
TRIPS FLEXIBILITIES

PART 1

Pre-grant Flexibilities

TRIPS flexibilities before the grant of a patent

- **Patentable Subject Matter**
- **Patent exclusions**
- **Patentability Criteria (including prohibition of evergreening)**
- **High Disclosure Standards**
- **Pre-grant Patent Oppositions**

TRIPS flexibilities after the grant of a patent

- **Research, Bolar and other exceptions**
- **Parallel Imports**
- **Personal Use/small quantity exceptions**
- **Post-grant Oppositions and Revocation**
- **Compulsory Licenses**
- **Use of Competition Law**

Working of the patent system

- **Pro-health patent examination and trainings**
- **Penalties for fraud on the system**
- **Limit and control divisionals**
- **Regulate Voluntary Licenses**
- **Working of the Patent**

TRIPS flexibilities in Enforcement of patents

- **No Border measures for patents**
- **Court proceedings to take public interest into account**
- **Limits on Injunctions and other orders**
- **Limits on Damages, “judicial” CLs**
- **Ensure Civil, not criminal remedies**

TRIPS Flexibilities before the grant of a patent: Prevention better than cure ?

- ❑ **Patentable Subject Matter/Patent exclusions**
- ❑ **Patentability Criteria (including prohibition of evergreening)**
- ❑ **High Disclosure Standards**
- ❑ **Pre-grant Patent Oppositions**

Patentable Subject Matter/Patent Exclusions

Patents only on products and processes



- 1990s – height of the HIV epidemic – huge pressure on US government to come up with treatment
- US government, Duke University and Wellcome started exploring “new” treatment
- In fact zidovudine was originally a cancer medicine and the research showed its effectiveness for HIV
- When the drug was introduced, the company announced it’s price: \$7000 – 10,000
- New USE; NOT a new product

Diagnostic, Medical, Surgical methods

U.S. Patent

Jan. 14, 1992

5,080,111

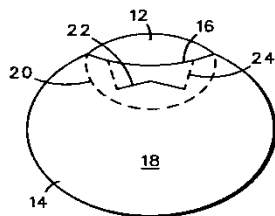


FIG. 1

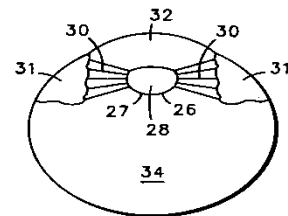


FIG. 2

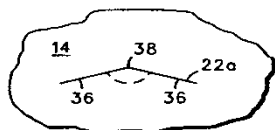


FIG. 3

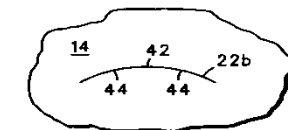


FIG. 4

- Doctor in the US patented a method of making a self-healing incision
- Charged \$4 to other surgeons
- Sued another doctor for using the method
- Court finally stopped him from enforcing his patent.
- US law prevents enforcement of such patents
- Article 27.3, TRIPS allows countries to specifically exclude such patents

Traditional Medicines



- Attempts in the US to patent turmeric for wound healing properties
- Country Options
 - Not Novel
 - Specific exemption:
 - Discoveries
 - Traditional Knowledge: “an invention which, in effect, is traditional knowledge or which is an aggregation or duplication of known properties of traditionally known component or components”
- Section 3 (p) of The Indian Patent Act,
- Other approaches include the Traditional Knowledge Digital Library

Patenting of Genes: Breast Cancer Gene



DNA

- 1990s scientists discover mutations in BRCA-1 gene.
- Mutations of this gene indicate a high risk of breast and ovarian cancer
- Discovery allows doctors and hospitals to screen women for this gene.
- In 1994 and 1995 Myriad (a US based company) patented both BRCA-1 and BRCA-2
- To screen women for this gene, you need to use the genes in testing machines.
- The test costs \$3400 [3 times the cost of pre-patent testing]
- Patents now invalidated in the US and Australia
- Specific exemptions: Discoveries; Brazil: 27.3. : *No patents for living beings or “biological materials found in nature”, even if isolated, including the “genome or germplasm” of any living being.*

Strict patentability criteria and pharmaceutical patents

What must be given a patent?

ANY INVENTION THAT IS

- 1) new**
- 2) involve an inventive step/non-obvious**
- 3) capable of industrial application**

Does not matter where it is invented (US, UK or your country) and your government cannot say they will only give a patent if you locally produce the medicine.

New or Novelty

- The novelty requirement is designed to ensure that knowledge that already exists in the public domain is not subjected to a statutory monopoly, which would be unjustified and would undermine the very basis for the grant of patent protection.
-

Example

- An invention shall be deemed to be new if it does not form part of the state of the art immediately before the priority date of that invention.
- *Option 1: The state of the art shall comprise all matter (whether a product, a process, information about either, or anything else) which has been made or is available to the public (whether in the Republic or elsewhere) by written or oral description, by use or in any other way.*
- **OR**
- *Option 2: The state of the art shall comprise all matter (whether a product, a process, information about either, or anything else) which has been made or is available to the public in the Republic by written or oral description, by use or in any other way.*
- Under the novelty test, the product or process must be **new (also known as novel or the novelty criteria)**: This means that there should be no publication that describes the invention before the patent application has been filed on it. Some countries base their laws on whether there has been a publication in their country before deciding if something is new – this is called relative novelty. Others have a much stricter criteria called absolute novelty and only consider something new if it has not been published or used anywhere in the world. **OPTION 1** is the absolute novelty standard and preferable for developing countries.

