

Intellectual property and access to medicines: Theory and overview

by

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What are Intellectual Property Rights?

“Intellectual property (IP) refers to creations of the mind, such as inventions; literary and artistic works; designs; and symbols, names and images used in commerce.” WIPO

- Intellectual property rights (IPRs) are rights conferred by law over innovations and other creations of the mind.
- IPRs are similar to other categories of property rights.
- The creator of intellectual property is usually entitled to time limited exclusive rights over the utilization of his or her property

IPRs as Human Rights

- IPRs are recognized as human rights
- Article 27(2) of the Universal Declaration of Human Rights
 - *“everyone has the right to the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author.”*

What are different forms of IPRs?

- Two broad categories of intellectual property rights
 - Copyright and related rights, and
 - industrial property rights.
- Copyright refers to rights granted to creators of :
 - literally and artistic works,
 - novels, poems and plays films, music, drawings, paintings, photographs and sculptures)and architectural design.
 - performers,
 - producers of sound recordings and broadcasting organizations.

Copyright-package inserts

Linezolid
Injection

NDC 63323-713-13
713013

600 mg per 300 mL
(2 mg per mL)

For Intravenous Infusion: Rx Only

USE IMMEDIATELY ONCE REMOVED FROM OVERWRAP.

Each mL contains: linezolid, 2 mg; dextrose, 50.24 mg; sodium citrate, 1.64 mg; citric acid, 0.85 mg; water for injection, qs. pH adjusted to 4.8 with sodium hydroxide or hydrochloric acid.

Single Use Only - Discard Unused Portion.

Usual adult dosage: see package insert. Do not add supplementary medication. Check for leaks by squeezing container, if leaks are found, discard, as sterility may be impaired. Check linezolid solution for clarity; it may exhibit a yellow color that intensifies over time, with no adverse effect on potency.

Store at 20° to 25°C (68° to 77°F); [see USP Controlled Room Temperature]. Linezolid is sensitive to light. Do not freeze.

The container closure is not made with natural rubber latex. Non-PVC. Non-DEHP. Sterile.

Manufactured for:
Frezeplus Kabi USA, LLC
Lake Zurich, IL 60047
Made in Norway

LOT: _____

1234567890
402767A
01-68-12-006A

EXP: _____



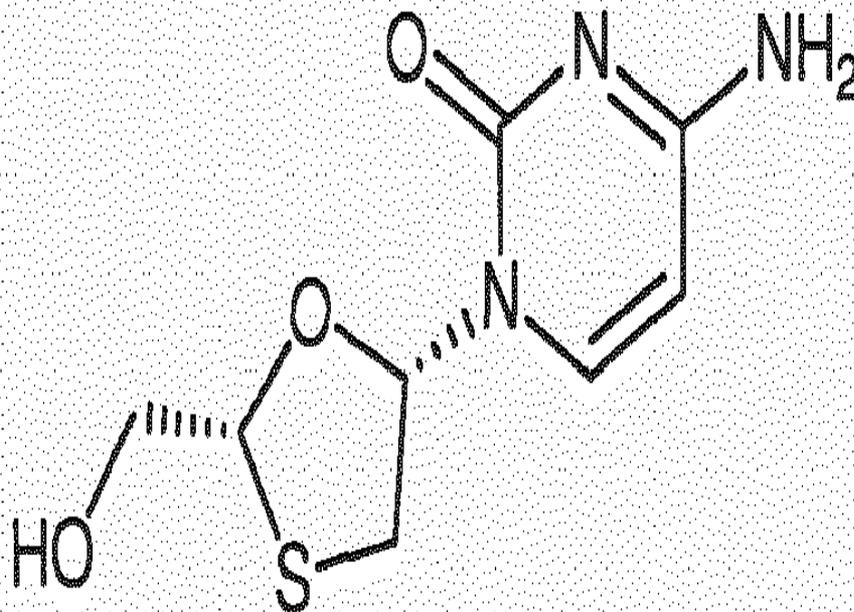
3 63323-713-13 3

“Pharmaceutical industry copyright owners can protect unique forms of designing or explaining their products, but the "science" in medical literature, including drug information leaflets, is not protected against third-party use.” Abbot

Industrial Property

- Industrial property embraces protection of :
 - Inventions/utility models
 - Trademarks
 - Industrial designs
 - Geographical indications
 - Layout designs ("chips")
 - Trade names
 - Trade secrets/undisclosed information
- Protection from unfair competition
- Special protection for **plant varieties.**

