

# Famous Episodes – Gleevec Case

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TWN

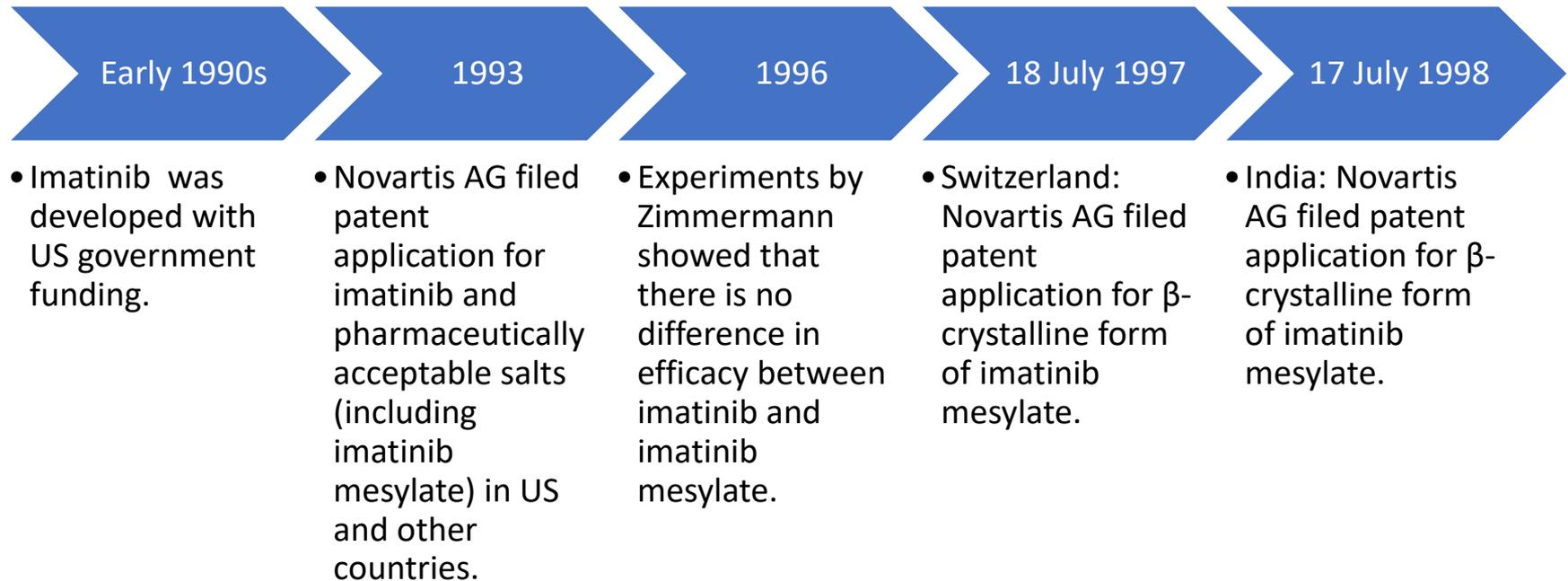
IPHU, Cape Town

2019

- India has been known as the primary supplier of many life-saving medicines for developing countries-produces Low cost and quality drugs.
- 67% of the medicines exported are purchased by the non-governmental organization (NGO), such as MSF or UNICEF and Countries for their national health programme.
- For HIV medicines, India is among the few countries in the world that are capable of making new medicines as generics.

- India was able to produce low cost drugs because
  - Patents Act, 1970-No product patents for pharmaceuticals
  - Domestic policies and institutions helping production of low cost drugs
- 2005: The situation changed in 2005, when India joined World Trade Organization.
  - Amended the Patents Act to introduced “product patents”
  - Also amended section 3(d) to exclude patents on new forms of existing drugs- salts, polymorphs, prodrugs, combinations etc.
  - Retained pre-grant opposition and introduced post-grant opposition

# GLEEVEC – HISTORY



# GLEEVEC – HISTORY

2001

- Novartis AG received USFDA approval for  $\beta$ -crystalline form of imatinib mesylate (*Gleevec*) to treat chronic myeloid leukemia.