Is this new?



DAILY NEWS 3 July 2001

Wheel patented in Australia

By Will Knight

An Australian man has been issued with an innovation patent for the wheel after setting out to test the workability of a new national patent system.

John Keogh was issued the innovation patent for a “circular transportation facilitation device” under a patent system introduced in May 2001.

The innovation patent is designed to provide a quick, easy and cheap alternative to a traditional patent for small businesses. It replaces the petty patent in Australia and is even easier to process. Applications for innovation patents can even be made online.

While a standard patent must be drafted by a lawyer with engineering or science qualifications and must also demonstrate a significant advance, the innovation patent need only to show an advance.

Keogh, who is a freelance patent lawyer himself, says that he applied for the patent in order to test this new class of new patents. He says that innovation patents are not examined in detail by the Australian patent office.

“The patent office would be required to issue a patent for everything,” he told The Age newspaper. “All they’re doing is putting a rubber stamp on it.”

Is this new?



Patents

Sealed crustless sandwich

US 6004596 A

ABSTRACT

A sealed crustless sandwich for providing a convenient sandwich without an outer crust which can be stored for long periods of time without a central filling from leaking outwardly. The sandwich includes a lower bread portion, an upper bread portion, an upper filling and a lower filling between the lower and upper bread portions, a center filling sealed between the upper and lower fillings, and a crimped edge along an outer perimeter of the bread portions for sealing the fillings therebetween. The upper and lower fillings are preferably comprised of peanut butter and the center filling is comprised of at least jelly. The center filling is prevented from radiating outwardly into and through the bread portions from the surrounding peanut butter.

Find prior art

Publication number	US6004596 A
Publication type	Grant
Application number	US 08/986,581
Publication date	Dec 21, 1999
Filing date	Dec 8, 1997
Priority date ?	Dec 8, 1997
Fee status ?	Lapsed

Also published as [CA2254445A1](#), [US20010009685](#), [US20010016221](#)

Inventors [Len C. Kretchman](#), [David Geske](#)

Original Assignee [Menusaver, Inc.](#)

Export Citation [BiBTeX](#), [EndNote](#), [RefMan](#)

[Patent Citations](#) (7), [Non-Patent Citations](#) (2), [Referenced by](#) (34), [Classifications](#) (10), [Legal Events](#) (10)

External Links: [USPTO](#), [USPTO Assignment](#), [Espacenet](#)

Traditional Medicines



Patents

Use of turmeric in wound healing

US 5401504 A

ABSTRACT

Method of promoting healing of a wound by administering turmeric to a patient afflicted with the wound.

IMAGES (7)

[Find prior art](#)

[Discuss this p](#)

Publication number	US5401504 A
Publication type	Grant
Application number	US 08/174,363
Publication date	Mar 28, 1995
Filing date	Dec 28, 1993
Priority date [?]	Dec 28, 1993
Fee status [?]	Lapsed
Inventors	Suman K. Das, Hari Har P. Cohly
Original Assignee	University Of Mississippi Medical Center
Export Citation	BIBTeX , EndNote , RefMan
Patent Citations (3), Non-Patent Citations (8), Referenced by (58), Classifications (12), Legal Events (7)	
External Links: USPTO , USPTO Assignment , Espacenet	

INVENTIVE STEP

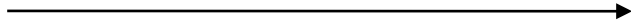
- The rationale behind the inventive step requirement is that a patent applicant should not be granted exclusive rights to an idea that was so obvious that the 'innovation' would have happened anyway.
- There are varying tests for determining whether an invention is sufficiently 'inventive' as compared to the state of the art
- Final determination always requires an essentially subjective judgment of whether the invention was sufficiently inventive, or 'non-obvious'.

Example

- Option 1: An invention shall be deemed to involve an inventive step if it is not obvious to a **person skilled in the art**, having regard to any matter which forms, immediately before the priority date of the invention, part of the state of the art.
- OR
- Option 2: An invention shall be deemed to involve an inventive step if it is not obvious to a **person with ordinary skill in the art**, having regard to any matter which forms, immediately before the priority date of the invention, part of the state of the art.
- OR
- Option 3: An invention shall be deemed to involve an inventive step if it is not obvious to a **person with expert knowledge and skill in the art**, having regard to any matter which forms, immediately before the priority date of the invention, part of the state of the art.

- To be patentable, the product or process must be **inventive or non-obvious**: This means that someone working in the field or area of technology that the patent is applied for would not have known or thought of this new product or process. Take the case of combivir or the lamivudine/zidovudine combination that is widely used as first line ART. You or I may consider it to be quite inventive that a company took two existing medicines and put it into one pill so it is easier for us to consume. BUT you or I are not the standard for judging whether something is inventive. It is people who work in that field i.e. in pharmaceuticals. For people working in this field, combining two drugs into one with a binding agent may be considered to be something that is very well known and they may consider that there is nothing inventive about it. They may thus consider the so-called invention to be **obvious**. This is also referred to as being **well known in the art or part of prior art**. The standard for obviousness differs across countries and some adopt a very high or strict standard and others adopt a low standard. Which is why the lamivudine/zidovudine combination is patented in some countries but not in others. The higher or stricter the standard, the fewer products and processes get patented as a significant number could be considered obvious. Option 3 provides a strict standard that may be preferable for developing countries.