Patent – (for inventions)



Formula I

Lamivudine

4-amino-1-(2R-hydroxymethyl-[1,3]oxathiolan-5S-yl)-1H-pyrimidin-2-one

TRADEMARKS

- “A trademark is a sign capable of distinguishing the goods or services of one enterprise from those of other enterprises.” WIPO



“The “brand names” of drugs are protected by trademark, but generic producers may market the same drug under a different brand name, and there is an international nomenclature system (INNs) that provides a generic identifier that is open to everyone for use.” Abbot
Counterfeiting- use of an identical trademark



Industrial Design



“An industrial design constitutes the ornamental or aesthetic aspect of an article. A design may consist of three-dimensional features, such as the shape or surface of an article, or of two-dimensional features, such as patterns, lines or color.”
WIPO

Territorial nature of IPRs

- Intellectual property rights are recognized globally.
 - But each country has its own system of IP law.
- There is no international IPR.
 - IPRs are territorial in nature and are only applicable and enforceable in the jurisdiction in which they have originated from or been granted.
- IP rights are granted by a state's national institutions (e.g. Patent Office) and are valid only on the national territory only for a limited period of time.
- Intellectual property laws have no effect or application outside the country where they were passed.
 - The same applies to rights granted under them.

What is a patent?

- “A patent is a title granted by the State in a specific country that:
 - gives **exclusive rights** over the **manufacture and use** of an invention to the owner of this invention in that country
 - in exchange of the **disclosure** of the invention to the public.” UNAIDS

Patents and the Right to Exclude

- A patent is an exclusive right granted to a person who:
 - invents or discovers some process or thing
 - to make, use, sell, or assign it for a certain period of time.
 - usually 20 years, in return for having disclosed and described it in clear terms

Patents are territorial

- There is no international patent:
 - A patent must be filed and granted in every country where protection is sought.

State/Inventor Bargain

- Patents are a bargain forged between an inventor and the public, through the agency of the State.
- The inventor is given monopoly rights over his invention
 - In return for public disclosure of the invention.
 - Patents are tools for promoting the progress of science and technology

Justifications

- Inventors have a natural right to property in their own ideas
 - the law should prevent ideas being taken without consent.
- Inventors deserve to be rewarded for their ingenuity
 - a temporary monopoly is the best method of providing appropriate rewards.

Justifications

- The prospect of a temporary monopoly provides an incentive for inventors to invest capital, time and effort in the development of inventions.
- Patents are tools for facilitating the disclosure of inventions which would otherwise have been kept secret
- Patents are tools for coordinating R&D
 - Bring researchers together, facilitate deal-making

Patentability criteria

- In order for an invention to be given patent protection it should be
 - new (novelty)
 - not be obvious (inventive)
 - Have practical applicability in the industrial context (industrial applicability)

Novelty (Quantitative)

- The requirement generally means that the information must not have been available the public prior to the original application date (priority date)
- If the invention has already been disclosed in literature then it cannot be new
- The disclosure must have taken place within a particular country or anywhere in the world
- The discovery of things already existing in nature is not an invention

Inventive step (Qualitative)