27 March  
2002

- Novartis AG approached Indian Patent Controller for EMR for *Gleevec* based on
  - Grant of patent to Novartis AG in Australia
  - Grant of marketing approval to Novartis Australia in Australia
  - Marketing approval in India

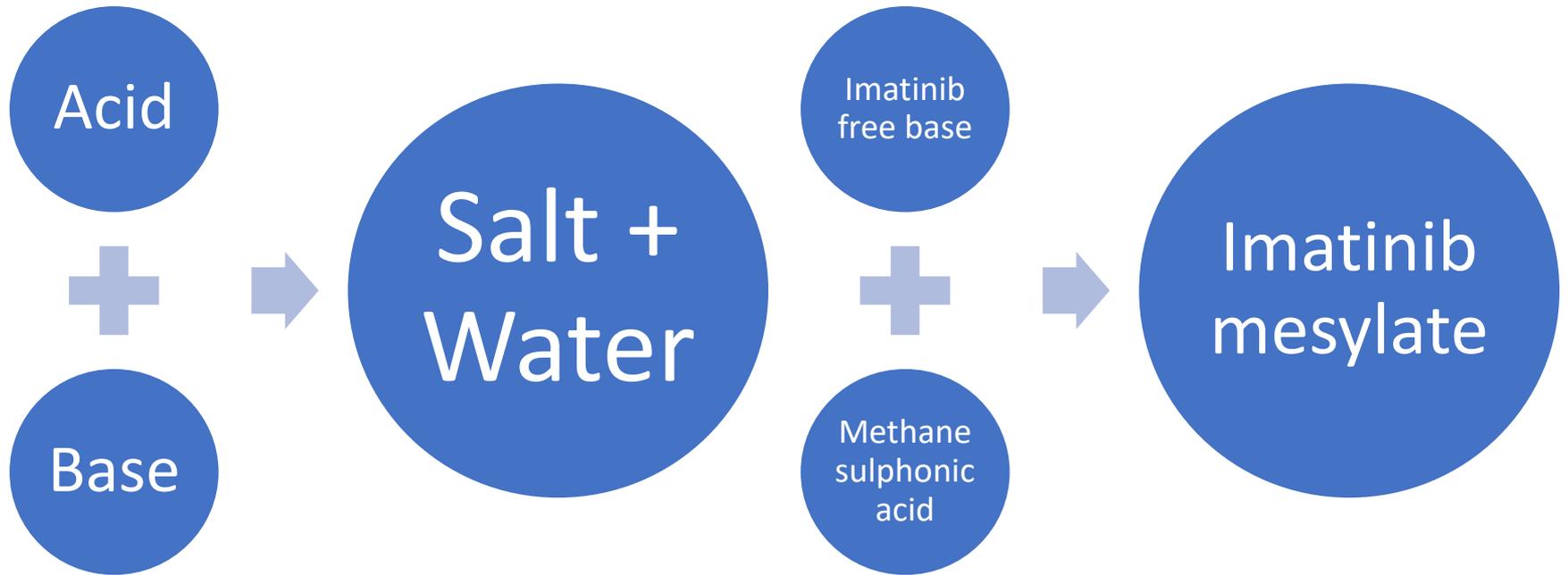
April-May  
2002

- Novartis AG launched *Gleevec* in India.

13 December  
2003

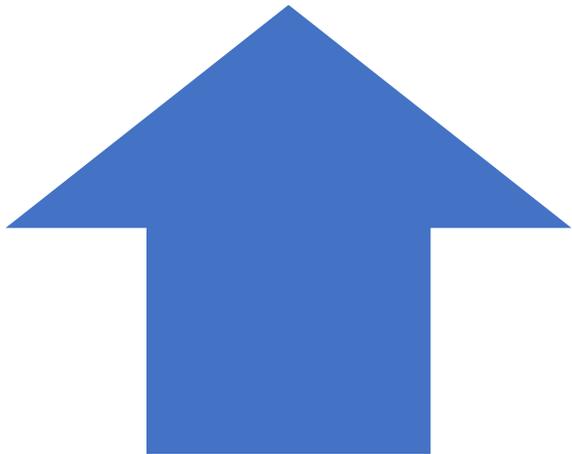
- Grant of EMR in India to Novartis AG for *Gleevec* published.