Is this inventive?



Industrial Applicability

- In most countries, the standard of industrial applicability (or utility, in some jurisdictions) is a relatively easy standard to satisfy.
 - Invention should be capable of being made or used in industry
 - Some countries have a lower standard of utility or usefulness
-

Is a surgical method capable of industrial application?



- Doctor in the US patented a method of making a self-healing incision
- Charged \$4 to other surgeons
- Sued another doctor for using the method
- Is such a patent capable of industrial application?
- Does it have some utility? Is it useful?

Country approaches to implementing strict patentability criteria

Brazil: ANVISA process

- Involvement of Health Ministry
 - Brazil: Since 1999 grant of patents on pharmaceutical products and processes dependent on the consent of the Brazilian Sanitary Surveillance Agency (ANVISA).
 - ANVISA scrutinizes patent applications first for compliance with the requirements of patentability and then sends those approved for further scrutiny to the patent office.
 - For the purpose of making judgments about patentability criteria such as the requirement of an inventive step ANVISA established a technical group of experts.



BRAZIL: ANVISA review of pharma patent applications

- 2001 to 2009:
- ANVISA analyzed 1,346 patent applications; 988 approved
- 11% rejection rate
- Of the 988 who received approval, 40% only after changes to the patent application including the scope of claims and improved disclosure.
- Under pharma pressure, now ANVISA only has power to file oppositions

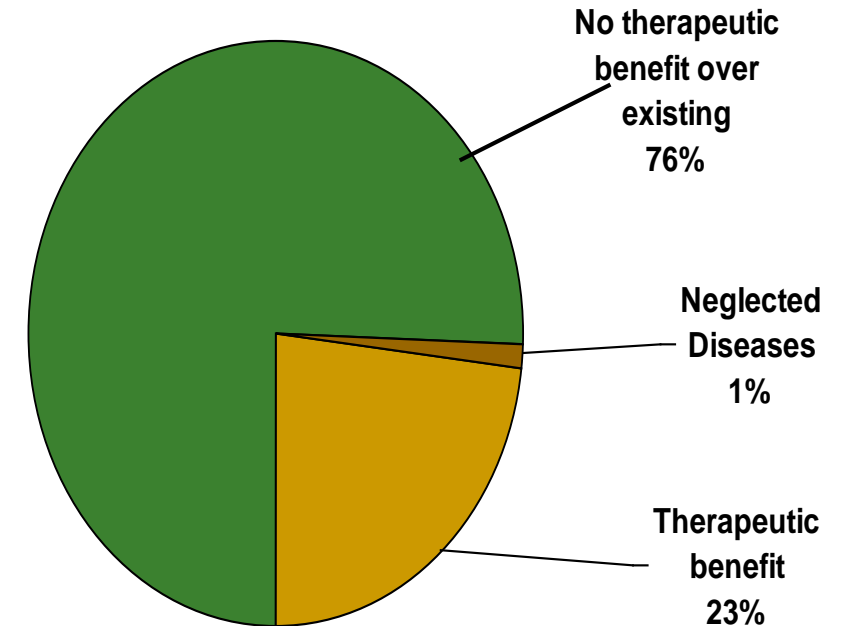
Main reason for denial of ANVISA's prior consent	n.	%
Lack of novelty (total or partial)	57	47.9%
Lack of inventive step	27	22.7%
Lack of sufficient description	19	16%
Product of nature	7	5.9%
Object not defined	6	5%
Late modifications on the application	2	1.7%
Application file outside the time limit	1	0.8%
Total	119	100%

“Evergreening”

Patents on most drugs introduced are for **new forms, new uses, or combinations** of existing drugs (crisis in “innovation”).

This is known as ‘**evergreening**’ – the practice of pharma companies to extend their patent terms by making small changes in existing medicines.

1,035 new drugs approved by FDA (1989-2000)