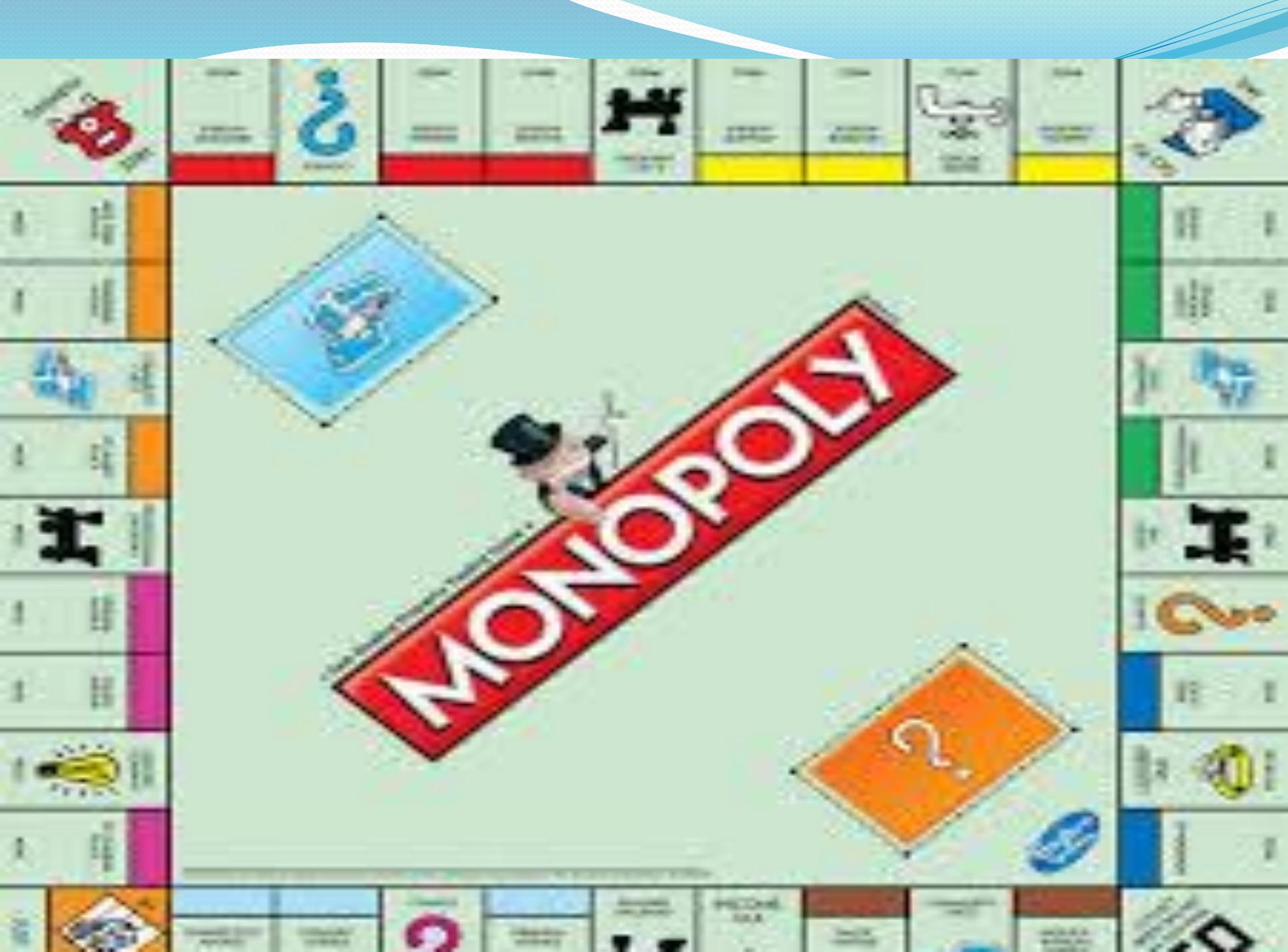
- The invention must not only be new
- But it must represent a development over existing technologies (Aha!!!)
- Must represent a technological breakthrough
- It must not be obvious to a person skilled in the art

Industrial applicability

- The invention must be capable of being made or used in any kind of industry
- Industry in this sense is any physical activity of a technical character
- It should not be too academic- ordinary skilled persons should easily appreciate why the invention is useful

The Right to Exclude

- A patent gives the patent holder the right to exclude others from:
 - making,
 - using,
 - Selling
 - patented pharmaceuticals
- Patent holder may block importation of pharmaceuticals



MONOPOLY



Too much IP vs too little IP

Too Much

- 1) The public cannot use new innovations
- 2) Innovation stagnates because inventors cannot improve them
- Too little:
 - Competition stifles innovation by making research less profitable

Patents and Pharma Monopolies

- Patents justified on grounds that they provide incentives for pharmaceutical invention and innovation
- Costs & risks of pharma R&D (clinical trials)-
 - A 2014 study by Tufts Center for the Study of Drug Development estimated the cost of developing and seeking marketing approval for a new drug at \$2,558 million

Tufts estimation

- The basis for the estimation of the sum of \$2,558 is as follows:
 - “Average out-of-pocket cost of \$1,395 million”
 - “Time costs (expected returns that investors forego while a drug is in development) of \$1,163 million”
- Blockbuster drug development models
 - Drugs that earn companies more than \$1 billion dollars-therapeutic breakthroughs and aggressive marketing

BIG PHARMA

RESEARCH
DIVISION

PROFIT
DIVISION

3RD WORLD GENOCIDE
DIVISION



Patents Divert R&D

- Patents incentivize big pharma to divert R&D into areas that might yield patentable results.
- Away from areas characterised by great medical need but absence of effective demand



Patents Divert R&D

- *“Most of the money now invested in R&D is spent on products of limited medical benefits*
 - *due to strong economic incentives to invest in similar products within a therapeutic class*
 - *and the tendency to use R&D budgets to generate information useful for marketing similar products*
 - *and maintaining ties with prescribing physicians.”* Jamie Love



Our goal isn't really to cure cancer, but to turn it into a long-term profitable business!



