Often, there will be no patent in the importing country and compulsory

licenses are only required where a valid patent has been issued. Under the WTO Declaration on TRIPS and Public Health (the Doha Declaration) of November 2001, Least Developed Countries are not even required to issue patents in the pharmaceutical sector until 2016. In addition, the limitations under the Ordinance of the pre-grant opposition rule contained in the previous law removes an important opportunity for People Living with HIV and other members of civil society to participate in an open and transparent process.

The implications of the current Ordinance are potentially devastating: the vast majority of countries hardest hit by AIDS do not have sufficient manufacturing capacity in the pharmaceutical sector and must rely upon imports from major producing countries such as India if they are to succeed in scaling up access to HIV treatment to the millions of their people in need.

UNAIDS strongly supports the rights of governments to avail themselves of the flexibilities in TRIPS in promoting the widest possible access to affordable medicines and technologies.

Therefore, we would respectfully urge you to consider all appropriate legal means to protect and scale up access to essential affordable medicines. The Doha Declaration, in which India played an important role, makes clear that the interests of public health and equitable access to medicines for all should be primary concerns in the application of the TRIPS Agreement and related trade and intellectual property rules.

UNAIDS has learnt that a Global Day of Action is planned for 26 February 2005 against the Indian Patent Ordinance. Civil society, organizations of people living with HIV and AIDS and the media will be watching closely. This day presents an opportunity for India to send out a strong message in support of both research innovation and access to affordable HIV-related pharmaceuticals and other essential medicines, while fully complying with the applicable multilateral trade and intellectual property agreements.

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Please accept, Excellency, the assurance of my highest consideration.

Achmat Dangor
Director
Advocacy, Communication and Leadership

cc: Dr Prasada Rao, UNAIDS Regional Director, Regional
Support Team, Bangkok
Permanent Mission of India to the United Nations and other International Organizations in Geneva"

78. It was thus under the twin pressure of time and anxiety to safeguard the public health objectives that Parliament was called upon to deliberate over the amendments required to be made in the patent law to make it fully compliant with the TRIPS Agreement.

79. On December 18, 2004, the Bill to further amend the Patents Act, 1970, which was materially the same as Ordinance No. 7 of 2004, was introduced in Parliament. The Bill evoked a highly insightful and informed debate on the subject. To anyone going through the debate on the Bill, Parliament would appear keenly alive to national interests, human-rights considerations and the role of India as the producer and supplier of drugs to different parts of the world where impoverished humanity is critically in need of those drugs at cheap and affordable prices. Cutting across party lines, member after member from the Opposition benches highlighted the grave risk in creating private monopolies in an area like pharmaceuticals, the abuses to which product patents in pharmaceutical products were vulnerable, and the ploys used by big companies to artificially extend the period of patent to keep competitors out and keep the prices of the patented product high. It was strongly argued that, while fulfilling its commitment under the TRIPS agreement, the Government must not bring in a patent regime where all the gains achieved by the Indian pharmaceutical industry are dissipated and large sections of Indians and people in other parts of the world are left at the mercy of giant multinational pharmaceutical companies.

80. One of the members from the Opposition benches said:

> "Sir, even if this were a Bill, which affects only India, still it would be an extremely important one. But it is a Bill, which affects most parts of the world. We are supplying 50 per cent of the cheapest drugs in the world to places like Papua New Guinea, Laos, Kenya, Africa, etc. All these countries have complained to the WHO about this Bill.
>
> The two biggest international health organizations in the world, namely WHO, and Medicines Sans Frontiers have written to the Government saying that this is a very very serious matter. This has been the subject of editorials all over the world right from America onwards to every country from Bangladesh, Cambodia, China, Indonesia, Nairobi, Korea, Laos, Thailand, Vietnam, etc. All of them have complained about our Bill. It is a Bill that affects so many parts of the world. Do you not think that we should have a slightly more serious discussion on it, rather than attempting to pass it through?"

The same member speaking at a later stage in the debate said:

> "India has benefited from the low cost generic industry to dominate 30 per cent of the low cost drugs in the world….
>
> Secondly, it (the bill) is vague about the evergreening effect in which companies extend their patent rights by switching from capsules to tablets, for instance. This extends monopolies. Parliament must make sure that it protects the rights of India to make these generic drugs. We should remove the provision that allows this evergreening. … What should and what should not be patentable has also been left open to interpretation. Earlier, the new use for a substance could not be patented. Now this has been qualified to allow it by putting "mere new use" instead of "new use".
>
> xxx
>
> Sir, I am going to limit my speech to six points only. This is what we need:
>
> 1. We need to limit the scope of patentability to only new chemical entities.
> 2. No patents for new usage and dosage of known drugs.
> 3. Retain pre-grant opposition in its original form.
> 4. Simple procedures with a time limit for grant of compulsory licences.
> 5. Immunity for generic drugs which are already available in the market.
> 6. Introduction of ceiling on royalty to pharmaceutical companies"

81. Another member, also from one of the parties in the Opposition, had this to say:

> "Sir, a lot of things have been said for and against the Bill. Certain basic positions have to be re-stated even now. That is, in India, we had legislation in 1891 on the Patents and Designs. That was product regime, under which it had been told that in India, in relation to medicines, at that time, 85 per cent of our medicinal requirements was met by import of medicines from abroad. In those days, probably, the transnational corporations were not as big as they are today. But even then, with the product regime that was there upto 1911, the situation in this country was such that we had to depend upon imports for the 85 per cent of our medicinal requirements.
>
> After 1970, when India adopted a new Patents legislation, where we had adopted a process regime, the situation was reversed. This 85 per cent of our country's medicinal requirement was met by our own products. That was a remarkable achievement. Not only that, we started exporting to countries which does not have the facility of infrastructure to produce their own medicines. We supplied medicine to meet their requirements. But will the Minister now assure that we will be able to meet our own requirements at a cheaper rate after adopting this product regime? Can it be assured that we would be able to meet the requirements of medicine of our people? Because, that was not our experience in the past. …"

82. It is interesting to note that in the Parliamentary debate, the names of the appellant company (Novartis) and the drug (Gleevec) being the subject matter of this case were repeatedly mentioned, and the excessively high price fixed for the drug after the grant of "exclusive marketing rights" to the appellant was expressly cited as the likely result of bringing in the product patent regime in pharmaceuticals. One of the members said:

> "Sir, a company which obtains a patent by changing their chemicals, before the expiry of the patent, they will again apply for a patent and again get a patent. So, in this way, they will continue to get a patent for the same medicine. For example, the drug called 'Glevic' (sic Gleevec/Glivec), is used for the treatment of Leukaemia. It is patented by Novartis. This was originally patented in 1993. The cost of the drug for the treatment of this disease comes to about Rs.1,20,000 per month[1] in India. At the same time, the generic versions are available in the country which cost only Rs.8,000 to Rs.10,000."

83. As the deliberations were going on in Parliament, negotiations were also held between the ruling party and some of the opposition parties, in course of which certain amendments were suggested in the Bill. And in order to allay the apprehensions and fears voiced by the Opposition, one of the members from the Government said:

> "Madam, I am concluding. I would only like to refer to the amendment which is being incorporated in Clause 3 which talks of the known inventions, the products which are not considered to be inventions and therefore cannot be covered by the patent and patents cannot be sought for them. A good amendment is being introduced to that effect in Clause 3 of the Bill which says:
>
> "The mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance of (sic or) the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant."
>
> The explanation to that should completely allay the fears of our friends on the other side. I hope they would accept that."

1 Here it will be unfair not to state that in course of hearing of the case when the Court expressed its bewilderment over the price of the drug, it was strenuously stated on behalf of the appellant that they also ran a huge charitable programme under which the drug was supplied free to the needy persons. However, to the question by the Court why the appellant could not abolish the charitable programme and at the same time bring down the price of the drug so as the total revenue from the sale of the drug remains the same as it is with the abnormally high price and the charitable programme, no satisfactory answer was provided on behalf of the appellant.

84. Speaking at the conclusion of the debate, the minister who had sponsored the Bill also referred to the amendment proposed in section 3(d). He said:

> "There are so many provisions here. In regard to evergreening, I just want to read out section 3(d) which says that a mere discovery of a new property or a new use for a known substance or the mere use of known process in a new product – these are exceptions, these will not be granted any patent – and substances obtained by a mere ad-mixture resulting only in aggregation of properties of the components thereof or, processes of producing such substances will not be given patents…"

85. Finally, after three days of debate (March 18, 21 and 22) the Bill, along with the amendments proposed by the minister, was passed by the Lok Sabha on March 22, 2005. Some of the very important amendments that were incorporated in the Bill related to section 2(1)(ja) and section 3(d), and the insertion of the provision for pre-grant opposition to grant of patent. After being passed by the Lok Sabha, the Bill was presented in the Rajya Sabha where it was passed on March 23, 2005. It received the assent of the President on April 4, 2005, and was published in the official gazette of April 5, 2005.

86. Thus, after deliberations that took place for just four days, the Patents Act, 1970, came in a completely new *avatar.* The haste with which the Government was constrained to rush the Bill through Parliament to make the law compatible with the TRIPS Agreement perhaps explains the somewhat unclear drafting of some very important provisions, which called for much greater clarity; the presence of some terms and expressions in the definition section[1] that are nowhere used in the Act; and a few loose ends that could have been properly tied up if more time and attention was given to the drafting.

87. We have seen in some detail the "why" and the "how" of the law. Let us now examine what the law is in light of its "why" and "how". In order to understand the

1 Section 2(1)(l): "New Invention", section 2(1)(ta) "Pharmaceutical substance".

meaning of "invention" under the Patents Act, 1970, as it stands today after its amendment by the amending Act of 2005, we must refer to clauses (ac), (j) and (ja) of section 2(1) of the Act[1]:

> "**Section 2. Definitions and interpretation.** — (1) In this Act, unless the context otherwise requires,—
>
> **(ac) "capable of industrial application"**, in relation to an invention, means that the invention is capable of being made or used in an industry;
>
> **(j) "invention"** means a new product or process involving an inventive step and capable of industrial application;
>
> **(ja) "inventive step"** means a feature of an invention that involves technical advance as compared to the existing knowledge or having economic significance or both and that makes the invention not obvious to a person skilled in the art;"

88. Section 2(1)(j) requires a product to satisfy three conditions to qualify as an invention.

(i) It must be "new", that is to say it must not have been *anticipated*;

(ii) Its coming into being must involve an "*inventive step*"; and

(iii) It must be "capable of industrial application", that is to say it must be capable of being made or used in an industry [section 2(1)(ac)].

89. "Inventive step" is separately defined in section 2(ja) to mean a feature of an invention that involves technical advance as compared to the existing knowledge, or having economic significance or both and that makes the invention *not obvious* to a person skilled in the art. To paraphrase, the invention that creates the product must have a feature that involves technical[2] advance as compared to the existing knowledge or having economic significance or both and this feature should be such as to make the invention not

1 Clauses (l) and (ta) of section 2(1) are also on the issue of "invention" but as noted above those provisions, though defined in section 2 are not used anywhere else in the Act and, therefore, we do not take those provisions in consideration for construing the meaning of "invention".

2 "Adjective: 1. of or relating to a particular subject, art, or craft or its techniques. 2. of, involving, or concerned with applied or industrial sciences" : The New Oxford Dictionary of English, Edition 1998.

obvious to a person skilled in the art.

90. On a combined reading of causes (j), (ac) and (ja) of section 2(1), in order to qualify as "invention", a product must, therefore, satisfy the following tests:

(i) It must be "new";

(ii) It must be "capable of being made or used in an industry"

(iii) It must come into being as a result of an invention which has a feature that:

(a) entails technical advance over existing knowledge;

Or

(b) has an economic significance

And

(c) makes the invention not obvious to a person skilled in the art.

91. We have seen the meaning of "invention"; we have also seen earlier that the Patents Act, 1970, dealt with "invention" and "patentability" as two distinctly separate concepts. The duality of the two concepts is best illustrated by section 4 of the Act, which prohibits the grant of patent (either process or product) "in respect of inventions relating to atomic energy falling within sub-section (1) of section 20 of the Atomic Energy Act, 1962", and which has not undergone any change since inception. It is, therefore, fundamental that for grant of patent the subject must satisfy the twin tests of "invention" and "patentability". Something may be an "invention" as the term is generally understood and yet it may not qualify as an "invention" for the purposes of the Act. Further, something may even qualify as an "invention" as defined under the Act and yet may be denied patent for other larger considerations as may be stipulated in the Act. Having, therefore, seen the meaning of "invention", we may now advert to section 3 as it stands after the amendment of the Act in

2005.

92. Section 3 is in Chapter II of the Act, which initially contained sections 3, 4 and 5, but after the deletion of section 5 with effect from January 1, 2005, Chapter II has only two sections: sections 3 and 4. The Chapter has the Heading "Inventions Not Patentable" and section 3 has the marginal heading "What are not inventions." As suggested by the Chapter heading and the marginal heading of section 3, and as may be seen simply by going through section 3, it puts at one place provisions of two different kinds: one that declares that certain things shall not be deemed to be "inventions" [for instance clauses (d) & (e)]; and the other that provides that, though resulting from invention, something may yet not be granted patent for other considerations [for instance clause (b)].