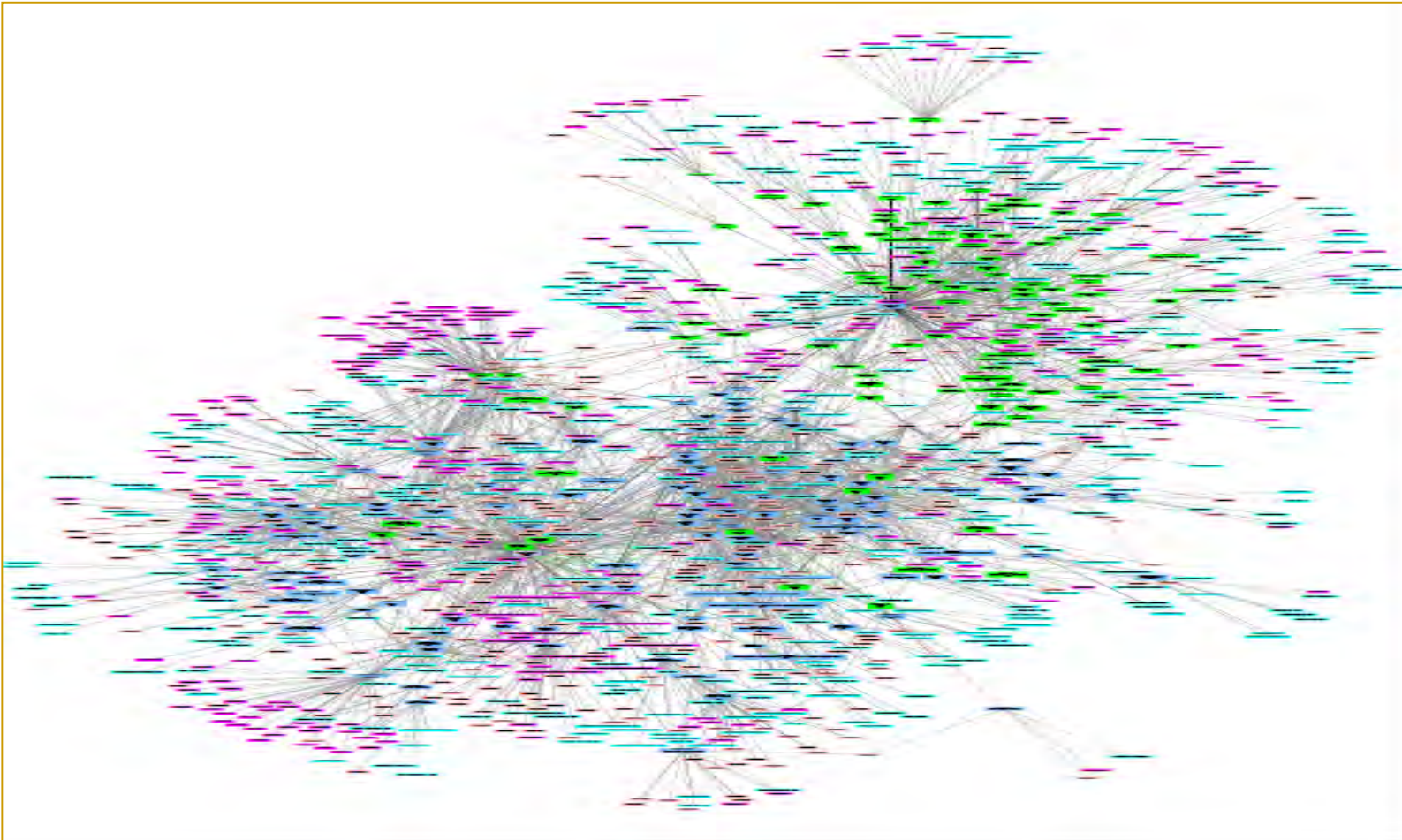


Understanding Evergreening



- The basic patents on Nevirapine (NVP) were applied for by Boehringer Ingelheim in November **1990**, and were due to expire in November **2010**.
- BI also applied for a patent on the hemihydrate form of NVP, used in the suspension in **1998**, which is due to expire **2018**.
- Additionally, BI applied for a patent on the extended release formulation of nevirapine in **2008**, which is due to expire in **2028**.
- **1998 application rejected in India; 2008 application should also be rejected**

Patent Thickets: The Ritonavir Patent Landscape



- Original patent filing: 1995
- **805 patent families**
- **Generic entry for lopinavir/ritonavir likely to be delayed 13-14 years after original patent expiry**

Developing country provisions

- **India: Section 3(d)**

- *(d) the mere discovery of a new form of a known substance which does not result in increased 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 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.*”

- **Philippines, Cheaper Medicines Act, 2008:**

- Includes a provision based on Section 3(d)

- **Zanzibar Industrial Property Act 2008**

- New forms and new uses are not patentable
- Regardless of efficacy
- Stricter than Indian law

- **Argentina (2012): Ministry of Industry, Ministry of Health and the National Institute for Intellectual Property of Argentina Joint resolution**

- New guidelines for the examination of patent applications related to chemical-pharmaceutical substances.
- Salts, combinations, polymorphs, derivatives
- Un-patentable regardless of efficacy
- Stricter than the Indian law

- **Thailand's New Patent Examination Guidelines for Chemicals, 2013**

Tightening of patent standards in developed countries

• United States

- *KSR Int'l Co. v. Teleflex Inc.*, (2007): United States Supreme Court interprets 'obviousness' requirement more strictly than was previously being employed by the US Patents and Trademark Office (USPTO).
- *“Granting patent protection to advances that would occur in the ordinary course without real innovation retards progress, and may, in the case of patents combining previously known elements, deprive prior inventions of their value or utility.”*
- *Molecular Pathology et al v. Myriad Genetics et al* (2013) US Supreme Court holds that naturally occurring genes cannot be patented

• Canada

- *Teva Canada Ltd. v. Pfizer Canada Inc.*, (2012) : Canadian Supreme Court voids Pfizer's patent on sildenafil (Viagra) for not meeting disclosure standards .
- *Eli Lilly* (2011): Patent on schizophrenia drug, Zyprexa invalidated for lack of “utility”
- Several other cases of patents on medicines similarly overturned in Canada
- Eli Lilly: Canada is an “outlier” in its interpretation of patent law