# NOVARTIS' INVENTION



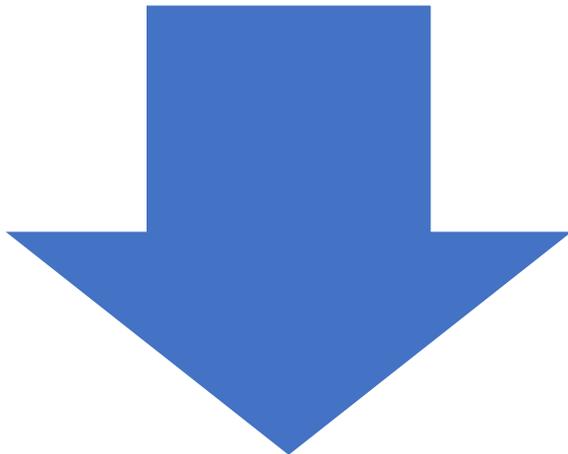
# NOVARTIS' INVENTION

Imatinib mesylate exists in at least two polymorphic forms:  $\alpha$ -crystalline form and  $\beta$ -crystalline form.



## $\beta$ -crystalline form of imatinib mesylate

- Compact crystal form  $\rightarrow$  more beneficial flow properties and better processability.
- Thermodynamically stable form at room temperature  $\rightarrow$  better stability.
- Less hygroscopic  $\rightarrow$  advantageous for processing and storing.



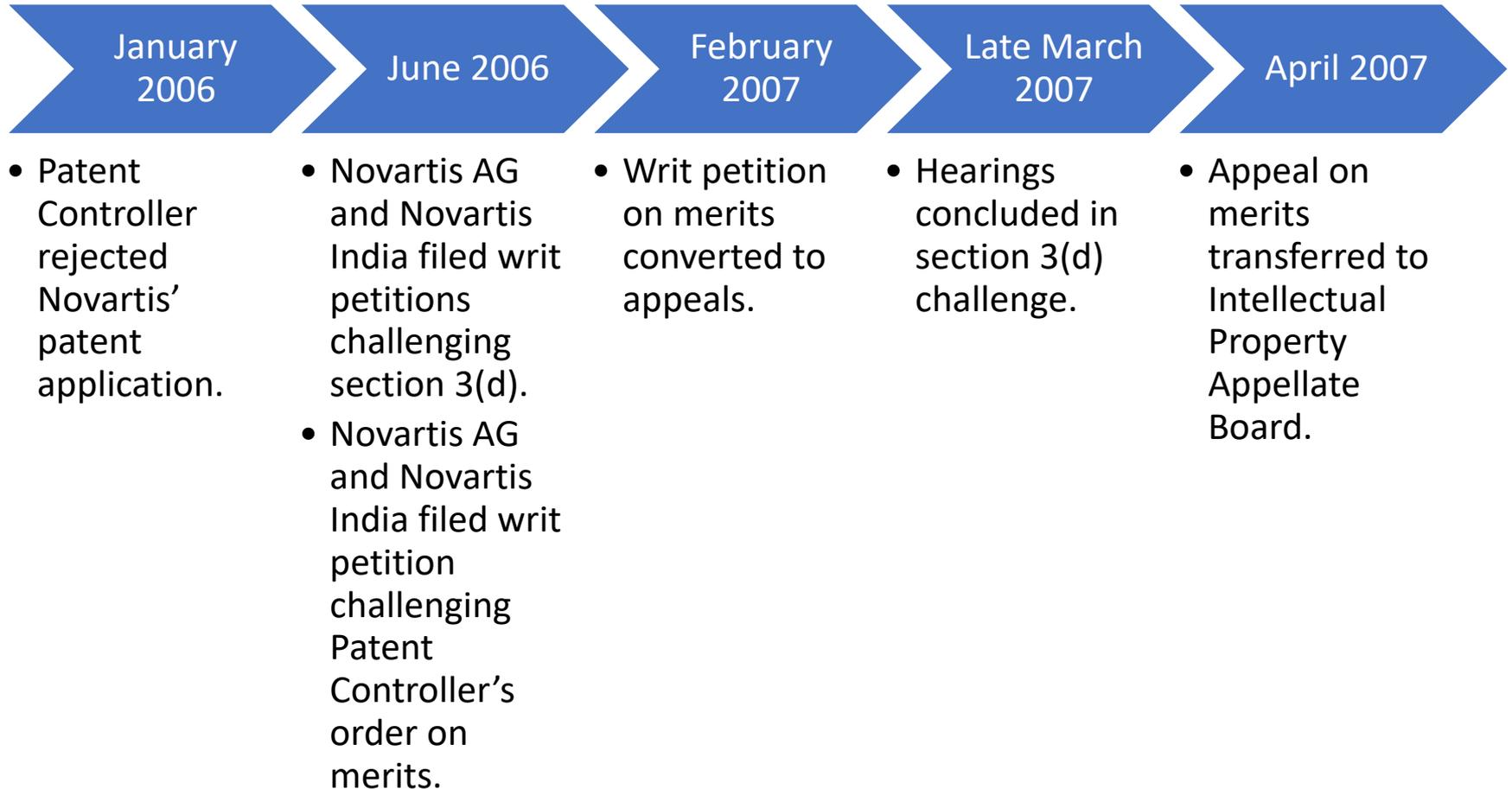
## $\alpha$ -crystalline form of imatinib mesylate