93. For the purpose of these appeals, however, we need only to focus on clause (d) of section 3.

94. We have seen earlier that, in course of the debate in Parliament, an amendment (by way of addition) in clause (d) of section 3 was proposed by the Government in order to allay the fears of the members from the Opposition concerning the introduction of product patents for pharmaceuticals and agricultural chemicals, and it was on the Government's assurance that the proposed amendment in section 3(d) (besides some other changes in the Act) would take care of the apprehensions about the abuse of product patent in medicines and agricultural chemical substances that the Bill was passed by Parliament. We once again examine here what was the amendment introduced in section 3(d) by the amending Act of 2005. Immediately before its amendment in 2005, section 3(d) was, in the Patents (Amendment) Ordinance, 2004 (Ordinance No. 7 of 2004), as under:—

> "**Section 3. What are not inventions.**– The following are not inventions within the meaning of this Act,—

(d) the mere discovery of any new property or *mere* new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant."

95. After the amendment with effect from Jan 1, 2005, section 3(d) stands as under: -

"**Section 3. What are not inventions.**– The following are not inventions within the meaning of this Act,—

(d) **the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or** the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant.

***Explanation.*—For the purposes of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy.**"

96. As may be seen, the amendment (i) adds the words "the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or" at the beginning of the provision; (ii) deletes the word "mere" before "new use"; and (iii) adds an explanation at the end of the clause.

97. A perusal of the Parliamentary debate would further reveal that the whole debate centered on medicines and drugs. It would not be an exaggeration to say that eighty per cent of the debate was focused on medicines and drugs and the remaining twenty per cent on agricultural chemicals. In the entire debate, no substance of any other kind came under discussion.

98. The aforementioned amendment in section 3(d) is one of the most crucial amendments that saw the Bill through Parliament and, as noted, the amendment is primarily in respect of medicines and drugs and, to some extent, agricultural chemical

substances.

99. In regard to section 3(d) both Mr. Andhyarujina and Mr. Subramanium, learned counsel appearing for the appellant, strenuously argued that section 3(d) is not meant to be an exception to clauses (j) and (ja) of section 2(1) of the Act. Both the learned counsel insisted that section 3(d) has no application to the case of the subject product. The subject product, having satisfied the tests of invention as provided in clauses (j) and (ja) of section 2(1), cannot be denied patent for allegedly failing to satisfy the tests under section 3(d). Mr. Andhyarujina submitted that section 3(d) is a provision put in *ex abundanti cautela non nocet*[1] to remove all doubts.

100. Mr. Subramanium submitted that section 3(d) is *ex majore cautela*[2]. The learned counsel submitted that the primary purpose of section 3(d), as is evidenced from the legislative history, is to prevent "evergreening" and yet to encourage incremental inventions. "Evergreening" is a term used to label practices that have developed in certain jurisdictions wherein a trifling change is made to an existing product, and claimed as a new invention. The coverage/protection afforded by the alleged new invention is then used to extend the patentee's exclusive rights over the product, preventing competition. Mr. Subramanium submitted that, by definition, a trifling change, or in the words of the section "a mere discovery of a new form of a known substance", can never ordinarily meet the threshold of novelty and inventive step under clauses (j) and (ja) of section 2(1). An invention cannot be characterized by the word "mere". The word "invention" is distinct from the word "discovery". He, therefore, submitted that section 3(d) operates only as *ex majore cautela*, ensuring that mere discoveries can never, by an effort at interpretation of

1 Abundant caution does no harm.
2 Out of abundant caution.

clauses (j) and (ja) of section 2(1), be considered inventions.

101. In regard to the concerns about public health issues and the flexibility of the TRIPS Agreement coupled with the Doha Declaration, allowing the scope to address the issues of public health, Mr. Subramanium submitted that those concerns are addressed in the Act, in provisions relating to compulsory licensing[1], revocation of patents[2], and the multiple stages for opposition to the grant of patent[3].

102. The submission may appear plausible if the scrutiny of the law is confined only to the Act as it stands today after undergoing the amendments in 2005. But examined in the larger perspective of the development of the law of patent over the past 100 years and especially keeping in mind the debates in the Parliament preceding the 2005 amendment, it would appear completely unacceptable. We find no force in this submission that section 3(d) is a provision *ex majore cautela*. To our mind, the submission completely misses the vital distinction between the concepts of invention and patentability – a distinction that was at the heart of the Patents Act as it was framed in 1970, and which is reinforced by the 2005 amendment in section 3(d).

103. We are clearly of the view that the importance of the amendment made in section 3(d), that is, the addition of the opening words in the substantive provision and the insertion of explanation to the substantive provision, cannot be under-estimated. It is seen above that, in course of the Parliamentary debates, the amendment in section 3(d) was the only provision cited by the Government to allay the fears of the Opposition members concerning the abuses to which a product patent in medicines may be vulnerable. We have, therefore, no doubt that the amendment/addition made in section 3(d) is meant especially

1 See Chapter XVI: "*Working of Patents, Compulsory Licences and Revocation*" in the Patents Act, 1970.
2 See sections 63, 64, and 65 of the Patents Act, 1970.
3 See section 25 of the Patents Act, 1970.

to deal with chemical substances, and more particularly pharmaceutical products. The amended portion of section 3(d) clearly sets up a second tier of qualifying standards for chemical substances/pharmaceutical products in order to leave the door open for true and genuine inventions but, at the same time, to check any attempt at repetitive patenting or extension of the patent term on spurious grounds.

104. We have so far seen section 3(d) as representing "patentability", a concept distinct and separate from "invention". But if clause (d) is isolated from the rest of section 3, and the legislative history behind the incorporation of Chapter II in the Patents act, 1970, is disregarded, then it is possible to see section 3(d) as an extension of the definition of "invention" and to link section 3(d) with clauses (j) and (ja) of section 2(1). In that case, on reading clauses (j) and (ja) of section 2(1) with section 3(d) it would appear that the Act sets different standards for qualifying as "inventions" things belonging to different classes, and for medicines and drugs and other chemical substances, the Act sets the invention threshold further higher, by virtue of the amendments made in section 3(d) in the year 2005.

105. Admittedly, the genesis of this patent application lies in one of the derivatives of N-phenyl-2- pyrimidine-amine in free base called Imatinib[1], vide example 21 of the Zimmermann patent. According to the appellant, beginning with Imatinib, the subject product, i.e., Imatinib Mesylate in beta crystalline form, was brought to being by not one but two inventions.

106. The first invention lies in selecting example 21 out of the 37 examples given in the Zimmermann patent and then choosing methanesulfonic acid to produce the

1 4-(4-methylpiperazin-1–ylmethyl)-N-[4-methyl-3-(4-pyridin-3-yl)pyrimidin-2-ylamino)phenyl] benzamide.

methanesulfonic acid addition salt of the free base Imatinib, called Imatinib Mesylate. It was emphasized by both Mr. Gopal Subramanium and Mr. Andhyarujina, Senior Advocates appearing for the appellant, that the Zimmermann patent did not teach or suggest to a person skilled in the art to select example 21 in preference to other compounds of which examples were given in the Zimmermann patent. Further, even if example 21 was selected, the Zimmermann patent did not teach a person to select one particular salt. The Zimmermann patent did not teach a person how to prepare Mesylate salt of example 21. Hence, the coming into being of Imatinib Mesylate from Imatinib in free base was the result of an invention that involved technical advance as compared to the existing knowledge and brought into existence a new substance.

107. In the second invention, the appellant arrived at the beta crystal form of methanesulfonic acid addition salt of Imatinib. It was contended on behalf of the appellant that once the salt form of Imatinib was arrived at, the inventors had to further research to be able to ensure that that particular salt form of Imatinib is suitable for administration in a solid oral dosage form. This research further required defining the process parameters that brought into being the beta crystalline form of Imatinib Mesylate. It was argued on behalf of the appellant that there is certainly no mention of polymorphism or crystalline structure in the Zimmermann patent. The relevant crystalline form of the salt that was synthesized needed to be invented. There was no way of predicting that the beta crystalline form of Imatinib Mesylate would possess the characteristics that would make it orally administrable to humans without going through the inventive steps. It was further argued that the Zimmermann patent only described, at most, how to prepare Imatinib free base, and that this free base would have anti-tumour properties with respect to the BCR ABL

kinase. Thus, arriving at the beta-crystalline form of Imatinib Mesylate for a viable treatment of Chronic Myeloid Leukemia required further invention – not one but two, starting from Imatinib in free base form, as stated above.

108. The subject product admittedly emerges from the Zimmermann patent. Hence, in order to test the correctness of the claim made on behalf of the appellant, that the subject product is brought into being through inventive research, we need to examine in some detail the Zimmermann patent and certain developments that took place on that basis

109. An application for grant of patent for the Zimmermann invention (Pyrimidine Derivatives and Processes for the Preparation thereof) was filed in the United States of America on April 2, 1993, by Ciba Geigy[1] (US Patent Application No. 08/042,322). This application was abandoned and another continuation-in-part application was then filed on April 28, 1994 (US Patent Application No. 5,521,184). The Zimmermann invention[2]

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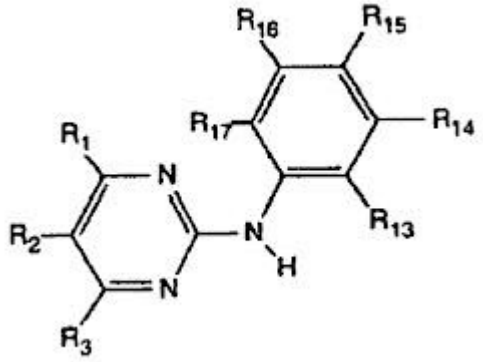
1 In 1996, CIBA Geigy merged with Sandoz to form Novartis, the present appellant.

2 The invention relates to N-phenyl-2-pyrimidine-amine derivatives, to processes for the preparation thereof, to medicaments comprising those compounds, and to the use thereof in the preparation of pharmaceutical compositions for the therapeutic treatment of warm-blooded animals.

The invention relates to N-phenyl-2-pyrimidine-amine derivatives of formula I



wherein

R_1 is 4-pyrazinyl, 1-methyl-1H-pyrrolyl, amino- or amino-lower alkyl-substituted phenyl wherein the amino group in each case is free, alkylated or acylated, 1H-indolyl or 1H-imidazolyl bonded at a five-membered ring carbon atom, or unsubstituted or lower alkyl-substituted pyridyl bonded at a ring carbon atom and unsubstituted or substituted at the nitrogen atom by oxygen,

R_2 and R_3 are each independently of the other hydrogen or lower alkyl,

one or two of the radicals R_4, R_5, R_6, R_7 and R_8 are each nitro, fluoro-substituted lower alkoxy or a radical of formula II

$$–N(R_9)–C(=X)–(Y)_n–R_{10}$$

wherein

R_9 is hydrogen or lower alkyl,

X is oxo, thio, imino, N-lower alkyl-imino, hydroximino or O-lower alkyl-hydroximino,

Y is oxygen or the group NH,

related to N-phenyl-2-pyrimidine-amine derivatives (called, "formula I" in the patent application), and the compounds thereof, the process for their preparation, and to their therapeutic uses. In the patent application, it was expressly stated that the compounds of formula I included their respective salts:

> "Salt-forming groups in a compound of formula I are groups or radicals having basic or acidic properties. Compounds having at least one basic group or at least one basic radical, for example a free amino group, a pyrazinyl radical or a pyridyl radical, **may form acid addition salts, for example with inorganic acids, such as hydrochloric acid, sulfuric acid or a phosphoric acid, or with suitable organic carboxylic or sulfonic acids**…"

Further:

> "Owing to the close relationship between the novel compounds in free form and in the form of their salts, including those salts that can be used as intermediates, for example in the purification of the novel compounds or for the identification thereof, hereinbefore and hereinafter **any reference to the free compounds should be understood as including the corresponding salts, where appropriate and expedient.**"
>
> (emphasis added)

110. As regards the pharmacological properties of the compounds of formula I it was stated in the application:

> "The compounds of formula I have valuable pharmacological properties and can be used, for example, as anti-tumoral drugs and as drags (sic drugs) against atherosclerosis."

111. The application also described the tests undertaken for determining the protein kinase C-inhibiting activities of compounds of formula I and their pharmaceutically acceptable salts as follows:

> "To determine protein kinase C-inhibiting activity, protein kinase C from pig

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n is 0 or 1 and

R_{10} is an aliphatic radical having at least 5 carbon atoms, or an aromatic, aromatic-aliphatic, cycloaliphatic, cycloaliphatic-aliphatic, heterocyclic or heterocyclic-aliphatic radical,

and the remaining radicals R_4, R_5, R_6, R_7 and R_8 are each independently of the others hydrogen, lower alkyl that is unsubstituted or substituted by free or alkylated amino, piperazinyl, piperidinyl, pyrrolidinyl or by morpholinyl, or lower alkanoyl, trifluoromethyl, free, etherified or esterifed hydroxy, free, alkylated or acylated amino or free or esterified carboxy,

and to salts of such compounds having at least one salt-forming group.

brain purified in accordance with the procedure described by T. Uchida and C. R. Filburn in J. Biol. Chem. 259, 12311-4 (1984) is used. The protein kinase C-inhibiting activity of the compounds of formula I is determined by the method of D. Fabbro et at., Arch. Biochem. Biophys. 239, 102-111 (1985). In that test the compounds of formula I inhibit protein kinase C at a concentration IC_{50} of as low as approximately from 0.1 to 10 µmol/liter, especially approximately from 0.05 to 5 µmol/liter. On the other hand, the compounds of formula I inhibit other enzymes, for example protein kinase A, phosphorylase protein kinase and certain types of tyrosine protein kinase, for example the tyrosine protein kinase of EGF (epidermal growth factor) receptors, only at a far higher concentration, for example 100 times higher. That is an indication of the selectivity of the compounds of formula I. With a view to reducing undesired side effects, it is important for the protein kinase C-inhibitors to be as selective as possible, i.e. inter alia to have as little effect as possible on other enzymes, especially when the effect of the activity of those other enzymes has no equivalent or synergistic effect on the disease to be treated.

xxx

As might already be expected on the basis of the inhibiting action on protein kinase C described above, the compounds of formula I wherein R_4 and R_8 are hydrogen, and their pharmaceutically acceptable salts, have anti-proliferative properties which can be demonstrated directly in the following, different test. In that test the inhibiting action of compounds of formula I on the growth of human T24 bladder carcinoma cells is determined…"

It was also stated:

"The tumour-inhibiting activity of the compounds of formula I can also be demonstrated in vivo.