Source: @OrganicLiveFood



BURNHAM INSTITUTE for MEDICAL RESEARCH
From Research, the Power to Cure

The 10/90 Gap

- Patents divert R&D towards medicines that are represented by rich or lucrative markets
- Diseases predominantly affecting the global poor are neglected
- Result: the 10/90 R&D gap
 - The Global Forum for Health Research found that only 10% of worldwide expenditure on health R&D targets problems that primarily affect the poorest 90% of the world's population.

Neglected Diseases

DALYs, 2004

Neglected tropical disease	DALYs (in thousands)
Human African trypanosomiasis	1673
Chagas disease	430
Schistosomiasis	1707
Leishmaniasis	1974
Lymphatic filariasis	5941
Onchocerciasis	389
Ascariasis	1851
Trichuriasis	1012
Hookworm disease	1092

The global burden of disease: 2004 update. Geneva, World Health Organization, 2008.



MEDICAL EXAMINER HEALTH AND MEDICINE EXPLAINED. MARCH 24 2015 11:33 AM

Slate   

The Most Neglected Disease

Tuberculosis isn't history, and it's much more dangerous than malaria or Ebola.

By Jens Erik Gould

  
1.3k 318 14



The Ebola Epidemic Is Coming to an End. Don't Celebrate.



Long Before A.I. Was Generating Nervous Think Pieces, This Robotic Turk Was Raising Eyebrows

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Suggested solutions to the neglected diseases problem

- **Reduce over-dependence on the patents system as an incentive for medical research**
- **delink price** of pharmaceutical products from the **costs of medical R&D.**
- Reward system, public funding of R&D,

What is TRIPS? Why Does it matter?

- The Agreement on Trade Related Aspects of Intellectual Property Rights
- The TRIPS Agreement came into force in 1995
- Minimum standards agreement
 - Introduced minimum standards for protecting and enforcing IPRs-
 - Members might introduce higher standards if they wish to

STATE OBLIGATIONS UNDER THE TRIPS AGREEMENT

- TRIPS obliges members to provide patent protection for inventions (products/processes)
 - in all fields of technology
- So long as they are new, inventive and capable of industrial application (useful)
- For a minimum term of 20 years

Non-discrimination

- The TRIPS agreement prohibits discrimination with respect to enjoyment of patent rights on the basis of:
 - The field of technology
 - Origin:
 - whether products are imported
 - or locally produced

IN RETURN,

- WTO members promised benefits of a regulated global trading regime, such as increased market access for developing Countries

Why Does TRIPS Matter?

- Patents create monopolies- adversely impact prices
- The inappropriate implementation of the TRIPS agreement can stifle generic competition and be costly for poor nations

IP and Access to medicines

- Until 2001- cost was a factor in the compilation of the WHO (Model) List of Essential Medicines
- Many essential drugs, ARVs inclusive excluded from the list due to patents

- It was irrelevant whether the drugs were medically essential
- As long as they were considered too expensive
- Cost limitations eliminated in 2001
- Hopefully, the number of patented drugs will increase on the list. (See Ford (2004), Patents , Access to Medicines and the Role of NGOs, Journal of Generic Medicines, Vol.1 (2))
- Patents remain an obstacle to access to generic versions of patented medicine



MEDECINS SANS FRONTIERES

- A recent MSF Report reveals that Patents still constitute an obstacle to access to newer drugs, especially in middle-income countries.
 - *Untangling the Web of Antiretroviral Price Reductions, 2014*
 - **Highlights:**
 - Drugs prices usually drop when there is competition from generic manufacturers
 - The price of first- and second-line ARVs have decreased owing to increased generic competition.
 - The price of first line treatments dropped from over \$10000 ppy in 2000 to around \$116ppy today for recommended regimens

Newer versions of Medicines still remain expensive

- Despite being more efficacious and better tolerated
- Second line- cost more than double the first line regimens
- **But**-Prices of most sources of 2nd line combinations continue to fall due to generic competition
- This is because Indian generic producers have now started producing generic (non-patented) versions of patented drugs
- The development has been partly triggered by Indian Civil Society groups –who opposed the granting of secondary patents for Lopinavir/ritonavir patent
 - using patent opposition strategies- ref –
 - <http://patentopposition.org/drugs>
- However darunavir a promising drug still costs \$810ppy

Third-line or salvage regimens

- Remain very expensive in middle-income countries e.g Armenia-more than US\$13,000 ppy- for raltegravir.
- Priced nearly 15 times higher than 1st line regimes
 - RAL+DRV+r+ETV costs \$2006 ppy
 - DRV patented until 2025 in South Africa
 - The high price owing to extensive patent protection in India on RAL- expiring 2022.
- Patents on newest drugs continue to block generic competition
- Future access scenario – bleak as people with HIV/AIDS live longer –the need for new combinations becomes imperative.