Concerns over patent quality in Developed Countries

- **US Federal Trade Commission 2003, 2011**
- **Generic companies were successful in 75% of patent disputes**
- **Leading to settlements between the companies that are harmful to consumers: delay generic entry**
- **2011: Overbroad patents are harming innovation**
- **EU Competition DG, Pharmaceutical Inquiry Report**
- Numerous patent applications - "patent clusters/thickets" : delay generics
- Nearly 100 product-specific patent families on single medicines: **Up to 1,300 patents & patent applications on one medicine alone**
- High number of patents/applications: uncertainty for generic competitors – affecting their ability to enter the market.
- Of the 149 cases in which courts rendered final judgments, generic companies won 62% of the cases.

Pre and post-grant patent oppositions

- Opposing patent applications
 - Opposing granted patents
 - Not just by competitors but by health groups, public interest groups
 - Provides information and assistance to the patent office – supports the patent office
 - Patent oppositions are legal, technical and scientific
-

RELATED KEY

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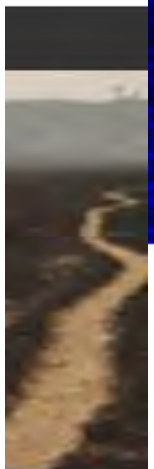
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China Patent Challenge Compels Gilead to Withdraw Key Patent Claims on Sofosbuvir Base Compound, Opening Life-Saving Hepatitis C Treatment Access for Millions

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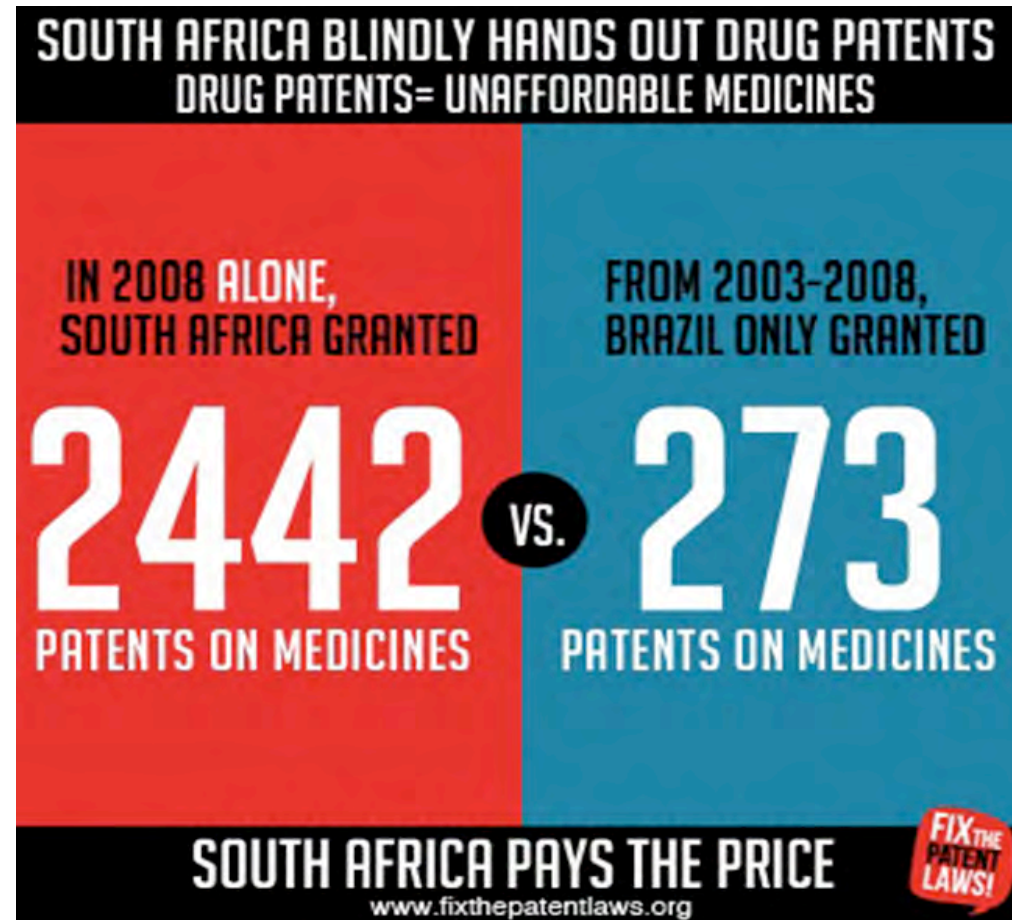


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South Africa: Impact of lack of substantive examination