The tumour-inhibiting activity is determined using female Balb/c nude mice in which human T24 bladder carcinoma has been transplanted…"

The application further claimed:

"Owing to the properties described, compounds of formula I can be used not only as tumour-inhibiting active ingredients but also as drugs against non-malignant proliferative diseases, e.g. atherosclerosis, thrombosis, psoriasis, sclerodermitis and fibrosis. They are also suitable for the further applications mentioned above for protein kinase C-modulators and can be used especially in the treatment of diseases that respond to the inhibition of PDGF-receptor kinase.

Some of the compounds of formula I, e.g. N-[3-(1,1,2,2-tetrafluoroethoxy)phenyl]-4-(3-indolyl)-2-pyrimidine-amine, furthermore inhibit the tyrosine kinase activity of the receptor for the epidermal growth factor (EGF). This receptor-specific enzyme activity is a key factor in the signal transmission in a host of mammalian cells, including human cells, especially

epithelial cells, cells of the immune system and cells of the central and peripheral nervous system."

It was also said in the application:

"These compounds of formula I, which inhibit the tyrosine kinase activity of the receptor for the epidermal growth factor (EGF) are therefore useful, inter alia, for the treatment of benign or malignant tumours. They are able to effect tumour regression and to prevent metastasic spread and the growth of micrometastases. In particular, they can be used for treating epidermal hyperproliferation (psoriasis), for treating neoplasms of epithelial character, e.g. mastocarcinomas, and leucemias. In addition, the compounds of formula I are useful for treating diseases of the immune system and inflammations, subject to the involvement of protein kinases. These compounds of formula I can also be used for treating diseases of the central or peripheral nervous system, subject to the involvement of signal transmission by protein kinases."

It was further stated in the application:

"**Acid addition salts can be convened into the free compounds in customary manner, for example by treatment with a suitable basic agent.**

xxx

The processes described above, including the processes for removing protecting groups and the additional process steps, are, unless otherwise indicated, carried out **in a manner known per se**, for example in the presence or absence of preferably inert solvents and diluents, if necessary in the presence of condensation agents or catalysts…"

It was also affirmed in the application:

"The invention relates also to a method of treating warm-blooded animals suffering from a tumoral disease, **which comprises administering to warm-blooded animals requiring such treatment an effective, tumour-inhibiting amount of a compound of formula I or of a pharmaceutically acceptable salt thereof**… Effective doses, for example daily doses of approximately from 1 to 1000 mg, especially from 50 to 500 mg, are administered to a warm-blooded animal of approximately 70 kg body weight according to species, age, individual condition, mode of administration and the individual syndrome.

The invention relates also to pharmaceutical compositions comprising an effective amount, especially an amount effective in the prevention or therapy of one of the above-mentioned diseases, **of the active ingredient together with pharmaceutically acceptable carriers that are suitable for topical, enteral, for example oral or rectal, or parenteral administration, and may be inorganic or organic, solid or liquid. For oral administration there are used especially tablets or gelatin capsules comprising the active ingredient**

> **together with diluents, for example lactose, dextrose, sucrose, mannitol, sorbitol, cellulose and/or glycerol**… **Tablets may also comprise binders,** for example magnesium aluminium silicate, starches, such as corn, wheat or rice starch, gelatin, methylcellulose, sodium carboxymethylcellulose and/or polyvinylpyrrolidone, and, if desired, disintegrators, for example starches, agar, alginic acid or a salt thereof, such as sodium alginate, and/or effervescent mixtures, or adsorbents, dyes, flavourings and sweeteners."

112. The application gave examples to illustrate the invention, making it clear at the same time that those illustrations did not limit the invention in any way. Example 21, which admittedly relates to Imatinib, the "e-duct" for the subject product, is as under:

> "EXAMPLE 21
>
> Analogously to Example 20, N-{5-[4-(4-methyl-piperazinomethyl)-benzoylamido]-2-methylphenyl}-4-(3-pyridyl)-2-pyrimidine-amine is prepared from 10.68 g (32.8 mmol) of 4-(4-methyl-piperazinomethyl)-benzoyl chloride; m.p. 211º-213º, R_f =0.33 (methylene chloride:methanol: 25% aqueous ammonia solution=95:5:1)."

Examples 35 to 37 were in respect of tablets in different doses.

113. In the claim at the end of the application under serial no. 23, it was stated as follows:

> "The compound according to claim 1 of the formula I, said compound being N-{5-[4-(4-Methyl-piperazino-methyl)-benzoylamido]-2-methyl-phenyl}-4-(3-pyridyl)-2-pyrimidine-amine **or a pharmaceutically acceptable salt thereof.**"
>
> **(**emphasis added**)**

114. The US Patent No. 5,521,184 (the Zimmermann patent) was granted on May 28, 1996.

115. Later, the appellant made the application for patent for beta crystalline form of Imatinib Mesylate (the subject of the present appeals) in the US on January 18, 2000. The US patent for beta crystalline form of Imatinib Mesylate was granted to the appellant about five and a half years later on May 17, 2005 following the order of the US Appellate Court dated November 23, 2003. It is, however, interesting to note that Gleevec, the drug was launched much earlier in the market, on the basis of the Zimmermann patent itself.

116. On April 9, 1998, the appellant filed the Investigational New Drug Application (IND # 55,666) for Gleevec and on February 27, 2001, the original New Drug Application (NDA # 21-335) before the Food and Drug Administration (FDA), USA, for Imatinib Mesylate, formerly STI571, CGP57148B (capsules) for the treatment of patients with Chronic Myeloid Leukemia. The application contained results of extensive preclinical, technical and clinical research, and it stated as under:

> "The clinical studies discussed in this NDA include one multiple dose tolerability/dose-finding study (phase I) and three large open, uncontrolled efficacy and safety studies (phase II), as an accelerated development to allow early registration in CML patients. A total of 1234 patients with CML and other Ph+ leukemias have been enrolled in these trials. The results of the Glivec studies are discussed in the perspective of the current state of knowledge in the treatment of CML as described with a comprehensive review of the literature for each target population (Appendix 4-6 of the Integrated Summary of Efficacy)."

117. In the patent information furnished in connection with the NDA as required under (US Code) 21 C.F.R. § 314.53, the active ingredient of the drug was stated as Imatinib Mesylate. The Drug Substance[1] (active ingredient), Drug Product[2] (composition/formulation) and method of use were declared to be covered by US Patent No. 5,521,184 (i.e. the Zimmermann patent). It was further declared that the United States Patent No. 5,521,184 covered the composition, formulation, and/or method of use of Imatinib Mesylate (STI571).

118. In the chemistry review(s) of the NDA # 21-335 (drug approval for capsules) made on March 27, 2001, there was again a reference to US Patent # 5,521,184 (expiration date – 5/28/2013).

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1 21 Code of Federal Regulations s 314.3: *Drug substance* means an active ingredient that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease or to affect the structure or any function of the human body, but does not include intermediates use in the synthesis of such ingredient.

2 21 Code of Federal Regulations s 314.3: *Drug product* means a finished dosage form, for example, tablet, capsule, or solution, that contains a drug substance, generally, but not necessarily, in association with one or more other ingredients.

119. The FDA approval for the drug Gleevec (Imatinib Mesylate) 50 mg and 100 mg capsules was granted vide Letter dated May 10, 2001.[3] Following this, the drug was commercially launched in the market long before the grant of patent for beta crystalline form of Imatinib Mesylate.

120. In the package insert of Gleevec™ (Imatinib Mesylate capsules) the description of the drug was stated as follows:

> "GLEEVEC™ capsules contain imatinib mesylate equivalent to 100 mg of imatinib free base. Imatinib mesylate is designed chemically as 4-[(4-Methyl-1-piperazinyl)methyl]-N-[4-methyl-3-[[4-(3-pyridinyl)-2-pyrimidinyl]amino]-phenyl]benzamide methanesulfonate…"

121. After the grant of drug approval for Gleevec, on July 3, 2001, the appellant made a Patent Term Extension Application for the Zimmermann patent (US Patent No. 5,521,184) under 35 USC § 156(g)(1)(B), for extending the term of the patent for the time taken in the regulatory review for Gleevec. This application leaves no room for doubt that Imatinib Mesylate, marketed under the name Gleevec, was submitted for drug approval as covered by the Zimmermann patent. In column 4 of the application, it was stated that the sole active ingredient in Gleevec is Imatinib Mesylate. Further, it was stated that Imatinib, or any salt thereof, including Imatinib Mesylate, had not previously been approved for commercial marketing under the Federal Food, Drug and Cosmetic Act prior to the approval of NDA # 21-235. In column 9 of the application, it was stated as under:

> "**(9) <u>Statement Showing How the Claims of the Patent for Which Extension is Sought Cover the Approved Product:</u>**
>
> The operative claims in question are Claims 1-5, 10-13, and 21-23. Each of claims 1-5, 10-13 and 23 claim a compound or compounds which include the approved product, <u>imatinib mesylate</u>. Claim 21 claims a composition containing a compound or compounds which include the approved product, <u>imatinib mesylate</u>. Claim 22

3 Later on the appellant also got the drug approval vide letter dated April 18, 2003 in NDA # 21-588 granting approval to commercially market Gleevec (Imatinib Mesylate) Tablets, 100 mg and 400 mg. Needless to say that in regard to the tablet as well the reference is to the Zimmermann patent.

claims a method of treating tumors in warm-blooded animals with a compound or compounds which include the approved product, imatinib mesylate."

122. The application was accepted and the term of the patent, which was due to expire on May 28, 2013, was extended for the period of 586 days.

123. It is noted above that the appellant had made an application no. 09/463,097 in the USA for grant of patent for beta crystalline form of Imatinib Mesylate. The application was rejected by the examiner and, against the examiner's decision, the appellant preferred an appeal (that is, appeal no. 2003-0919) before the Board of Patent Appeals and Interferences. The Board of Patent Appeals, by its judgment and order dated November 23, 2003, allowed the appellant's appeal and reversed the examiner's decision, rejecting claims 1 through 8, 10, and 13 through 16. Dealing with the examiner's rejection of appellant's claim 14 under 35 USC § 112, the Board of Patent Appeals referred to claims 21 and 22 of the Zimmermann patent. With reference to those claims in the Zimmermann patent, the Board of Patent Appeals observed and held as under:

> "Under the provisions 35 U.S.C. § 282, a patent shall be presumed valid; and each claim of a patent shall be presumed valid independently of the validity of other claims.
>
> Accordingly, claims 21 and 22 of the U.S. Patent No.5,521,184 (the Zimmermann patent), shall be presumed valid. **We may presume, therefore, that claims 21 and 22 are based on an enabling disclosure; and that the specification of the Zimmermann patent teaches any person skilled in the art how to use a compound of formula I, or a pharmaceutically acceptable salt thereof, in a pharmaceutical composition for treating tumours or in a method of treating warm-blooded animals suffering from a tumoral disease. In claim 23, Zimmermann recites imatinib, a specific compound within the scope of formula I, or a pharmaceutically acceptable salt thereof. In light of 35 U.S.C. § 282, therefore, we may presume that the specification of the Zimmermann patent teaches any person skilled in the art how to use imatinib, or a pharmaceutically acceptable salt thereof, in a pharmaceutical composition for treating tumours or in a method of treating warm-blooded animals suffering from a tumoral disease.** On these facts, we disagree that the examiner has set forth adequate reasons or evidence

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> to doubt the objective truth of statements in applicants' specification that an effective amount of the β–crystal form of imatinib mesylate may be administered to a patient as the manipulative step in a method for treating tumour disease in a patient.
>
> The rejection under 35 U.S.C. § 112, first paragraph, is reversed."
>
> (emphasis added)

124. From the above passage from the judgment, it is evident that, according to the Board of Patent Appeals, the Zimmermann patent teaches any person skilled in the art how to use Imatinib, a compound of formula I, or a pharmaceutically acceptable salt thereof, in a pharmaceutical composition for treating tumours or in a method of treating warm-blooded animals suffering from a tumoral disease. However, the Board of Patent Appeals held that the teaching in the Zimmermann patent did not go beyond Imatinib Mesylate and did not extend to beta crystalline form of Imatinib Mesylate, which represented a *manipulative step*[1] in a method of treating tumor disease in a patient.