- Not as free flowing.
- Less thermodynamically stable.
- Hygroscopic.

# GLEEVEC Patent Appln Rejected in India

- 25 January, 2006: Indian Patent Office rejected patent for Novartis' CML (a type of leukemia) drug, known as Glivec, because it was only a minor modification of an existing compound.
- Dismay with that decision, Novartis took the Indian government as well as the patients and generics to court.
- This company not only challenged the India's decision on its patent, but also a part of India's law, Section 3(d), on which the decision was based.

# SUBSEQUENT DEVELOPMENTS



## SECTION 3(d) – JUDGMENT

*“We have borne in mind the object which the Amending Act wanted to achieve, namely ... to provide easy access to the citizens of this country to life saving drugs and to discharge their Constitutional obligation of providing good health care to its citizens.”*

-Madras High Court on the section 3(d)  
Constitutional Challenge

# SUBSEQUENT DEVELOPMENTS

August  
2007

- Madras High Court transfers the appeals to Intellectual Property Appellate Board (IPAB)

October  
2008

- IPAB reconstituted after Novartis' protest of possible bias in the appointment of technical member

June 2009

- IPAB dismisses Novartis' appeal since it did not satisfy section 3(d) and it also added granting patent to Gleevec affects moral standard due to high price.

August  
2009

- Novartis files appeal before the Indian Supreme Court for an interpretation of section 3(d)

December  
2012

- Two Supreme Court Judges recused themselves from hearing the case
- Finally hearing concluded.

# Protests and Campaigns





NOVARTIS PRICE  
FOR CANCER DRUG  
= RS. 1,20,000 A  
MONTH



# OPEN LETTER TO NOVARTIS

The **Open Letter** follows a public call made by Patrick Durisch, health programme Coordinator of Berne Declaration, a HAI Europe member organisation, **during the Annual General Meeting of Novartis' shareholders** last Tuesday. Durisch underlined the negative consequences of this judicial saga:

“The stakes go far beyond the granting of the patent for this anticancer drug. This action aims at weakening a public health safeguard clause – section 3(d) of the Indian Patents Act – which limits the multiplication of abusive or useless patents on an already-known substance”, said Mr Durisch. “Without this disposition, access to affordable medicines would be threatened in most developing countries, since India is one of the primary suppliers of generic medicines worldwide, in particular in the field of HIV/AIDS.”



Berne Declaration, Act Up and Oxfam asked Novartis annual management and shareholders meeting in Basel **“to abandon its legal action in India for obtaining a Glivec patent.”** “We will not stand by silently and watch our source of affordable medicines dry up in the future — we rely on these drugs to do our work in more than 60 countries today.”

**Forty activists gathered outside the Novartis building, erecting a booth and hoisting banners denouncing Novartis' position.**

# Support from Key Leaders

- At a meeting of South African church leaders and healthcare workers Archbishop Desmond Tutu said, **“People, not profits, must be at the centre of patent law for medicines.”**
- The former **UN special envoy for HIV and AIDS in Africa, Stephen Lewis**, and the head of the Global Fund to Fight AIDS, Tuberculosis and Malaria, Michel Kazatchkine, have also denounced the company's actions.
- **“The Doha declaration tries to find a balance between intellectual property rights and public health,” said Ruth Dreifuss, a former member of the Swiss Federal Council.** **“This balance can be achieved only if countries make use of the flexibilities contained in the TRIPS agreement, and this is what the Indian law does. By challenging it Novartis is sacrificing public health objectives and weakening the whole system.”**

# Protests, Campaigns and Advocacy

Health Action International (HAI) Europe, in collaboration with Berne Declaration, HAI Africa, HAI Asia Pacific, Third World Network and Knowledge Ecology International, have urged the pharmaceutical company Novartis to put an end to its five year legal actions in India regarding the patenting of the anticancer drug Glivec.