SOUTH AFRICA BLINDLY HANDS OUT DRUG PATENTS PATENT MONOPOLIES = UNAFFORDABLE PRICES

IF SOUTH AFRICA REFORMED HOW IT GRANTS PATENTS,



80 % OF MEDICINE PATENTS
WOULD BE REJECTED
AND DRUG PRICES WOULD FALL

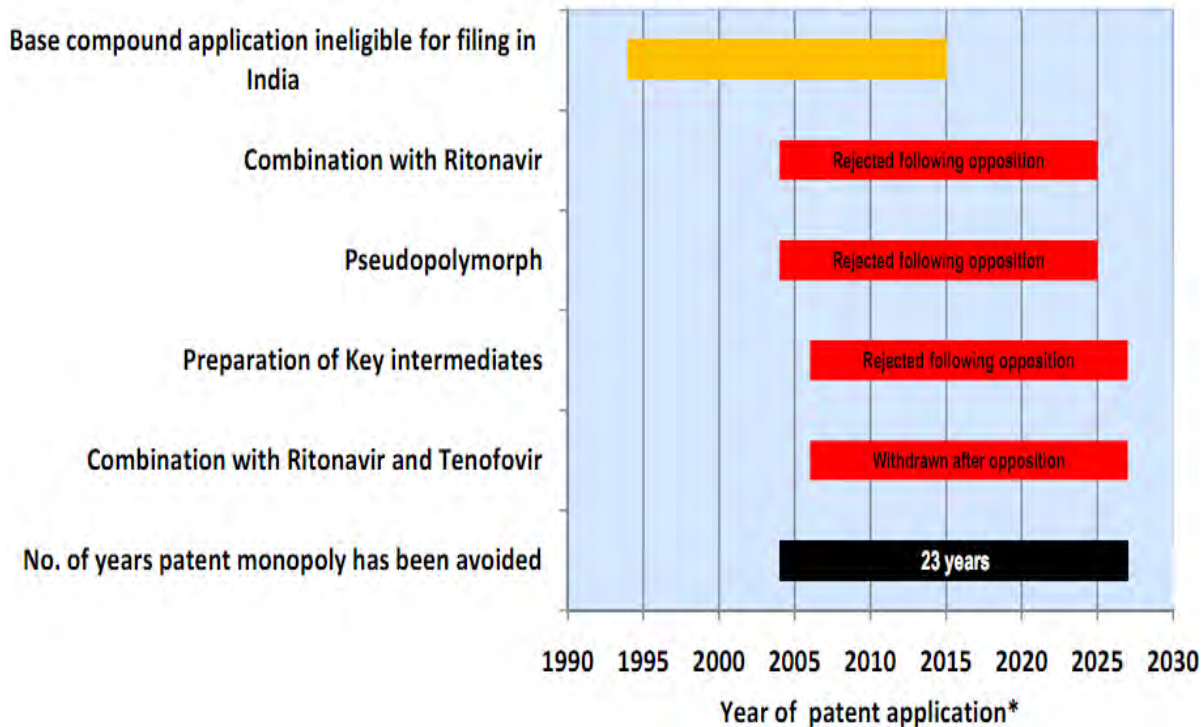
SOUTH AFRICANS PAY THE PRICE

www.fixthepatentlaws.org

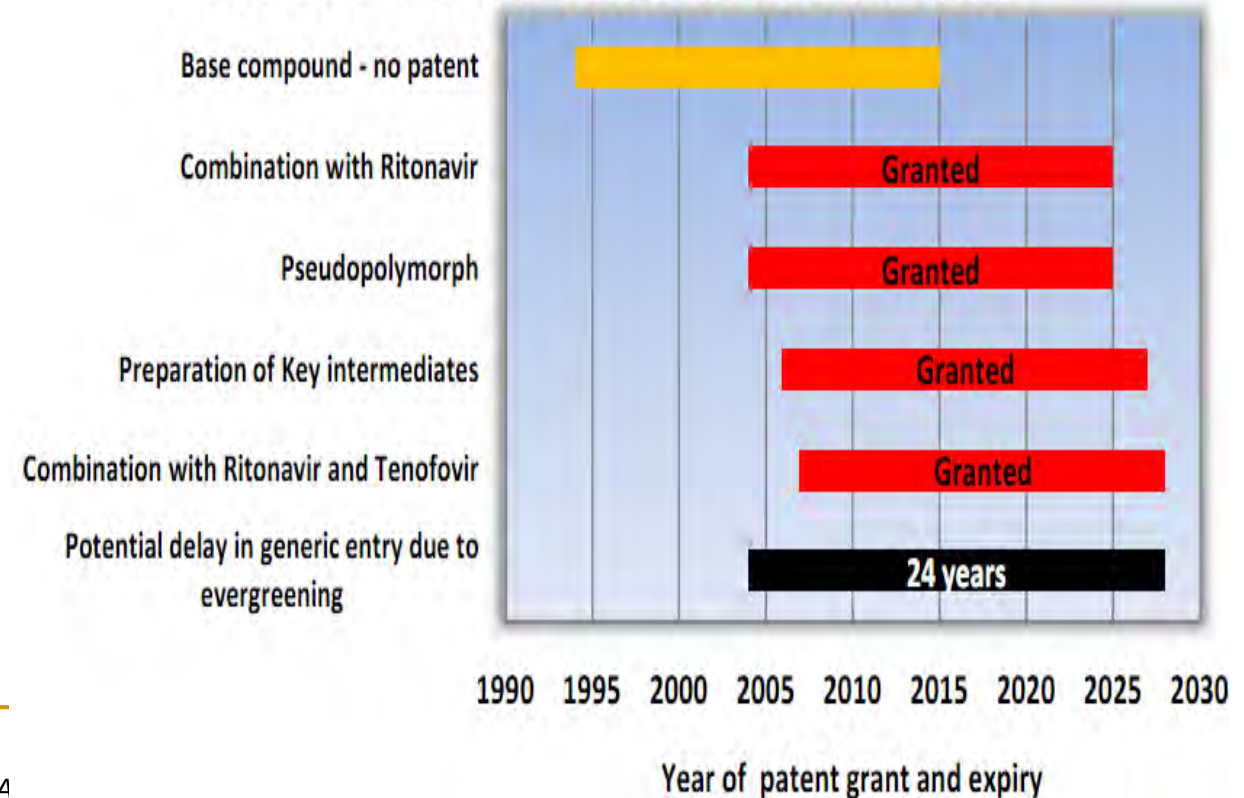
**FIX THE
PATENT
LAWS!**

Use of patent examinations & oppositions to stop Ever-greening & allow early generic entry

Darunavir Patent Applications in India



Darunavir Patent Status in South Africa



Source: WHY SOUTH AFRICA SHOULD EXAMINE PHARMACEUTICAL PA (RIS), Briefing document, 2012. * The graph shows the year in which the patents would have expired if they had been granted

Other countries

- **Thailand**

- Civil society succeeds in having the patent on didanosine (DDI) revoked
- Combivir: Opposition filed by PLHIV networks leads to withdrawal of patent application
- Opposition on patents on new HepC medicines filed

- **China**

- One patent on an HIV drug revoked
- One patent on crucial Hep C medicine recently rejected
- Patents for other medicines being opposed and have been successful

- **Vietnam:** PLHIV network has filed oppositions on key HIV medicines

Importance of Patent Oppositions

- Importance of patent oppositions and revocations: critical support for patent offices
 - Huge burdens on patent offices: India complied with TRIPS in 2005 and had a mailbox: nearly 10,000 pharma patent applications when opened
 - In the US, Generic applicants have prevailed in challenging patents in 73 percent of the cases in which a court has resolved the patent dispute (US Generic FTC Study).
 - PCT has led to massive increase in patent applications coming into developing country patent offices
 - Primary trainings of patent examiners comes from developed country patent offices that do not have or use TRIPS flexibilities or may have different, lower patentability criteria
-

Public interest based patent law reform

- **South Africa Draft IP Policy 2013**

- “A country like India resorted to pre- and post-grant opposition to facilitate a possibility of opposing weaker patents as described above... This procedure has been a success to challenge “weaker” patents or patents that do not meet the requirements of “newness”, “novelty, ”obviousness” and “usefulness for trade/agriculture.”