125. Further, NATCO Pharma Ltd., one of the Objectors to the grant of patent to the appellant in this country, had marketed a drug called VEENAT 100 (capsules) in the UK. A legal notice on behalf of the appellant was given to NATCO Pharma Ltd. on February 13, 2004. The notice stated that the appellant was the proprietor of European patent EP-A-0 564 409 (the Zimmermann patent) and that this patent claimed, among other things, the compound Imatinib and acid addition salts of that compound such as the Mesylate salt. In the notice it was pointed out that NATCO Pharma Ltd. was selling, in the UK market, VEENAT 100 capsules, the active pharmaceutical ingredient of which was Imatinib Mesylate as claimed in the Zimmermann patent. The importation, sale and offer to sell VEENAT 100 capsules in the UK market infringed the Zimmermann patent and NATCO

1 Not an "*inventive step*"! A "*manipulative step*" may or may not be an "*inventive step*", which is the requirement under Indian law.

Pharma Ltd. was therefore warned to immediately cease the importation, sale and promotion of VEENAT 100 capsules and other pharmaceutically substances containing "Imatinib". The matter was finally settled out of court, we are told, at considerable expense to NATCO Pharma Ltd. which of course had to stop marketing its drug VEENAT 100 capsules in the UK.

126. From the above discussion it would be clear that the drug Gleevec directly emanates from the Zimmermann patent and comes to the market for commercial sale. Since the grant of the Zimmermann patent, the appellant has maintained that Gleevec (that is, Imatinib Mesylate) is part of the Zimmermann patent. It obtained drug approval for Gleevec on that basis. It claimed extension of the term of the Zimmermann patent for the period of regulatory review for Gleevec, and it successfully stopped NATCO Pharma Ltd. from marketing its drug in the UK on the basis of the Zimmermann patent. Not only the appellant but the US Board of Patent Appeals, in its judgment granting patent for beta crystalline form of Imatinib Mesylate, proceeded on the basis that though the beta crystal form might not have been covered by the Zimmermann patent, the Zimmermann patent had the teaching for the making of Imatinib Mesylate from Imatinib, and for its use in a pharmacological compositions for treating tumours or in a method of treating warm-blooded animals suffering from a tumoral disease. This finding was recorded by the US Board of Patent Appeals, in the case of the appellant itself, on the very same issue that is now under consideration. The appellant is, therefore, fully bound by the finding and cannot be heard to take any contrary plea.

127. We have looked, so far, at the Zimmermann patent and the developments that have taken place on its basis. We now propose to take a look at certain publications. A journal

called *Cancer Research*, in its issue of January 1996, published an article under the title "Inhibition of the Abl Protein-Tyrosine Kinase in Vitro and in Vivo by a 2-Phenylaminopyrimidine Derivative". This article was authored by several people, including Jürg Zimmermann. In this article there is a detailed discussion about the anti-tumoral properties of Imatinib and its methanesulfonate salt, i.e., Imatinib Mesylate. In the abstract at the beginning of the article, it is stated as under:

> "ABSTRACT
>
> Oncogenic activation of Abl proteins due to structural modifications can occur as a result of viral transduction or chromosomal translocation. The tyrosine protein kinase activity of oncogenic Abl proteins is known to be essential for their transforming activity. Therefore, we have attempted to identify selective inhibitors of the Abl tyrosine protein kinase. **Herein we describe an inhibitor (CGP 57148[1]) of the Abl and platelet-derived growth factor (PDGF) receptor protein-tyrosine kinases from the 2-phenylaminopyrimidine class, which is highly active *in vitro* and *in vivo*.** Submicromolar concentrations of the compound inhibited both v-Abl and PDGF receptor autophosphorylation and PDGF-induced *c-fos* mRNA expression selectively in intact cells. … Furthermore, anchorage-independent growth of *v-abl*- and *v-sis*-transformed BALB/c 3T3 cells was inhibited potently by CGP 57148. When tested *in vivo*, CGP 57148 showed antitumor activity at tolerated doses against tumorigenic *v-abl*- and *v-sis*- transformed BALB/c 3T3 cells. In contrast, CGP 57148 had no antitumor activity when tested using *src*-transformed BALB/c 3T3 cells. These findings suggest that CGP 57148 may have therapeutic potential for the treatment of diseases that involve abnormal cellular proliferation induced by Abl protein-tyrosine kinase deregulation or PDGF receptor activation."
>
> (emphasis added)

128. Under the heading "MATERIALS AND METHODS", it is stated as under:

> "**Materials.** CGP 57148 **and its methane sulfonate salt (CGP 57148B[2])** were synthesized by CIBA Pharmaceuticals Division, as will be described elsewhere. For *in vitro* and cellular assays, a stock concentration of 10 mM CGP 57148 was prepared in Me_2SO and stored at – 20ºC. No significant difference in results could be seen between the two forms of CGP 57148. The form used in *in vitro* experiments is indicated in the text and legends. All *in vivo* experiments were performed using CGP 57148B. …"

1 Imatinib.
2 Imatinib Mesylate.

129. The article goes on to discuss the *in vivo* experiments and the *in vitro* selectivity of CGP 57148 for inhibition of protein kinases: Identification of CGP 57148 as an inhibitor of v-Abl kinase. The article also discussed the *in vivo* anti-tumour activity of CGP 57148B and it states as follows:

> "***In Vivo* Antitumor Activity.**
>
> The maximally tolerated dose for a single p.o. or i.p. administration of CGP 57148B in BALB/c mice was >500 mg/kg. BALB/c AMuLV and BALB/c 3T3 v–*sis* cells, which were sensitive in the colony-forming assay, were used to test CGP 57148B for antitumor activity in female BALB/c nude mice. Once daily i.p. applications of 50, 12.5, or 3.13 mg/kg CGP 57148B given for 30 consecutive days resulted in a strong antitumor effect against AMuLV-transformed BALB/c 3T3 tumors (Fig. 5A). Similarly, anti-tumor experiments using v–*sis*- transformed BALB/c 3T3 cells revealed dose-dependent antitumor activity (Fig. 5B). Maximal T/C (X100%) values of 4% (AMuLV tumors) and 11% (v–*sis* tumors) were obtained when CGP 57148B was administered at 50mg/kg body weight. In contrast, CGP 57148B showed no antitumor activity against tumors derived from NIH-527*src* cells when 50 mg/kg were administered p.o. once daily for 30 days (T/C, 102%). Using the same route of application, T/C values of 7 and 22% against AMuLV and v–*sis* tumors, respectively, were obtained when 50 mg/kg CGP 57148B were given."

It is further stated in the article:

> "CGP 57148 selectively inhibited the *in vitro* activity of the v-Abl protein-tyrosine kinase and showed preferential inhibition of v-Abl autophosphorylation in cells. We have examined the specificity of CGP 57148 by analyzing its effects on signal transduction via different tyrosine kinase receptor-mediated pathways. Although the ligand-induced activation of the EGF, bFGF, insulin, and IGF-1 receptor tyrosine kinases were not affected by CGP 57148, the PDGF pathway was sensitive to inhibition by the compound. The antiproliferative activity of CGP 57148 against both v-*abl*- and v-*sis*-transformed BALB/c 3T3 support the selectivity profile of CGP 57148 further."

The article concludes by observing as follows:

> "The reported findings with CGP 57148 suggest that it may be a development candidate for use in the treatment of Philadelphia chromosome-positive leukemias. Additional potential applications for CGP 57148 may include proliferative diseases that involve abnormal PDGF receptor activation."

130. Another article was published in *Nature Medicine* magazine of the year 1996 under

the title "Effects of a selective inhibitor of the Abl tyrosine kinase on the growth of Bcr-Abl positive cells". This article, too, was authored by several people, including Jürg Zimmermann. In this article also, there is a discussion about Imatinib as a compound designed to inhibit Abl protein tyrosine kinase.

131. In the face of the materials referred to above, we are completely unable to see how Imatinib Mesylate can be said to be a new product, having come into being through an "invention" that has a feature that involves technical advance over the existing knowledge and that would make the invention not obvious to a person skilled in the art. Imatinib Mesylate is all there in the Zimmermann patent. It is a known substance from the Zimmermann patent.

132. That Imatinib Mesylate is fully part of the Zimmermann patent is also borne out from another circumstance. It may be noted that after the Zimmermann patent, the appellant applied for, and in several cases obtained, patent in the US not only for the beta and alpha crystalline forms of Imatinib Mesylate, but also for Imatinib in a number of different forms. The appellant, however, never asked for any patent for Imatinib Mesylate in non-crystalline form, for the simple reason that it had always maintained that Imatinib Mesylate is fully a part of the Zimmermann patent and does not call for any separate patent.

133. We thus find no force in the submission that the development of Imatinib Mesylate from Imatinib is outside the Zimmermann patent and constitutes an invention as understood in the law of patent in India.

134. Mr. Andhyarujina and Mr. Gopal Subramanium, learned Senior Advocates appearing for the appellant, strenuously argued that the patent information furnished by the

appellant before the US FDA, or its Patent Term Extension Application, or the legal notice given at its behest to NATCO Pharma Ltd. should not be construed to mean that Imatinib Mesylate was anticipated in the Zimmermann patent. Mr. Andhyarujina submitted that the Zimmermann patent did not disclose Imatinib Mesylate. The Zimmermann patent did not describe any working method for converting Imatinib to Imatinib Mesylate. It only stated that a salt may be formed by acid without disclosing any method, but simply calling the method to be "*per se*". The Zimmermann patent mentioned multiple choices of compounds including Imatinib free base but not any salt of any compound, much less Imatinib Mesylate. Mr. Andhyarujina further submitted that it is well settled that the disclosure of an invention must be in a manner clear enough and complete enough for the invention to be performed by a person skilled in the art (Terrell on Law of Patents 16th edition, page no. 51, para 3.2/7). The learned counsel further submitted that there was a difference between that which is *covered* and that which is *disclosed*. Imatinib Mesylate is *covered* by the Zimmermann patent but not *disclosed* therein. He further submitted that, in any case, in patent law subsequent conduct of the patentee is irrelevant in construing the patent (Terrell on Law of Patent 16th edition, page no. 192 citing *Glaverbel vs. British* (1993) RPC 80). Referring to the two articles in *Cancer Research* and *Nature Medicine*, Mr. Andhyarujina submitted that though in the first article there was a reference to Imatinib Mesylate, there was no teaching as to how it is to be prepared. In the *Nature Medicine* article there was no reference to Imatinib Mesylate but only to Imatinib.

135. Mr. Gopal Subramanium submitted that the Zimmermann patent is a patent for "Pyrimidine Derivatives and Processes for the Preparation thereof". The patent is related to a genus of compounds, and each of the compounds within the genus shares a common

chemical structure (Markush structure) and common properties with respect to the inhibition of certain tyrosine kinases (there being a total of 518 kinases in existence). Mr. Subramanium further submitted that the appellant in its application before the US Food and Drug Administration Authority had made a reasonable assertion that the Zimmermann patent *covers* the product that was made out of the beta crystalline form of Imatinib Mesylate, i.e., Gleevec[1]. Further, on the basis of the US FDA approval, the appellant obtained an extension of the period of protection under the Zimmermann patent with respect to Gleevec.

136. Mr. Subramanium further submitted that the scope of *coverage* is distinct from the scope of *disclosure* in a patent. Imatinib Mesylate could be said to be not new and known from the Zimmermann patent only in case there was a complete *disclosure* of the method of its preparation in the Zimmermann patent. The learned counsel strongly contended that *coverage* under a patent of the Markush kind cannot lead to any presumption of *disclosure*, much less any *enabling disclosure* of all the compounds within the genus. The learned counsel further contended that *coverage* that is granted in respect of a patent is not always coextensive with what is *disclosed* in that patent. In certain circumstances, where it is a pioneering invention (as in the case of the Zimmermann invention), the patent may be entitled to larger *coverage* than what is specifically *disclosed* in it. The learned counsel argued that *coverage* cannot be used to presume an *enabling disclosure* of the beta crystalline form of Imatinib Mesylate in the Zimmermann patent. *Disclosure* in a specification can never be presumed, and that is a question of the clear teaching contained in the specification. The teaching of a patent lies in the *disclosure*/*specification* that

1 There is a factual error in the submission in as much as in the Drug Approval application before the US FDA the drug Gleevec is represented as Imatinib Mesylate. Before the US FDA there is no reference to the beta crystalline form of Imatinib Mesylate.

supports the claim. The *disclosure* describes the invention. The claim defines through language the various ways the invention could be used, i.e., possible but not actualized products. This is the scope of protection granted under the patent. For the purpose of *prior art*, it is the *disclosure* in the *specification* supporting the claim and not the written description or the claims themselves, that must be assessed. The claim can never be the teaching. He further contended that it would be wrong to say that the appellant's claims for beta crystalline form of Imatinib Mesylate is a case of double or repeat patenting, that is, the same invention is being sought to be patented twice. The claim for patent for beta crystalline form of Imatinib Mesylate relates to a second and different invention. Though the invention in the first part (Imatinib) may be necessary to arrive at the invention in the second part, the final product does not come into existence without inventions. The principle is that if a product is *covered*, it means that it infringes a patent. Whether the patent infringed disclosed every aspect of the product in its specification is a separate inquiry.

137. Mr. Subramanium maintained that the boundary of the Zimmermann patent was extended up to Imatinib Mesylate but the enablement or disclosure made therein ended at Imatinib. He submitted that it was possible for Zimmermann himself, or for anyone else, to invent Imatinib Mesylate starting from Imatinib. The inventor of Imatinib Mesylate, be it Zimmermann or anyone else, would also be entitled to get patent for Imatinib Mesylate, but in case the inventor was anyone other than Zimmermann, he would require Zimmermann's permission for marketing Imatinib Mesylate, since Imatinib had the protection of the Zimmermann patent[1].