- **Abacavir Sulphate (ABC) – Wellcome (GSK)**

–

- Expired -2010
- hemisulfate salt, AP2009 (expiry 2018)
- composition for ped.use, AP 1212, (expiry 2019),
- Comb with 3TC or FTC (and AZT), AP 652 (expiry 2016)
- **Atazanavir—Norvatis-** No ARIPO Patent, (Expiry 2017)

- **Darunavir –Searle Monsanto –No ARIPO Patent (Expiry 2022)**
 - Pseudo polymorph- (Expiry 2013) -----AP 2052
- **Didanosine (enteric coated), BMS, AP1206, (expiry 2018)**
- **Efavirenz (EFV), Merck (MSD), No ARIPO patent (Expiry August 2013)**
 - Comb with FTC/TDF (Atripla), Gilead/MSD, No Aripo Patent, (Exp2026)
- **Lamivudine (3TC), IAF Biochem/GSK, AP 136, (Expired: Feb 2010),**
 - Liquid composition, AP 1141, (Expiry 2018)

ARV Patents

- **Lopinavir (LPV)**, Abbot, No ARIPO Patent
 - Lopinavir (LPV/r) –tablet formulation- (Expiry 2026) No ARIPO Patent
- **Nevirapine (NVP)**, Boerlinger, Extended Release Formulation, ARIPO Patent status unknown, (Expiry 2028)
- **Ritonavir** – No ARIPO patent
- **Rilpivirine**- Janssen (TMC 278) (Expiry 2022) AP2022
 - Salt Form – (Expiry 2025) AP2478
 - Comb w/FTC+ TDF – Tibotec Gilead (Expiry 2024) AP 2109.

- **Tenofovir Alafenamide Fumarate** Gilead (Expiry 2021)- AP1466
- **Tenofovir Disoproxil Phosphate Fumerate – Viread-(TDF) , (Expiry 2018)**
 - Comb w/FTC+RIL – Tibotec Gilead -2024 (Granted AP 2109)
- **Emticitabine-** Emory Univ. (Gilead)- 2011/12 ---No ARIPO Patent
 - Comb w/TDF (Truvada), (Expiry 2024) AP2109
- **Etravirine-** Jansen Tibotec- (Expiry 2019) AP 1683
 - Solid Formulation- (Expiry 2020) AP 1639
- **Zidovudine - Expired**

Dolutegravir

- The FDA recently (13/08/2013) approved **dolutegravir (DTG)** [**Tivicay**] (a protease inhibitor- and a promising drug) – effective at reducing viral load and fewer side effects
- Shown to be promising in 1st line
- Clinical trial data reveals that ABC/3TC/DTG more promising superior to recommended TDF/FTC/EFV- in achieving viral suppression&control (MSF)
- GSK/Shionogi -Patents for intermediates useful for the synthesis of dolutegravir
- ARIPO designated in international application

TB

groundup.org.za/content/life-saving-tb-drug-costs-r676-pill



Life-saving TB drug costs R676 per pill!

26 November 2013 - Koketso Moeti and GroundUp staff



Phumeza Tisile, who was cured of drug-resistant TB, calls for more access to life-saving TB drugs. Photo by Roy Potterill.

NEWS Over 15,000 people were diagnosed with drug-resistant tuberculosis (TB) in South Africa last year. The risk of death for people with ordinary treatable TB is high. But it is much higher for patients whose illness cannot be treated using the standard TB medicines.

Development of new TB drugs is painfully slow, and one of the more promising drugs to emerge recently is extremely expensive.

The drug is called linezolid and it is patented by the multinational pharmaceutical company Pfizer. One pill costs R676 per day.