- Recommendation: The Patents Act should be amended to **have both pre- and post-grant opposition** to effectively foster the spirit of granting stronger patents.”

- **Brazil Review of Patent Law**

- Report examines Indian example in detail and recommends amendment of patent law to exclude:
 - (i) **patents for new forms of known substances that do not result in the improvement of the known efficacy of the substance, for they are mere discoveries and lack inventive step**, and
 - (ii) patents that claim any new property or new use of a known substance, for they are mere discoveries, lack novelty and industrial application...

Is it sufficient to have a good law on the books?
The importance of patent oppositions

MEDICINE	WHO HAS APPLIED FOR THE PATENT AND WHERE	WHO HAS OPPOSED THE PATENT APPLICATION (<i>DOES NOT INCLUDE GENERIC COMPANIES</i>)	WHAT IS THE STATUS OF THE PATENT APPLICATION
Imatinib mesylate <i>Cancer</i>	Novartis Chennai	Cancer Patients Aid Association	Patent Application Rejected
Zidovudine/ lamivudine <i>First-line ARV</i>	GSK Kolkata	Manipur Network of People living with HIV/AIDS, Indian Network for People living with HIV/AIDS	Patent Application Withdrawn
Nevaripine Hemihydrate (syrup) <i>First-line ARV</i>	Boehringer Ingelheim Delhi	Positive Womens Network and Indian Network for People living with HIV/AIDS	Patent Application Rejected
Tenofovir Fumarate or TDF (two applications) <i>Preferred first -line ARV</i>	Gilead Sciences Delhi	Delhi Network of Positive People and Indian Network for People living with HIV/AIDS; Brazilian Interdisciplinary AIDS Association (ABIA) and Sahara (Centre for Residential Care and Rehabilitation)	Patent Application Rejected
Amprenavir <i>Second-line ARV</i>	GSK Delhi	Uttar Pradesh Network of Positive People and Indian Network for People living with HIV/AIDS	Pending
Atazanavir <i>Second-line ARV</i>	Novartis Chennai	Karnataka Network for People Living with HIV and AIDS and Indian Network for People living with HIV/AIDS	ABANDONED; PATENT APPLICATION ON BISULPHATE REJECTED
Valgancyclovir <i>OI medicine</i>	F Hoffmann-La Roche Chennai	Tamil Nadu Network of Positive People and Indian Network for People living with HIV/AIDS	PATENT OVERTURNED
Abacavir <i>Second-line arv</i>	GSK Kolkata	Indian Network for People living with HIV/AIDS	PATENT APPLICATION WITHDRAWN