138. The submissions of Mr. Andhyarujina and Mr. Subramanium are based on making a

1 Blocking Patents!

distinction between the *coverage* or claim in a patent and the *disclosure* made therein. The submissions on behalf of the appellant can be summed up by saying that the boundary laid out by the claim for *coverage* is permissible to be much wider than the *disclosure*/*enablement*/*teaching* in a patent.

139. The dichotomy that is sought to be drawn between *coverage* or claim on the one hand and *disclosure* or *enablement* or *teaching* in a patent on the other hand, seems to strike at the very root of the rationale of the law of patent. Under the scheme of patent, a monopoly is granted to a private individual in exchange of the invention being made public so that, at the end of the patent term, the invention may belong to the people at large who may be benefited by it. To say that the *coverage* in a patent might go much beyond the *disclosure* thus seem to negate the fundamental rule underlying the grant of patents.

140. In India, section 10(4) of the Patents Act, 1970 mandates:

> "**Section 10. Contents of specifications.–** (4) Every Complete specification shall –
>
> (a) fully and particularly describe the invention and its operation or use and the method by which it is to be performed;
>
> (b) disclose the best method of performing the invention which is known to the applicant and for which he is entitled to claim protection; and
>
> (c) end with a claim or claims defining the scope of the invention for which protection is claimed;
>
> (d) be accompanied by an abstract to provide technical information on the invention:
>
> Provided that –
>
> (i) the Controller may amend the abstract for providing better information to third parties; …"

And, section 10(5) provides as under:

> "(5) The claim or claims of a complete specification shall relate to a single invention, or to a group of inventions linked so as to form a single inventive concept, shall be clear and succinct and shall be fairly based on the matter disclosed in the specification."

141. The UK Patents Act, 1977, in sub-sections (2), (3), and (5) of section 14, provides as under:

> "**Making of an application**
>
> 14. – (2) Every application for a patent shall contain –
>
> (a) a request for the grant of a patent;
>
> (b) a specification containing a description of the invention, a claim or claims and any drawing referred to in the description or any claim; and
>
> (c) an abstract;
>
> but the foregoing provision shall not prevent an application being initiated by documents complying with section 15(1) below.
>
> (3) The specification of an application shall disclose the invention in a manner which is clear enough and complete enough for the invention to be performed by a person skilled in the art.
>
> (5) The claim or claims shall –
>
> (a) define the matter for which the applicant seeks protection;
>
> (b) be clear and concise;
>
> (c) be supported by the description; and
>
> (d) relate to one invention or to a group of inventions which are so linked as to form a single inventive concept."

142. Further, section 112(a) of the Title 35 of US Code provides as under:

> "**35 U.S.C. § 112**[1]
>
> (a) IN GENERAL.– The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor or joint inventor of carrying out the invention."

143. Terrell on the *Law of Patents* (Seventeenth Edition, 2011) in Chapter 9: "Construction of the Specification and Claims", under the heading "Principles equally applicable to infringement and validity" states:

1 Recall that it is on the basis of this provision that the U.S. Board of Patent Appeals had held in the case regarding the appellant's claim for patent for beta crystalline form of Imatinib Mesylate that "in light of 35 U.S.C. § 282, therefore, we may presume that the specification of the Zimmermann patent teaches any person skilled in the art how to use Imatinib, or a pharmaceutically acceptable salt thereof,…".

"9.05 – Section 125(1) defines an "invention" as (unless the context otherwise requires) that specified in a claim of the specification, and both validity (see sections 1 to 4 and 72 of the Act) and infringement (see section 60) are to be tested by reference to the "invention". It is, of course, a fundamental principle that the construction of a claim is the same whether validity or infringement is to be considered; **no patentee is entitled to the luxury of an "elastic" claim which has a narrow meaning in the former case but a wide meaning in the latter.** Under English procedure, infringement and validity are normally litigated at the same time and therefore the court is astute to avoid such a result. …"

(emphasis added)

144. Chisum on *Patents: A Treatise on the Law of Patentability, Validity, and Infringement* (Vol. 3, June 2007) in Chapter: "Adequate Disclosure" notes:

"**§ 7.03 – The Enablement Requirement**

Since 1790, the patent laws have required that the inventor set forth in a patent specification sufficient information to enable a person skilled in the relevant art to make and use the invention.

The "invention" that must be enabled is that defined by the particular claim or claims of the patent or patent application. This is consistent with the general principle of patent law that the claim defines the invention for purposes of both patentability and infringement."

145. Nevertheless, both Mr. Andhyarujina and Mr. Subramanium strenuously argued that the *coverage* or the claim, and the *disclosure* or the teaching, have different parameters in a patent, and that the former may have an extended boundary within which *disclosure* or teaching may be confined to a narrower extent. In support of the submission, Mr. Andhyarujina relied upon a decision of the Court of Appeal in *A.C. Edwards Ltd. v. Acme Signs & Displays Ltd.*[1] and another of the High Court of Justice Chancery Divisions Patent Court in *Astellas Pharma Inc v. Comptroller-General of Patents*[2].

146. Mr. Gopal Subramanium strongly relied upon the decision of United States Court of

1 [1992] R.P.C. 131
2 [2009] EWHC 1916 (Pat)

Customs and Patent Appeals in *In re Hogan*[1] in support of his contention.

147. In *Hogan*, the Court of Customs and Patent Appeals held that a patent application that disclosed and enabled a method of making the crystalline form of polymer was entitled to a claim for the method of making a solid polymer, because the only known method for making a solid polymer at the time was the applicants' method of making the crystalline form.

148. The Hogan decision was rendered in a jurisdiction that has the historical background of Blocking Patents. Further, *Hogan* that relates to the saga of acrimonious litigation over the claim of priority of invention for crystalline polypropylene among five competing companies was a rather unusual decision even in the US.

149. In *Hogan*,[2] the Court of Custom and Patent Appeals had before it an appeal from the decision of the Board of Appeals, affirming the rejections by the Patent and Trademark Office (PTO) of the applicant's claims 13-15 for "Solid Polymers of Olefins" under 35 USC § 102, 103, 112 (first paragraph) and 132.

150. The application, though filed in 1971, was in continuation of the first application filed on January 27, 1953. One of the main issues involved in the case was whether a "later state of the art" could be taken as evidence to support a rejection of the patent claim.

151. Among the reasons given by the Board for rejecting the claim of the applicant was that the disclosure in the original 1953 Hogan and Banks' application was not enabling, because the disclosure was limited to making crystalline polymers. But the claims which the Board rejected included an amorphous polymer as well, which was manifestly outside the scope of the enabling teaching present in the case. The Court of Customs and Patent

1 559 F.2d 595

2 The following discussion on the *Hogan* decision is partially based on the article "Allocating Patent Rights Between Earlier and Later Inventions" by Charles W Adams, Professor of Law at the University of Tulsa College of Law, published in the *Saint Louis University Law Journal* (Vol. 54-55, 2009, pp 56-112).

Appeals reversed the decision of the Board of Patent Appeals, observing and holding as under:

> "The PTO has not challenged appellants' assertion that their 1953 application enabled those skilled in the art in 1953 to make and use "a solid polymer" as described in claim 13. Appellants disclosed, as the only then existing way to make such a polymer, a method of making the crystalline form. To now say that appellants should have disclosed in 1953 the amorphous form which on this record did not exist until 1962, would be to impose an impossible burden on inventors and thus on the patent system. There cannot, in an effective patent system, be such a burden placed on the right to broad claims, To restrict appellants to the crystalline form disclosed, under such circumstances, would be a poor way to stimulate invention, and particularly to encourage its early disclosure. To demand such restriction is merely to state a policy against broad protection for pioneer inventions, a policy both shortsighted and unsound from the standpoint of promoting progress in the useful arts, the constitutional purpose of the patent laws."

152. The Court seems to have taken the view that the amorphous form did not exist at the time of the patent application and therefore, that the patentee could not have been expected to claim the amorphous form at that time. The Court further took the view that the broad claim for a solid polymer would satisfy the enablement requirement under the state of the art, as that was known at the time of the filling of the patent application, because the amorphous form was not known at that time. The Court observed:

> "Consideration of a later existing state of the art in testing for compliance with § 112, first paragraph, would not only preclude the grant of broad claims, but would wreak havoc in other ways as well. The use of a subsequently-existing improvement to show lack of enablement in an earlier-filed application on the basic invention would preclude issuance of a patent to the inventor of the thing improved, and in the case of issued patents, would invalidate all claims (even some "picture claims") therein. Patents are and should be granted to later inventors upon unobvious improvements. Indeed, encouragement of improvements on prior inventions is a major contribution of the patent system and the vast majority of patents are issued on improvements. It is quite another thing, however, to utilize the patenting or publication of later existing improvements to "reach back" and preclude or invalidate a patent on the underlying invention."

153. The polypropylene case in the US gave rise to an extraordinary legal precedent for the enablement requirement, according to which a patentee is free to claim a genus that includes unknown species that may be discovered in the future, if the specification describes and enables all the species that are known at the time of filing the patent application. The rationale on which the decision is based is described by Professors Merges and Duffy as the "*temporal paradox*"[1]. The professors explain that, approached in this way, the description and enablement requirements for the genus are determined as of the date of filling the patent, and the patentee gets the benefit of any addition to the genus discovered later.

154. It needs to be noted here that even in the US, *Hogan* represents a decision given in the context of the special set of facts and circumstances of the litigation over polypropylene. In later decisions, the Federal Circuit appears to have drastically narrowed *Hogan's* scope as a precedent. In *Plant Genetics System, N.V. v. DeKalb Genetics Corp*,[2] the effect of Hogan was considerably constricted and its effect is virtually eliminated in *Chiron Corp. v. Genentech, Inc*[3]. Since *Chiron*, the Federal Circuit has not referred to *Hogan* in any of its cases that involve claims to a genus where a single species was enabled.

155. Mr. Subramanium refers to the *Hogan* decision in order to support his contention that the Zimmermann patent is a patent covering a genus with certain known species, and many other species that were unknown at that time, but which are equally covered by the patent, even though there is no enabling disclosure in the patent in respect thereof. But it is

1 Apart from the Hogan Decision, Mr. Subramanium also relied upon the relevant passage under the heading "Enablement and the Temporal Paradox" from the book "Patent Law and Policy: Cases and Materials" (Fifth Edition) by Robert Patrick Merges and John Fitzgerald Duffy…at pg. 298- 300

2 315 F. 3d 1335, 1341 (Fed. Cir. 2003)

3 363 F. 3d 1247, 1257 (Fed. Cir. 2004)

already found and held earlier that Imatinib Mesylate is a known substance from the Zimmermann patent. The finding that Imatinib Mesylate is a known substance from the Zimmermann patent is not based on the conduct of the appellant alone, as objected to by Mr. Andhyarujina, but the finding has been arrived at on an objective consideration of all the material facts and circumstances. In view of that finding, we fail to see any application of the *Hogan* decision to the facts of the case. We have also considered the two decisions relied upon by Mr. Andhyarujina. Those two decisions also have no application to the facts of the present case, for the same reason as in case of *Hogan*.

156. However, before leaving *Hogan* and proceeding further, we would like to say that in this country the law of patent, after the introduction of product patent for all kinds of substances in the patent regime, is in its infancy. We certainly do not wish the law of patent in this country to develop on lines where there may be a vast gap between the *coverage* and the *disclosure* under the patent; where the scope of the patent is determined not on the intrinsic worth of the invention but by the artful drafting of its *claims* by skillful lawyers, and where patents are traded as a commodity not for production and marketing of the patented products but to search for someone who may be sued for infringement of the patent.

157. In light of the discussions made above, we firmly reject the appellant's case that Imatinib Mesylate is a new product and the outcome of an invention beyond the Zimmermann patent. We hold and find that Imatinib Mesylate is a known substance from the Zimmermann patent itself. Not only is Imatinib Mesylate known as a substance in the Zimmermann patent, but its pharmacological properties are also known in the Zimmermann patent and in the article published in the *Cancer Research* journal referred to

above. The consequential finding, therefore, is that Imatinib Mesylate does not qualify the test of "invention" as laid down in section 2(1)(j) and section 2(1)(ja) of the Patents Act, 1970.

158. This leaves us with the beta crystal form of Imatinib Mesylate, which, for the sake of argument, may be accepted to be new, in the sense that it is not known from the Zimmermann patent. (Whether or not it involves an "inventive step" is another matter, and there is no need to go into that aspect of the matter now). Now, the beta crystalline form of Imatinib Mesylate being a pharmaceutical substance and moreover a polymorph of Imatinib Mesylate, it directly runs into section 3(d) of the Act with the explanation appended to the provision. Mr. Subramanium, however, contended that section 3(d) has no application in this case. The main ground on which he denied the applicability of section 3(d) to decide the question of grant of patent to the beta crystalline form of the Imatinib Mesylate is earlier held to be untenable. He, however, questioned the applicability of section 3(d) on another ground. Mr. Subramanium submitted that in order to attract section 3(d), the subject product must be a new form of a *known* substance having *known* efficacy. The learned counsel laid some stress on the expression "known" that equally qualifies the substance of which the subject product may be another form, and the efficacy of that substance. The learned counsel submitted that a "conceivable" substance is not a "known substance" within the meaning of the provision. He contended that the word "known" here connotes proven and well-established; "known efficacy" implies efficacy established empirically and proven beyond doubt. He further contended that neither Imatinib nor Imatinib Mesylate had any known efficacy and that, therefore, there was no question of showing that the beta crystalline form of Imatinib Mesylate had any enhanced efficacy

over Imatinib or Imatinib Mesylate.