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NCDs

The screenshot shows a web browser window with the URL www.independent.co.uk/news/uk/home-news/the-real-cancer-killer-rip-off-prices-for-drugs-set-by-profiteering-big-pharma-giants-8591825.html. The page features a navigation menu with categories like NEWS, VIDEO, PEOPLE, VOICES, SPORT, TECH, LIFE, PROPERTY, ARTS + ENTS, TRAVEL, MONEY, INDYBEST, STUDENT, and OFFERS. The main headline reads "The real cancer killer: rip-off prices for drugs set by 'profiteering' Big Pharma giants". Below the headline is a large image of a red liquid being dispensed from a syringe. To the right, there is a sidebar with a "100 NOW TRENDING" section, where the top item is "1 Whenever you think of migrants arriving in Europe think of this image".

glivec - Fufuzani ndi Goo... x
www.msface.org/sites/... x
The real cancer killer: rip-c... x
www.independent.co.uk/news/uk/home-news/the-real-cancer-killer-rip-off-prices-for-drugs-set-by-profiteering-big-pharma-giants-8591825.html

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100 NOW TRENDING

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- **Trastuzumab Emtansine (Herceptin)**
 - Swiss pharmaceutical giant recently announced that it is relinquishing the patent for its anticancer drug Herceptin
 - tactical move to avoid compulsory licensing and bad publicity
 - Costs more than £90,000 per patient per year



- 
- 27 July 2013- Indian Federal Board of Patent revoked a patent on a slightly modified form of a breast cancer drug **Lapatinib** (sold by GSK as Tykerb)
 - But allowed other patents that will protect the drug from generic competition until 2019.

- 
- Cervical Cancer – most prevalent for women in LDCs
 - Vaccine –patented – very expensive- (WHO Global Report on NCDs)
 - No easy compromise around cancer drugs

● Treatment for

- Chronic myeloid leukaemia
- Gastro Intestinal Stromal Tumour (GIST) – a rare type of stomach cancer
- Acute lymphoblastic leukaemia that is Philadelphia chromosome positive
- A rare type of sarcoma called dermatofibrosarcoma protuberans

£21000 per patient per year.



Article 27 of the Universal Declaration of Human Rights

- (1) Everyone has the right freely to participate in the cultural life of the community, to enjoy the arts and to share in scientific advancement and its benefits.
- (2) Everyone has the right to the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author.

General Comment No. 17 (2005)

- *“The right of authors to benefit from the protection of the moral and material interests resulting from their scientific, literary and artistic productions **cannot be isolated** from the other rights recognized in the Covenant. States parties are therefore obliged to strike **an adequate balance** between their obligations under article 15, paragraph 1 (c), on one hand, and under the other provisions of the Covenant, on the other hand, with a view to promoting and protecting the full range of rights guaranteed in the Covenant. **In striking this balance, the private interests of authors should not be unduly favoured and the public interest in enjoying broad access to their productions should be given due consideration.....States parties thus have a duty to prevent unreasonably high costs for access to essential medicines.**”*

UN Human Rights Council Resolution A/HRC/23/L.10/Rev.1 of 11 June 2013

- On access to medicines in the context of the right of everyone to the enjoyment of the highest attainable standard of physical and mental health
- Urges
 - "States to promote access to medicines for all, including through the use, to the full, of the provisions of the Agreement on Trade-Related Aspects of Intellectual Property Rights which provide flexibility for that purpose."

FLEXIBILITIES

- The TRIPS agreement obliges members to abide by minimum standards of IP protection
- However, member states retain important policy options, flexibilities and safeguards to facilitate access to medicines:

TRIPS FLEXIBILITIES INCLUDE

- **Preventative** -
 - exclusions from patentability- exclude new uses, minor modifications, methods of treatment
 - Setting and applying strict patentability criteria—ensuring that only deserving inventions are protected
 - The idea is to prevent “evergreening”

“Ever greening” 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.” Novartis AG v India

Section 3(d) of the Indian Patents Act.

Incorporated into the Act in January, 2005

Section 3(d) of the Indian Patents Act: “The following are not inventions within the meaning of this Act,

- 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.”