**The NGOs also called on the Swiss company to refrain from attempting to influence the Indian government over laws and policies that would hinder access to medicine.**

Source: <https://www.publiceye.ch/en/media-corner/press-releases/detail/joint-open-letter-calling-novartis-to-cease-seemingly-endless-legal-process-in-india/>

# Protests, Campaigns and Advocacy

- Nearly half a million people signed Drop the Case petition, including Archbishop Desmond Tutu, author John Le Carré and former Swiss president Ruth Dreifuss.



# Judges Training/ IP Conferences- Conflict of Interest

**THE TIMES OF INDIA**  
INDIA

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THIS STORY IS FROM APRIL 2, 2013

## Novartis case: How two SC judges had recused themselves from the case

Manoj Mitta | TNN | Updated: Apr 2, 2013, 2:13 IST

✉️ 🖨️ A- A+



DownToEarth

## The fine line for judges

Judges have recused themselves in a number of cases but there are no clear guidelines on what constitutes conflict of interest

By [Latha Jishnu](#)

Last Updated: Sunday 07 June 2015

Latha Jishnu writes .....”A letter was written by **five activists** complaining to the ministers of law, commerce, health and family **welfare about Justice Dalveer Bhandari, one of two judges hearing the case.**” “ the complaint stated that Justice Bhandari attended International conferences on intellectual property (IP) **matters organised by the Intellectual Property Owners Association (ipoa), a lobby group of the world’s top IT and pharmaceutical companies of which Novartis is a member.**

# Supreme Court rejects Novartis' plea for patent on cancer drug



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.**

# Media Coverage

The Washington Post  
Democratic Voice in Parliament

India rejects Novartis drug patent

By Rama Lakshmi  
April 1, 2013

Discover Thomson Reuters

REUTERS  
BUSINESS NEWS APRIL 1, 2013 / 7:26 AM / 7 YEARS AGO

**Novartis loses landmark drug patent case**

Kaustubh Kulkarni, Suchitra Mohanty

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**The Telegraph**

**Novartis loses landmark patent case**

India's Supreme Court dealt a significant blow to Western Monday when it rejected an application by the Swiss pharmaceutical Novartis to patent an anti-cancer drug.

By Dean Nelson, in New Delhi  
1:51PM BST 22.9K followers

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**Novartis loses Indian patent case**

By Amy Kazmin, New Delhi  
Updated 1556 GMT (2356 HKT) April 1, 2013

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**Novartis loses seven-year Glivec battle**

PT. Jyothi Datta | Mumbai/Coimbatore | Updated on March 12, 2018 | Published on April 01, 2013

- Novartis says breakthrough drug Glivec has patent in 40 countries
- Novartis patient access programme has given away Glivec worth \$1.7 billion free since 2002
- Most of the 16,000 patients using Glivec in India got it free, Novartis says. By contrast, generic Glivec is used

Cancer drug fails to meet requirement of 'new invention', rules Supreme Court Monday



**THE BIG DRUG**

Swiss Novartis is a blockbuster anti-cancer

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at pre-... — a ploy... nt period by... a formulation... ant change in

medicine, but an... f a known com-... not satisfy the test... tiveness", SC said... patent request

**WHAT DOES IT MEAN FOR PATIENTS**  
Keeps the drug affordable

<b>₹1.2 lakh</b> average cost of monthly dose of patented Glivec	<b>₹8,000</b> average cost of monthly dose of generic version
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Will allow continued supply of cheap generics and save lives in poorer nations, say activists

**WHAT DOES IT MEAN FOR INDIAN FIRMS**

- Will give a boost to domestic generic drug manufacturers
- They can continue to sell copies of drug at lower price
- Provides clarity on extent of innovation required to retain patents

**WHAT DOES IT MEAN FOR GLOBAL GIANTS**

- A blow for those banking on easy patent power
- Innovator firms may hold back drug launches, fearing weak intellectual property protection
- 1.8% fall in Novartis India share prices on Monday