159. There is no sanction to construe the expression "known" in section 3(d) in the manner suggested by Mr. Subramanium, and the submission is unacceptable both in law and on facts. It may be noted here that clauses (e) and (f) of section 64(1) of the Act, which contain two of the grounds for revocation of patents, also use the expression "publicly known". The expression "publicly known" may normally be construed more widely than "known", and in that sense it is closer to the submission made by Mr. Subramanium. But even the expression "publicly known" received quite the opposite interpretation by this Court in *Monsanto Company v. Coramandal Indag Products (P) Ltd*.[1] In paragraph 6 of the judgment, Justice Chinnappa Reddy, speaking for the Court, held and observed as under:

> "…To satisfy the requirement of being publicly known as used in clauses (e) and (f) of Section 64(1), it is not necessary that it should be widely used to the knowledge of the consumer public. It is sufficient if it is known to the persons who are engaged in the pursuit of knowledge of the patented product or process either as men of science or men of commerce or consumers. The section of the public, who, as men of science or men of commerce, were interested in knowing about Herbicides which would destroy weeds but not rice, must have been aware of the discovery of Butachlor. There was no secret about the active agent Butachlor as claimed by the plaintiffs since there was no patent for Butachlor, as admitted by the plaintiffs. Emulsification was the well-known and common process by which any herbicide could be used. Neither Butachlor nor the process of emulsification was capable of being claimed by the plaintiff as their exclusive property. The solvent and the emulsifier were not secrets and they were admittedly not secrets and they were ordinary market products. From the beginning to the end, there was no secret and there was no invention by the plaintiffs. The ingredients, the active ingredients the solvent and the emulsifier, were known; the process was known, the product was known and the use was known. The plaintiffs were merely camouflaging a substance whose discovery was known through out the world and trying to enfold it in their specification relating to Patent Number 125381. The patent is, therefore, liable to be revoked. …"

1 (1986) 1 SCC 642

160. On facts also we are unable to accept that Imatinib Mesylate or even Imatinib was not a known substance with known efficacy. It is seen above that Imatinib Mesylate was a known substance from the Zimmermann patent. In the NDA submitted by the appellant before the US FDA, it was clearly stated that the drug had undergone extensive preclinical, technical and clinical research. The clinical studies included one multiple dose tolerability/dose-finding study (Phase I) and three large open, uncontrolled efficacy and safety studies (Phase II); and a total of 1,234 patients with CML and other Ph+ leukemias were enrolled in the studies. The efficacy of Imatinib was equally known, as is evident from the Zimmermann patent itself, besides the two articles referred to above.

161. The subject product, that is, beta crystalline form of Imatinib Mesylate, is thus clearly a new form of a known substance, i.e., Imatinib Mesylate, of which the efficacy was well known. It, therefore, fully attracts section 3(d) and must be shown to satisfy the substantive provision and the explanation appended to it.

162. We now proceed to examine how far the beta crystalline form of Imatinib Mesylate stands up to the test of section 3(d) of the Act. It is noted, in the earlier part of judgment, that the patent application submitted by the appellant contains a clear and unambiguous averment that all the therapeutic qualities of beta crystalline form of Imatinib Mesylate are also possessed by Imatinib in free base. The relevant extract from the patent application is once again reproduced here:

> "It goes without saying that **all the indicated inhibitory and pharmacological effects are also found with the free base**, 4-(4-methylpiperazin-1-ylmethyl)-N-[4-methyl-3-(4-pyridin-3-yl) pyrimidin-2-ylamino)phenyl] benzamide, **or other cells thereof**. The present invention relates especially to the β–crystal form of the methanesulfonic acid addition salt of a compound of formula I in the treatment of one of the said diseases or in the preparation of a pharmacological agent for the treatment thereto."
>
> (emphasis added)

163. Now, when all the pharmacological properties of beta crystalline form of Imatinib Mesylate are equally possessed by Imatinib in free base form or its salt, where is the question of the subject product having any enhanced efficacy over the known substance of which it is a new form?

164. It may also be stated here that while going through the Zimmermann patent one cannot but feel that it relates to some very serious, important and valuable researches. The subject patent application, on the other hand, appears to be a loosely assembled, cut-and-paste job, drawing heavily upon the Zimmermann patent. As a matter of fact, Mr. Kuhad, learned Additional Solicitor General, submitted before us a tabular chart showing over a dozen statements and averments made in the subject application that are either lifted from the Zimmermann patent or are very similar to corresponding statements in the Zimmermann patent. The aforesaid chart is appended at the end of the judgment as Appendix II.

165. It further needs to be noted that, on the issue of section 3(d), there appears to be a major weakness in the case of the appellant. There is no clarity at all as to what is the substance immediately preceding the subject product, the beta crystalline form of Imatinib Mesylate. In course of the hearing, the counsel appearing for the appellant greatly stressed that, in terms of invention, the beta crystalline form of Imatinib Mesylate is two stages removed from Imatinib in free base form. The same is said in the written notes of submissions filed on behalf of the appellant. But this position is not reflected in the subject application, in which all the references are only to Imatinib in free base form (or to the alpha crystalline form of Imatinib Mesylate in respect of flow properties, thermodynamic stability and lower hygroscopicity). On going through the subject application, the

impression one gets is that the beta crystalline form of Imatinib Mesylate is derived directly from Imatinib free base. This may, perhaps, be because once the beta crystalline form of the methanesulfonic acid salt of Imatinib came into being, the Imatinib free base got seeded with the nuclei of Imatinib Mesylate beta crystalline form and, as a result, starting from Imatinib one would inevitably arrive directly at the beta crystalline form of Imatinib Mesylate. But all this is nowhere said in the subject application.

166. Apart from the subject application, the appellant filed four affidavits before the Controller. Two of the affidavits are meant to explain and refute the results of the experiments conducted by the IICT at the instance of one of the objectors, NATCO Pharma Ltd. But the other two, one by Paul William Manley, dated July 22, 2005, and the other by Giorgio Pietro Massimini, dated __September 2005, were filed to meet the requirements of section 3(d), which was amended while the application lay in the "mailbox".

167. Massimini, in paragraph 8 of the affidavit, explained that it was being filed to meet the conditions under section 3(d) of the Act. He stated that the proviso to section 3(d) was unique to India and there was no analogous provision in any other country of the world. The appellant was, therefore, never called upon to satisfy the tests laid down in section 3(d) of the Act to establish the patentability of the patent subject. He further stated that since no occasion to do so had arisen earlier, no study relating to the efficacy of the free base was carried out in the past. Upon coming to know the requirement of section 3(d), the deponent, asked by the appellant, immediately commenced such a study, ensuring that accuracy and universally accepted scientific and ethical guidelines were not sacrificed.

168. Manley, in paragraph 8 of his affidavit, stated:

"The **physical properties** of the Free Base and imatinib mesylate differ in that the Free Base is only very slightly soluble in water (0.001 g/100 ml) while imatinib mesylate is very soluble in water (beta crystalline form: 130 g/100 ml). Other physical characteristics of the subject compound are described at pages 2 – 3 of the specification. The attendant advantages because of these properties are also simultaneously described therein. These characteristics and hence the attendant properties/advantages are not shared by the Free Base. Furthermore, the Beta form significantly differs from the alpha form:

***Physical attributes*:**

(a) The beta crystal form has substantially more beneficial flow properties and thus results in better processability than the alpha crystal form.

(b) The beta-crystal form of the methanesulfonic acid addition salt is the thermodynamically more stable form at room temperature. Greater stability is thus to be expected.

(c) The beta-crystal form is less hygroscopic than the alpha-crystal form of the methanesulfonic acid addition salt of a compound of formula I.

(d) The lower hygroscopicity is a further advantage for processing and storing the acid addition salt in the beta-crystal form."

(emphasis added)

169. Massimini, in paragraph 9 of his affidavit stated:

"A study conducted in rats provided statistical evidence for a difference in the relative bioavailability of the Free Base and Imatinib mesylate in the beta crystalline form. In such study, a mean AUC (0-48h) value of 264.000 h*ng/mL was found for the Free Base compared with a mean AUC (0-48h) value of 344000 h*ng/mL for Imatinib mesylate having the beta crystal form. In other words, an about 30% improvement in bioavailability was observed for the beta crystalline for of Imatinib mesylate compared to the Free Base. The test results are attached herewith as Annexure "A"."

170. It is to be noted that the higher solubility of the beta crystalline form of Imatinib Mesylate is being compared not to Imatinib Mesylate but, once again, to Imatinib in free base form. The whole case of the appellant, as made out in the subject application and the affidavits, is that the subject product, the beta crystalline form of Imatinib Mesylate, is derived from Imatinib, and that the substance immediately preceding the beta crystalline form is not Imatinib Mesylate but Imatinib in free base form. This position is sought to be

canvassed in the subject application and the affidavits on the premise that the Zimmermann patent ended at Imatinib in free base and did not go beyond to Imatinib Mesylate. Not only is this premise unfounded as shown earlier, but the appellant itself appears to take a somewhat different stand, as before this Court it was contended that the subject product, in terms of invention, is two stages removed from Imatinib in free base, and the substance immediately preceding the subject product is Imatinib Mesylate (non-crystalline).

171. That being the position, the appellant was obliged to show the enhanced efficacy of the beta crystalline form of Imatinib Mesylate over Imatinib Mesylate (non-crystalline). There is, however, no material in the subject application or in the supporting affidavits to make any comparison of efficacy, or even solubility, between the beta crystalline form of Imatinib Mesylate and Imatinib Mesylate (non-crystalline).

172. As regards the averments made in the two affidavits, for all one knows the higher solubility that is attributed to the beta crystalline form of Imatinib Mesylate may actually be a property of Imatinib Mesylate itself. One does not have to be an expert in chemistry to know that salts normally have much better solubility than compounds in free base form. If that be so, the additional properties that may be attributed to the beta crystalline form of Imatinib Mesylate would be limited to the following:

i. More beneficial flow properties,

ii. Better thermodynamic stability, and

iii. Lower hygroscopicity

173. The aforesaid properties, ("physical attributes" according to Manley), would give the subject product improved processability and better and longer storability but, as we shall see presently, on the basis of those properties alone, the beta crystalline form of Imatinib

Mesylate certainly cannot be said to possess enhanced *efficacy* over Imatinib Mesylate, the known substance immediately preceding it, within the meaning of section 3(d) of the Act.

174. We have so far considered the issue of enhanced efficacy of the subject product in light of the finding recorded earlier in this Judgment that Imatinib Mesylate (non-crystalline) is a known substance from the Zimmermann patent and is also the substance immediately preceding the patent product, that is, Imatinib Mesylate in beta crystalline form.

175. Let us now consider the case of the appellant as made out in the subject application and the supporting affidavits, and examine the issue of enhanced efficacy of the beta crystalline form of Imatinib Mesylate vis-à-vis Imatinib in free base form. It is seen above that all the pharmacological effects of Imatinib Mesylate in beta crystalline form are equally possessed by Imatinib in free base form. The position is not only admitted but repeatedly reiterated in the patent application. Mr. Subramanium, with his usual fairness and candour, explained the position by stating that Imatinib free base is *actually* the active therapeutic ingredient, but in free base form Imatinib has very little or no solubility. It is, therefore, not capable of being administered as a drug to human beings. In the words of Mr. Subramanium, if given in solid dosage form, Imatinib free base would sit in the stomach like a brick and would pass out with no therapeutic effect. The invention of methanesulfonic acid addition salt of Imatinib makes the therapeutic ingredient (that continues to be the same) highly soluble, and therefore very suitable for being administered as a drug to humans. The further invention of the beta crystalline form of Imatinib Mesylate adds to its properties and makes it an even better drug than Imatinib Mesylate. The subject product, that is, the beta crystalline form of Imatinib Mesylate, thus

demonstrates a definite and tangible enhancement of efficacy over Imatinib in free base form.

176. The way in which the case is presented by Mr. Subramanium is an entirely new case made before this Court for the first time. Nevertheless, let us consider the case of the appellant as presented by Mr. Subramanium.

177. The portion added in section 3(d) by the 2005 amendment reads as under:

> The mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance… [is not inventions within the meaning of the Act].

178. The *Explanation* to section 3(d) also added by the 2005 amendment provides as under:

> "*Explanation.*—For the purposes of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy."

179. It may be seen that the word "efficacy" is used both in the text added to the substantive provision as also in the explanation added to the provision.

180. What is "efficacy"? Efficacy means[1] "the ability to produce a desired or intended result". Hence, the test of efficacy in the context of section 3(d) would be different, depending upon the result the product under consideration is desired or intended to produce. In other words, the test of efficacy would depend upon the function, utility or the purpose of the product under consideration. Therefore, in the case of a medicine that claims to cure a disease, the test of efficacy can only be "therapeutic efficacy". The question then arises, what would be the parameter of therapeutic efficacy and what are the

1 The New Oxford Dictionary of English, Edition 1998.

advantages and benefits that may be taken into account for determining the enhancement of therapeutic efficacy? With regard to the genesis of section 3(d), and more particularly the circumstances in which section 3(d) was amended to make it even more constrictive than before, we have no doubt that the "therapeutic efficacy" of a medicine must be judged strictly and narrowly. Our inference that the test of enhanced efficacy in case of chemical substances, especially medicine, should receive a narrow and strict interpretation is based not only on external factors but there are sufficient internal evidence that leads to the same view. It may be noted that the text added to section 3(d) by the 2005 amendment lays down the condition of "enhancement of the known efficacy". Further, the explanation requires the derivative to "differ significantly in properties **with regard to efficacy**". What is evident, therefore, is that not all advantageous or beneficial properties are relevant, but only such properties that directly relate to efficacy, which in case of medicine, as seen above, is its therapeutic efficacy.