Norvatis AG v Union of India & ORS

- Norvatis applied for a patent in India over a beta-crystalline form of Glivec (Gleevec) – Imatinib Mesylate
 - Used to treat chronic myeloid leukemia
- The patents office rejected the application in the basis that it was “*a mere discovery of a new form of a known substance which did not result in the enhancement of the known efficacy of that substance (Glivec)*”
- Norvatis challenged the decision
- The Supreme Court ruled against it



SUPREME CT

- *“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.”* **Aftab Alam J**
- <http://www.ip-watch.org/2013/04/04/the-judgment-in-novartis-v-india-what-the-supreme-court-of-india-said/>

Norvatis Case- “Efficacy”

- *“Efficacy means “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..... the test of efficacy would depend upon the function, utility or the purpose of the product under consideration. 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.”*

Properties that have nothing to do with therapeutic efficacy: Novartis

- The physico-chemical properties of beta crystalline form of Imatinib Mesylate, namely:
 - more beneficial flow properties
 - better thermodynamic stability, and
 - 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.”*

Bioavailability

“Increased bioavailability alone may not necessarily lead to an enhancement of therapeutic efficacy. Whether or not 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.”

- **Aftab Alam J**

Holding

- *“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.” Aftab Alam J*

Preventative Flexibilities

- Allowing pre-grant and post-grant opposition
 - <http://www.patentoppositions.org/>
- **Waivers and transition periods-
including LDC waivers**

Preventative Flexibilities: Exclusions from Patentability

- Members may exclude from patentability inventions
 - If the commercial exploitation of the invention needs to be prevented to protect *ordre public* or morality
 - Including to protect human, animal or plant life or health or to avoid serious prejudice to the environment
- **States have the right to protect public interest**
 - The term *ordre public* is derived from French Law
 - **It expresses concerns about matters threatening the social structures which tie the society together**

TRIPs, Articles 27.2

Members may exclude from patentability:

“diagnostic, therapeutic and surgical methods for the treatment of humans or animals” (Art.27.3(a))

Remedial Flexibilities

- Parallel importation
 - Importation without the authorisation of the patent holder of a patented product which has been placed on the market in a different country without the consent of a patent holder
 - This normally happens when the product in question is cheaper in that market
- Voluntary licensing
 - This is where a patent holder voluntarily permits a third party to manufacture a patented product (Kenya- Cosmos Ltd - voluntarily licensed by GSK & Boehringer to manufacture 3TC, AZT and NPV)

- Use of an innovation without authorization of patent holder
- States have
 - the freedom to determine the grounds upon which such CLs are granted
 - the right to determine what constitutes a national emergency or other circumstances of extreme urgency-
 - Compulsory Licenses-
 - Compulsory Licenses Solely or Largely for export (30th August decision)
 - Public non-commercial use/Government use

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REPUBLIC OF ZAMBIA
MINISTRY OF COMMERCE, TRADE AND INDUSTRY

OFFICE OF THE MINISTER
 P.O. BOX 31
 LUSAKA

In reply please quote

No.

COMPULSORY LICENCE No. CL 01/2004

The Government of Zambia, conscious that the HIV / AIDS pandemic constituted a serious handicap in the national struggle against hunger, illness, under development and misery;

and taking into consideration that high rates of morbidity and mortality have put Zambia among the ten countries in Africa most hit by this disease. Current estimates are that, at the end of 2003, over **917,718** Zambians were infected by HIV, of whom unestimated number are suffering from full-blown AIDS. The AIDS death toll is so far in excess of **835,904** and about **750,504** children have been orphaned by this pandemic, creating a situation where 75% of house-holds below 14 years headed more than 130,000 orphans, and that children are a total of 1,905,000, and that;

In spite of the multiplicity and diversity of vigorous prevention campaigns, the spread of the virus is still on an upward trend as shown by the high number of infections;

Taking into account the gravity of the situation being faced by most African Countries, including Zambia, the need to ensure access to drugs at affordable prices, while respecting the protection of intellectual property, is well recognised. For this reason;

On 14 November, 2001 the World Trade Organisation, while recognising Members' commitment to the TRIPS Agreement, declared the right of each Member State to take measures aimed at protecting public health and in particular to promote access to medicines for all, by utilising to the full, the flexibilities in the TRIPS Agreement relating to among others, the granting of compulsory licences, in cases which constitute a national emergency or other circumstances of extreme urgency and of public health crisis including those relating to HIV/AIDS, tuberculosis, malaria or other epidemics which can represent a national emergency or other circumstances of extreme urgency.

Remedial Flexibilities: Exceptions – TRIPS Article 30.