MEDICINE	WHO HAS APPLIED FOR THE PATENT AND WHERE	WHO HAS OPPOSED THE PATENT APPLICATION (<i>DOES NOT INCLUDE GENERIC COMPANIES</i>)	WHAT IS THE STATUS OF THE PATENT APPLICATION
Lopinavir <i>Second-line arv</i>	Abbott Laboratories Mumbai	Delhi Network of Positive People, Network of Maharashtra by People living with HIV and AIDS and Indian Network for People living with HIV/AIDS	PATENT APPLICATION REJECTED
Lopinavir/Ritonavir (Soft Gel) <i>Second-line ARV</i>	Abbott Laboratories Mumbai	Delhi Network of Positive People, and Indian Network for People living with HIV/AIDS	Patent Application Deemed Abandoned
Lopinavir/Ritonavir (Tablet) <i>Second line ARV</i>	Abbott Laboratories	I-MAK	PATENT APPLICATION REJECTED
Tenofovir or td <i>First-line ARV</i>	Gilead Sciences Delhi	Delhi Network of Positive People, and Indian Network for People living with HIV/AIDS	Pending
Ritonavir <i>Second-line ARV</i>	Abbott Laboratories Mumbai	Delhi Network of Positive People, and Indian Network for People living with HIV/AIDS	PATENT APPLICATION REJECTED
Efavirenz (post-grant opposition) <i>First-line ARV</i>	Bristol Myers Squibb Mumbai	Delhi Network of Positive People	Pending
Valgancyclovir (post-grant opposition) <i>OI medicine</i>	F Hoffmann-La Roche Chennai	Delhi Network of Positive People	PATENT OVERTURNED
Pegylated Interferon alpha 2b <i>Hepatitis C</i>	F Hoffmann-La Roche Chennai	Sankalp Rehabilitation Trust	PATENT OVERTURNED

Is it sufficient to have a good law on the books?
*The importance of patent oppositions **by civil society***

Indian generic industry: merged and acquired

Target company	Acquirer	Country of origin	of year	Amount (USD)
Matrix lab	Mylan Inc	US	August 2006	\$736 million
Dabur Pharma	Fresenius Kabi	Singapore	April 20, 2008	\$219 million
Ranbaxy Laboratories Limited	Daiichi Sankyo	Japan	June 11, 2008	\$4.6 billion
Shantha Biotech	Sanofi Aventis	France	July 27, 2009	\$783 million
Orchid Chemicals (injectible business)	Hospira	US	December 16, 2009	\$400 million
Piramal Healthcare (domestic formulation)	Abbott Laboratories	US	21 May 2010	\$ 3.72 billion

Source: compiled from various news reports

Voluntary Licenses, Medicines Patent Pool



IPA, Natco withdraw opposition to Gilead's drug

We wanted to tell the big pharma that IPA is not unreasonable and we are not blindly following an idea, said IPA

Gireesh Babu | Chennai

September 14, 2015 Last Updated at 00:23 IST



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Is it sufficient to have a good law on the books?
*How are patentability and disclosure standards being
applied?*

Applying strict patent criteria: **trainings, technical assistance**

- **Developed Country patent office trainings (USPTO, EPO, JPO) :**
 - Training of Judges
 - Training of patent examiners, patent offices



SC judge under attack from health activists

TNN | Sep 6, 2011, 08.28 AM IST

NEW DELHI: Two years ago, Justice Markandeya Katju of the Supreme Court had withdrawn from hearing a patent dispute vitally concerning pharmaceutical majors. Justice Dalveer Bhandari, the head of the bench that has since been dealing with the case, is now under attack, this time from health activists.

Though he did not himself give any reason for it, Katju's recusal in 2009 from the appeal filed by Novartis was then widely attributed to an article written by him in a legal journal conceding, much to the embarrassment of multinational companies, that "many of the medical drugs available in the market are too costly for the poor people in India" and that "ways and means should therefore be thought out for making these drugs available to the masses at affordable prices".

In what seems virtually a reversal of the situation, the health activists demanded on Monday, on the eve of the next hearing of the case, that the government should seek Justice Bhandari's recusal as he had participated in at least two international conferences for judges organized by the US-based Intellectual Property Owners Association (IPOA), whose members include Novartis, among a host of pharmaceutical and IT giants.

The sofosbuvir patent decision

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PHARMALOT

India Rejects Gilead Patent Bid for Sovaldi Hepatitis C Treatment

By ED SILVERMAN

Jan 14, 2015 2:25 pm ET

0 COMMENTS

In a setback for [Gilead Sciences](#), India's patent office has rejected an application for its Sovaldi hepatitis C treatment. The decision means that locally-based drug makers can sell lower-cost generic versions of the medicine, which costs \$1,000-a-day in the U.S. for



Gilead's \$1,000 pill gets patent in India

Rupali Mukherjee | TNN | May 10, 2016, 03:02 AM IST

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Representative image

Mumbai: In what could be a major setback for access to treatment in high-burden countries, the Indian Patent Office on Monday granted a patent to Gilead Pharmasset on Sovaldi (sofosbuvir), its blockbuster drug for hepatitis C for which the company charges \$1,000 per pill in the US.

Several patient groups - Sankalp Rehabilitation Trust, I-MAK and Delhi Network of Positive People - and generic companies (Optimus, BDR