181. While dealing with the explanation it must also be kept in mind that each of the different forms mentioned in the explanation have some properties inherent to that form, e. g., solubility to a salt and hygroscopicity to a polymorph. These forms, unless they differ significantly in property with regard to efficacy, are expressly excluded from the definition of "invention". Hence, the mere change of form with properties inherent to that form would not qualify as "enhancement of efficacy" of a known substance. In other words, the explanation is meant to indicate what is not to be considered as therapeutic efficacy.

182. We have just noted that the test of enhanced therapeutic efficacy must be applied strictly, but the question needs to be considered with greater precision. In this connection, we take note of two slightly diverging points of view urged before this Court.

183. Mr. Anand Grover, learned counsel appearing for one of the Objectors, Cancer Patients Aid Association, took a somewhat rigid position. The learned counsel submitted that in the pharmaceutical field, drug action is explained by "pharmacokinetics" (effect of the body on the drug) and "pharmacodynamics" (effect of the drug on the body). He further submitted that efficacy is a pharmacodynamic property, and contended that, in the field of pharmaceuticals, efficacy has a well-known meaning. Efficacy is the capacity of a drug to produce an effect. The IUPAC describes efficacy as "the property that enables drugs to produce responses". It is that property of a drug which produces stimulus. When comparing the efficacy of two substances, efficacy describes "the relative intensity with which agonists vary in the response they produce even when they occupy the same number of receptors". [IUPAC Glossary of Terms used in Medicinal Chemistry, 1998 in CPAA volume 9, at page 7]. In the words of Goodman and Gilman, "the generation of response from the drug receptor complex is governed by a property described as efficacy". They further clarify that "efficacy is that property intrinsic to a particular drug that determines how good an agonist the drug is" [Goodman and Gilman in CPAA compilation, volume 9, at page 22, LHC]. Another source describes efficacy as "the ability of the drug to produce the desired therapeutic effect" [Dorland's Medical dictionary in Novartis' volume P, at page 19].

184. Mr. Grover further submitted that in pharmacology, efficacy is distinct from affinity, potency and bioavailability. Affinity, a pharmacodynamics property, "is the tendency of a molecule to associate with another". The affinity of a drug is its ability to bind to its biological target (receptor, enzyme, transport system, etc.). Potency is "the dose of drug required to produce a specific effect of given intensity as compared to a standard

reference". Bioavailability, on the other hand, is a pharmacokinetic property. It "is the term used to indicate the fraction extent to which a dose of drug reaches its site of action or a biological fluid from which the drug has access to its site of action" [Goodman and Gilman in CPAA compilation, volume…, internal page 4]; or "the degree to which a drug or other substance becomes available to the target tissue after administration" [Dorland's Medical Dictionary in Novartis' volume B, at page 65]. A demonstration of increase in bioavailability is not a demonstration of enhanced efficacy.

185. Prof. Basheer, who appeared before this Court purely in academic interest as an intervenor-cum-amicus, agreed that not all advantageous properties of a new form (such as improved processability or flow characteristics, storage potential, etc.) ought to qualify under section 3(d), but only those properties that have some bearing on efficacy. However, taking a less rigid position than Mr. Grover, Prof. Basheer argued that safety or significantly reduced toxicity should also be taken into consideration to judge enhanced therapeutic efficacy of a pharmaceutical product in terms of section 3(d).[1]

186. We have taken note of the submissions made by Mr. Grover and Prof. Basheer in deference to the importance of the issue and the commitment of the counsel to the cause. However, we do not propose to make any pronouncement on the issues raised by them, as this case can be finally and effectively decided without adverting to the different points of

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1 Prof. Basheer traced the origins of the amended part of section 3(d) in Article 10(2)(b) of European Drug Regulatory Directive, 2004 which defines a "generic medicinal product" as:

> "a medicinal product which has the same qualitative and quantitative composition in active substances and the same pharmaceutical form as the reference medicinal product, and whose bioequivalence with the reference medicinal product has been demonstrated by appropriate bioavailability studies. The different salts, esters, isomers, mixtures of isomers, complexes or derivatives of an active substance shall be considered to be the same active substance, unless they differ significantly in properties with regard to safety and/or efficacy. In such cases, additional information providing proof of the safety and/or efficacy of the various salts, esters or derivatives of a authorized active substance must be supplied by the applicant."

He pointed out that the expressions used in a different context in the European Drug Regulatory Directive were incorporated in the Patents Act for an altogether different purpose and raised some important and interesting points for interpretation of section 3(d) but in this case we see no reason to go into those aspects of the matter.

view noted above.

187. In whatever way therapeutic efficacy may be interpreted, this much is absolutely clear: that the physico-chemical properties of beta crystalline form of Imatinib Mesylate, namely (i) more beneficial flow properties, (ii) better thermodynamic stability, and (iii) lower hygroscopicity, may be otherwise beneficial but these properties cannot even be taken into account for the purpose of the test of section 3(d) of the Act, since these properties have nothing to do with therapeutic efficacy.

188. This leaves us to consider the issue of increased bioavailability. It is the case of the appellant that the beta crystalline form of Imatinib Mesylate has 30 per cent increased bioavailability as compared to Imatinib in free base form. If the submission of Mr. Grover is to be accepted, then bioavailability also falls outside the area of efficacy in case of a medicine. Leaving aside the submission of Mr. Grover on the issue, however, the question is, can a bald assertion in regard to increased bioavailability lead to an inference of enhanced therapeutic efficacy? Prof. Basheer quoted from a commentator[1] on the issue of bioavailability as under:

> "It is not the intent of a bio-availability study to demonstrate effectiveness, but to determine the rate and extent of absorption. If a drug product is not bio-available, it cannot be regarded as effective. **However a determination that a drug product is bio-available is not in itself a determination of effectiveness.**"
>
> (emphasis added)

189. Thus, even if Mr. Grover's submission is not taken into consideration on the question of bioavailability, the position that emerges is that just increased bioavailability alone may not necessarily lead to an enhancement of therapeutic efficacy. Whether or not

1 42 FR 1640 (1977). Cf. Moffitt, Jane, Appropriateness of Bioavailability and Bioequivalency as Pre-Market Clearance Considerations, 34 Food Drug Cosm. L.J. 640 (1979)

an increase in bioavailability leads to an enhancement of therapeutic efficacy in any given case must be specifically claimed and established by research data. In this case, there is absolutely nothing on this score apart from the adroit submissions of the counsel. No material has been offered to indicate that the beta crystalline form of Imatinib Mesylate will produce an enhanced or superior efficacy (therapeutic) on molecular basis than what could be achieved with Imatinib free base *in vivo* animal model.

190. Thus, in whichever way section 3(d) may be viewed, whether as setting up the standards of "patentability" or as an extension of the definition of "invention", it must be held that on the basis of the materials brought before this Court, the subject product, that is, the beta crystalline form of Imatinib Mesylate, fails the test of section 3(d), too, of the Act.

191. We have held that the subject product, the beta crystalline form of Imatinib Mesylate, does not qualify the test of Section 3(d) of the Act but that is not to say that Section 3(d) bars patent protection for all incremental inventions of chemical and pharmaceutical substances. It will be a grave mistake to read this judgment to mean that section 3(d) was amended with the intent to undo the fundamental change brought in the patent regime by deletion of section 5 from the Parent Act. That is not said in this judgment.

192. Section 2(1)(j) defines "invention" to mean, "a new product or …", but the new product in chemicals and especially pharmaceuticals may not necessarily mean something altogether new or completely unfamiliar or strange or not existing before. It may mean something "different from a recent previous" or "one regarded as better than what went before" or "in addition to another or others of the same kind"[1]. However, in case of chemicals and especially pharmaceuticals if the product for which patent protection is

1 The New Oxford Dictionary of English Edition 1998

claimed is a new form of a known substance with known efficacy, then the subject product must pass, in addition to clauses (j) and (ja) of section 2(1), the test of enhanced efficacy as provided in section 3(d) read with its explanation.

193. Coming back to the case of the appellant, there is yet another angle to the matter. It is seen above that in the US the drug Gleevec came to the market in 2001. It is beyond doubt that what was marketed then was Imatinib Mesylate and not the subject product, Imatinib Mesylate in beta crystal form. It is also seen above that even while the appellant's application for grant of patent lay in the "mailbox" awaiting amendments in the law of patent in India, the appellant was granted Exclusive Marketing Rights on November 10, 2003, following which Gleevec was marketed in India as well. On its package[1], the drug was described as "Imatinib Mesylate Tablets 100 mg" and it was further stated that "each film coated tablet contains: 100 mg Imatinib (as Mesylate)". On the package there is no reference at all to Imatinib Mesylate in beta crystalline form. What appears, therefore, is that what was sold as Gleevec was Imatinib Mesylate and not the subject product, the beta crystalline form of Imatinib Mesylate.

194. If that be so, then the case of the appellant appears in rather poor light and the claim for patent for beta crystalline form of Imatinib Mesylate would only appear as an attempt to obtain patent for Imatinib Mesylate, which would otherwise not be permissible in this country.

195. In view of the findings that the patent product, the beta crystalline form of Imatinib Mesylate, fails in both the tests of invention and patentability as provided under clauses (j), (ja) of section 2(1) and section 3(d) respectively, the appeals filed by Novartis AG fail and are dismissed with cost. The other two appeals are allowed.

1 A copy of the package is enclosed at the end of the judgment as appendix III.

196. Before putting down the records of this case, we would like to express our deep appreciation for the way the hearing of the case took place before the Court. Every counsel presented the issues under consideration from a different angle and every counsel who addressed the Court had something important and valuable to contribute to the debate. It was also acknowledged that the illuminating addresses of the counsel were the result of the hard work and painstaking research by the respective teams of young advocates working for each senior advocate. The presence of those bright young ladies and gentlemen in the court room added vibrancy to the proceedings and was a source of constant delight to us.

..……..J.
(Aftab Alam)

..……..J.
(Ranjana Prakash Desai)

New Delhi;
April 01, 2013

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APPENDIX I

Table (1)

Comparative Table of Applications for Patents in India during the periods (a) 1930-38: (b) 1949-58

1930-1938				1949-58			
Year	**Total number of applications filed**	**By Indians**	**By other than Indian**	**Year**	**Total number of applications filed**	**By Indians**	**By other than Indians**
1930	1, 099	114	985	1949	1,725	345	1,380
1931	940	109	831	1950	1,851	352	1,499
1932	928	162	766	1951	2,108	422	1,686
1933	954	199	755	1952	2,272	473	1,799
1934	1,007	203	804	1953	2,235	406	1,829
1935	980	156	824	1954	2,497	403	2,094
1936	1,068	199	869	1955	2,736	403	2,333
1937	1,246	202	1,044	1956	3,067	482	2,585
1938	1,243	220	1,023	1957	3,456	527	2,929
1939	1,060	238	822	1958	3,572	529	3,043
	10,525	1,802 (17%)	8,723		25,519	4,342 (17%)	21,177

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Table (2)

Patents Granted From 1950-57- analysed according to the subject of the inventions

	Food				
Year	**Indian**		**Foreign**		**Total**
	No.	Percentage	No.	Percentage	
1950	22	16.5	111	83.5	133
1951	35	28.6	87	71.4	122
1952	18	18.9	77	81.1	95
1953	30	18.8	129	81.2	159
1954	31	8.3	341	91.7	372
1955	48	10.0	430	90.0	478
1956	30	7.0	402	93.0	432
1957	8	13.5	51	86.5	59
Total	222		1628		1850
Chemical					
1950	13	4.5	271	95.4	284
1951	33	8.7	378	91.3	411
1952	36	8.0	414	92.0	450
1953	27	7.1	351	92.9	378
1954	44	9.7	409	90.3	453
1955	56	12.5	448	87.5	504
1956	34	6.6	479	93.4	513
1957	68	9.3	656	90.7	727
Total	311		3406		3717

Table (3)

Applications for Patents relating to Drugs and Pharmaceuticals

Pharmaceuticals					
Year	**Indian**		**Foreign**		
	No.	Percentage	No.	Percentage	
1947	12	7.7 (sic 17.7)	143	72.3	155
1948	7	5.5	121	94.5	128
1949	5	3.5	139	96.5	144
1950	8	5.0	151	95.0	159
1951	17	7.7	203	92.3	220
1952	18	6.2	224	93.8	242
1953	18	6.3	267	93.7	285
1954	13	4.1	300	95.9	312
1955	7	2.1	325	97.9	332
1956	13	2.6	476	97.4	489
1957	25	5.3	543	94.7	568
Total	143		2892		3035

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Table (5)

Number of Patents in force on the 1st January, 1958

Total Number	13,774
Owned by Indians	1,157
Owned by Indians and Foreigners jointly	21
Owned by Foreigners	12,596

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APPENDIX II

Comparative Chart of Zimmermann Patent & Application for Beta-Crystalline form of Imatinib Mesylate in India

	Zimmermann Patent (Vol. C-4)	**Beta-crystal Application in India (Vol. C-4)**
1.	Column 4: The compounds of formula I have valuable pharmacological properties and can be used, for example, as anti-tumoral drugs and as drags (sic drugs) against atherosclerosis.	Page No. 60: The methanesulfonic acid addition salt of a compound of formula I, which is preferably used in the β-crystal form…possesses valuable pharmacological properties and may, for example, be used as an anti-tumour agent, as an agent to treat atherosclerosis.
2.	Column 5: "…and anti-bacterial active ingredients.."	Page No. 60: "…preventing the invasion of warm-blooded animal cells by certain bacteria, such as Porphyromonas gingivalis."
3.	Column 4: The phosphorylation of proteins has long been known as an important step in the differentiation and proliferation of cells. The	Page No. 60: The phosphorylation of proteins has long been known as an essential step in the differentiation and division of cells. Phosphorylation is catalysed

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	phosphorylation is catalysed by protein kinases which are divided into serine/threonine kinases and tyrosine kinases. The serine/threonine kinases include protein kinase C and the tyrosine kinases the PDGF (platelet-derived growth factor)-receptor tyrosine kinase.	by protein kinases subdivided into serine/threonine and tyrosine kinases. The tyrosine kinases include PDGF (Platelet-derived Growth Factor) receptor tyrosine kinase.
4.	Column 7: PDGF (platelet-derived growth factor) is a very frequently occurring growth factor which plays an important role both in normal growth and in pathological cell proliferation, such as in carcinogenesis and disorders of the smooth muscle cells of blood vessels, for example in atherosclerosis and thrombosis.	Page No. 60: PDGF (Platelet-derived Growth Factor) is a very commonly occurring growth factor, which plays an important role both in normal growth and also in pathological cell proliferation, such as is seen in carcinogenesis and in diseases of the smooth-muscle cells of blood vessels, for example in atherosclerosis and thrombosis.
5.	Column 7: The inhibition of PDGF-stimulated receptor tyrosine kinase activity in vitro is measured in PDGF receptor	Page No. 60: The inhibition of PDGF-stimulated receptor tyrosine kinase activity in vitro is measured in PDGF receptor

	immunocomplexes of BALB/c 3T3 cells, analogously to the method described by E. Andrejauskas-Buchdunger and U. Regenass in Cancer Research 52, 5353-5358 (1992). The compounds of formula I described in detail above inhibit PDGF-dependent cell-free receptor phosphorylation at concentrations of from 0.005 to 5 µmol/liter, especially from 0.01 to 1.0, more especially from 0.01 to 0.1µmol/liter. The inhibition of PDGF-receptor tyrosine kinase in the intact cell is detected by means of Western Blot Analysis, likewise analogously to the method described by E. Andrejauskas-Buchdunger and U. Regenass in Cancer Research 52, 5353-5358 (1992). In that test the inhibition of ligand-stimulated PDGF-receptor autophosphorylation in BALB/c mouse cells is measured	immune complexes of BALB/c 3T3 cells, as described by E. Andrejauskas-Buchdunger and U. Regenass in Cancer Research 52, 5353-5358 (1992). A compound of formula I described in more detail hereinbefore, such as especially its β-crystal form, inhibits PDGF-dependent acellular receptor phosphorylation.

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	with the aid of anti-phosphotyrosine antibodies. The compounds of formula I described in detail above inhibit the tyrosine kinase activity of the PDGF receptor at concentrations of from 0.005 to 5 µmol/liter, especially from 0.01 to 1.0 and more especially from 0.01 to 0.1 µmol/liter. At concentrations below 1.0 µmol/liter, those compounds also inhibit the cell growth of a PDGF-dependent cell line, namely BALB/c 3T3 mouse fibroblasts.	
6.	Column 8: The compounds of this invention inhibit enzyme activity by 50% (IC_{50}) typically in a concentration of 0.1 to 10 µm.	Page No. 61: "…the corresponding methanesulfonate salt inhibit the tyrosine kinase activity of the PDGF receptor at an IC_{50} (concentration at which activity is inhibited by 50% compared with the control) of about 120 nM and about 100 nM, respectively."
7	Column 7: Owing to the properties described,	Page No. 61: On the basis of the described

	compounds of formula I can be used not only as tumour-inhibiting active ingredients but also as drugs against non-malignant proliferative diseases, e.g. atherosclerosis, thrombosis, psoriasis, sclerodermitis and fibrosis. They are also suitable for the further applications mentioned above for protein kinase C- modulators and can be used especially in the treatment of diseases that respond to the inhibition of PDGF-receptor kinase.	properties, the methanesulfonic acid addition salt of a compound of formula I, such as especially the β-crystal form thereof, may be used not only as a tumour-inhibiting substance, for example in small cell lung cancer, but also as an agent to treat non-malignant proliferative disorders, such as atherosclerosis, thrombosis, psoriasis, scleroderma, and fibrosis… It may especially be used for the treatment of diseases which respond to an inhibition of the PDGF receptor kinase.
8.	Column 9: In addition, the compounds of formula I prevent the development of resistance (multi-drug resistance) in cancer treatment with other chemotherapeutic drugs or remove existing resistance to other chemotherapeutic drugs.	Page No. 62: In addition, the methanesulfonic acid addition salt of a compound of formula I, such as especially its β-crystal form C, prevents the development of multidrug resistance in cancer therapy with other chemotherapeutic agents or

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		abolishes a pre-existing resistance to other chemotherapeutic agents.
9.	Column 6: Some of the compounds of formula I wherein R_4 and R_8 are hydrogen inhibit not only protein kinase C but, at a concentration IC_{50} as low as approximately from 0.01 to 5 µmol/liter, especially approximately from 0.05 to 1 µmol/liter, also certain tyrosine kinases, such as especially PDGF-receptor kinase or abl-kinase, for example v-abl-kinase.	Page No. 62: Also abl kinase, especially v-abl kinase, is inhibited by 4-(4-methylpiperazin-1-ylmethyl) –N-(4-methyl-3-(4-pyridin-3-yl)pyrimidin-2-ylamino) phenyl] benzamide and its methanesulfonate salt.
10.	Column 7: The above-mentioned inhibition of v-abl-tyrosine kinase is determined in accordance with the methods of N. Lydon et at., Oncogene Research 5, 161 – 173 (1990) and J.F. Geissler et al., Cancer Research 52, 4492-4498 (1992). In those methods [Val^5]-angiotensin II and [γ-^{32}P]-ATP are used as substrates.	Page No. 62: The inhibition of v-abl tyrosine kinase is determined by the methods of N. Lydon et at. Oncogene Research 5, 161 – 173 (1990) and J.F. Geissler et al., Cancer Research 52, 4492-8 (1992). In those methods [Val^5]-angiotensinII and [y-^{32}P]-ATP are used as substrates.
11.	Column 20:	Page No.68:

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	The invention relates also to a method of treating warm-blooded animals suffering from a tumoral disease, which comprises administering to warm-blooded animals requiring such treatment an effective, tumour-inhibiting amount of a compound of formula I or of a pharmaceutically acceptable salt thereof.	The invention relates also to a process for the treatment of warm-blooded animals suffering from said diseases, especially a tumour disease, ….is administered to warm-blooded animals in need of such treatment.
12.	Column 20: The invention relates further to the use of a compound of formula I or of a pharmaceutically acceptable salt thereof for inhibiting PDGF-receptor kinase or to the use of a compound of formula I wherein R_4, and R_8 are each hydrogen, or of a pharmaceutically acceptable salt thereof, for inhibiting protein kinase C in warm-blooded animals or for preparing pharmaceutical compositions for use in the therapeutic treatment of the human	Page No.68 : The invention relates moreover to the use of the β-crystal form of the methanesulfonic acid addition salt of a compound of formula I for the inhibition of the above-mentioned tyrosine kinases, especially PDGF receptor kinase, v-abl kinase, and/or c-kit receptor kinase, or for the preparation of pharmaceutical compositions for use in treating the human or animal body.

	or animal body.	
13.	Column 20: Effective doses, for example daily doses of approximately from 1 to 1000 mg, especially from 50 to 500 mg, are administered to a warm-blooded animal of approximately 70 kg body weight according to species, age, individual condition, mode of administration and the individual syndrome.	Page No. 68: Depending on species, age, individual condition, mode of administration, and the clinical picture in question, effective doses, for example daily doses of about 1-2500 mg, preferably 1-1000 mg, especially 5-500 mg, are administered to warm-blooded animals of about 70 kg bodyweight.
14.	Column 20: The invention relates also to pharmaceutical compositions comprising an effective amount, especially an amount effective in the prevention or therapy of one of the above-mentioned diseases, of the active ingredient together with pharmaceutically acceptable carriers that are suitable for topical, enteral, for example oral or rectal, or parenteral administration, and may be inorganic or organic, solid or	Page No. 68: The invention relates also to pharmaceutical preparations which contain an effective amount, especially an effective amount for prevention or treatment of one of the said diseases, of the methanesulfonic acid addition salt of a compound of formula I in the –crystal (sic β-crystal) form, together with pharmaceutically acceptable carriers which are suitable for topical, enteral for example oral or rectal, or

	liquid. For oral administration there are used especially tablets or gelatin capsules comprising the active ingredient together with diluents, for example lactose, dextrose, sucrose, mannitol, sorbitol, cellulose and/or glycerol, and/or lubricants, for example silicic acid, talc, stearic acid or salts thereof, such as magnesium or calcium stearate, and/or polyethylene glycol. Tablets may also comprise binders, for example magnesium aluminium silicate, starches, such as corn, wheat or rice starch, gelatin, methylcellulose, sodium carboxymethylcellulose and/or polyvinylpyrrolidone, and, if desired, disintegrators, for example starches, agar, alginic acid or a salt thereof, such as sodium alginate, and/or effervescent mixtures, or adsorbents, dyes, flavourings and	parenteral administration and may be inorganic or organic and solid or liquid. Especially tablets or gelatin capsules containing the active substance together with diluents, for example lactose, dextrose, sucrose, mannitol, sorbitol, cellulose and/or glycerin, and/or lubricants, for example silicic, talc, stearic acid, or salts thereof, typically magnesium or calcium stearate, and/or polyethylene glycol, are used for oral administration. Tablets may likewise contain binders, for example magnesium aluminium silicate, starches, typically corn, wheat or rice starch, gelatin, methylcellulose, sodium carboxymethylcellulose and/or polyvinylpyrrolidone, and, if so desired, disintegrants, for example starches, agar, alginic acid or a salt thereof, typically sodium alginate,

	sweeteners. The pharmacologically active compounds of the present invention can also be used in the form of parenterally administrable compositions or in the form of infusion solutions. Such solutions are preferably isotonic aqueous solutions or suspensions, which, for example in the case of lyophilised compositions that comprise the active ingredient alone or together with a carder, for example mannitol, can be prepared before use. The pharmaceutical compositions may be sterilised and/or may comprise excipients, for example preservatives, stabilisers, wetting agents and/or emulsifiers, solubilisers, salts for regulating the osmotic pressure and/or buffers. The present pharmaceutical compositions which, if desired, may comprise further pharmacologically	and/or effervescent mixtures, or adsorbents, colouring agents, flavours, and sweetening agents. The pharmacologically active compounds of the present invention may further be used in the form of preparations for parenteral administration or infusion solutions. Such solutions are preferably isotonic aqueous solutions or suspensions, these possibly being prepared before use, for example in the case of lyophilised preparations containing the active substance either alone or together with a carrier, for example mannitol. The pharmaceutical substances may be sterilised and/or may comprise excipients, for example preservatives, stabilisers, wetting agents and/or emulsifiers, solubilisers, salts for regulation of the osmotic pressure, and/or buffers.

	active substances, such as antibiotics, are prepared in a manner known per se, for example by means of conventional mixing, granulating, confectioning, dissolving or lyophilising processes, and comprise approximately from 1% to 100%, especially from approximately 1% to approximately 20%, active ingredient(s).	The present pharmaceutical preparations which, if so desired, may contain further pharmacologically active substances, such as antibiotics, are prepared in a manner known per se, for example by means of conventional mixing, granulating, coating, dissolving or lyophilising processes, and contain from about 1% to 100%, especially from about 1% to about 20%, of the active substance or substances.
15.	Column 21: The following Examples illustrate the invention but do not limit the invention in any way. The R_f values are determined on silica gel thin-layer plates (Merck, Darmstadt, Germany). The ratio to one another of the eluants in the eluant mixtures used is given in proportions by volume (v/v), and temperatures are given in degrees Celsius.	Page No. 69: The following Examples illustrate the invention without limiting the scope thereof. R_1 – values are determined on TLC plates coated with silica gel (Merck, Darmstadt, Germany). The ratio of the solvents to one another in the solvent systems used is indicated by volume (v/v), and temperatures are given in degrees Celsius (ºC).

APPENDIX III

NOVARTIS

Imatinib Mesylate

Tablets 100 mg

Glivec®100 mg

FOR ORAL USE

WARNING :
To be sold by retail on the prescription of an Oncologist only.

10 film-coated tablets

Each film coated tablet contains :
100 mg Imatinib (as mesylate).

Dosage : As directed by the physician.
Do not store above 30° C.
Store in original package.
Keep out of reach and sight of children.

Manufactured by:
Novartis Pharma Stein AG.,
Schaffhauserstrasse, 4332 Stein, Switzerland.
Imported and marketed in India by:
Novartis India Limited
Sandoz House, Dr. A. B. Road,
Worli, Mumbai 400018.

Mfg. Lic. No. : KD-2069-A

Stickered by :
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Purna Village,
Bhiwandi-421 302, Thane.
At :
Shantisthal, Shirgaon,
Palghar, Thane - 401 407.

Imp. Lic. No. : FF-52-7

Max. Retail Price Rs. 10288.00
Incl. of all Taxes

Glv100/BS/0809/2

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