- Research experimental use exception
- Early working (Bolar)
 - **“allows interested (generic) manufacturers to start producing test-batches of a product before the patent expires, in order to collect the necessary data for submission to the registration authorities; this will reduce the delay for generic products to enter the market after the patent has expired, and thereby enhance competition.” (WHO)**
- EU v Canada, WT/DS114/R 17 March 2000
- https://www.wto.org/english/tratop_e/dispu_e/7428d.pdf

EU v Canada

- The EU Challenged two provisions of the Canadian Patent Act that permitted generic drug manufacturers to override rights of patent owners in some exceptional cases :
- The provisions included the:
 - (i) "regulatory review provision (Sec. 55.2(1))" 2; and
 - (ii) "stockpiling provision (Sec. 55.2(2))"

Summary EU vs Canada

- Stockpiling provision:
 - “The Panel concluded that the stockpiling provision was inconsistent with Art. 28.1 as it constituted a “substantial curtailment of the exclusionary rights” granted to patent holders.” WTO
- Regulatory review provision
 - “The Panel found that Canada's regulatory review provision was justified under Art. 30 by meeting all three cumulative criteria: the exceptional measure (i) must be limited; (ii) must not “unreasonably conflict with normal exploitation of the patent”; and (iii) must not “unreasonably prejudice the legitimate interests of the patent owner”, taking account of the legitimate interests of third parties.”
 - These three cumulative criteria are necessary for a measure to be justified as an exception under Art. 30.

Remedial Flexibilities

- Enforcement related
 - decriminalization of infringement
- Competition laws

TRIPS WAIVER FOR LDCs

- LDCs are exempted from implementing the general provisions of the TRIPS save for Articles 3, 4 and 5 until 1st July 2021

Paragraph 7 of the Doha Declaration

- “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.”

Pharma Extension

- ❑ LDCs are exempted from implementing protecting and enforcing patents on pharmaceuticals until 1 January 2033.
- ❑ The waiver is in line with article 66 of the TRIPs
 - ❑ which recognizes the “the special needs and requirements of least-developed country Members, their economic, financial and administrative constraints, and their need for flexibility to create a viable technological base.”
 - ❑ The exemption was for an initial period of 10 years.
 - ❑ This period was made subject to extension upon a duly motivated request by an LDC.

Extension

- The extensions do not prevent LDCs from reforming existing Patent legislation to take advantage of TRIPS flexibilities to achieve developmental/social objectives
 - Especially in the areas of Public Health and Agriculture.
- What is important is that LDCs should actively use the policy space that has been given to design our IP laws in line with their national needs and priorities.

Uganda Industrial Property Act, 2014

- Section 8(3) The following shall not be regarded as inventions and shall be excluded from patent protection—
“pharmaceutical products and test data until 1st January 2016 or such other period as may be granted to Uganda or least developed countries by the Council responsible for administering the Agreement on trade related aspects of intellectual property under the World Trade Organization.”

DECLARATION ON TRIPS AND PUBLIC HEALTH (Doha, Sept.2001)

- Recognized the “importance of creating a positive, mutually reinforcing link between the IP system and access to medicines”
- Recognized the gravity of public health problems- HIV/AIDS, TB Malaria
- The TRIPS does not and should not prevent members from taking measures to protect public health
 - Should be interpreted in a manner supportive of public health
- Reaffirms the rights of member states to use to the full the flexibilities provided for under the TRIPS

Paragraph 6 of Doha

- Recognised that 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
- Reason – compulsory licence is subject to strict conditions- including that CL shall be authorized predominantly be for the supply of the local market [Art. 31(f)]

PARAGRAPH 6 SOLUTION

- The decision of the General Council of the WTO of 30th August 2003 – on the implementation of Paragraph 6 of the Doha Declaration
- Waives/Relaxes the requirement of TRIPS Art 31(f) relating to CL predominantly for domestic use
- Allows CL for exports to countries with little or insufficient manufacturing capacity (incl. LDCs)
- Intending to import generics to address public health problems
- Subject to strict conditions

Paragraph 6 system

- Waives the requirement that CL should be predominantly for domestic use- where it is necessary to export to a country with limited capacity
- Modifies the requirement to pay adequate remuneration for CLs – avoid double remuneration to the holder given that CL issued in both the importing and exporting country
- Remuneration to take into account economic value to the importing member

Paragraph 6 conditions

- Pre-requisite for the use of the system- the TRIPS Council must be notified by importing member
- Contents of notification
 - Names and expected quantities of products
 - Confirmation of eligibility
 - Where a product is patented by importer-confirmation that a CL has been granted or will be granted
 - Alternatively an LDC must state that it is availing itself of the additional transitional period

Paragraph 6 Solution

- Exporter must issue a CL permitting production for exportation-
- Conditions of CL-
 - only amounts necessary to meet needs of the importing member to be manufactured
 - Entire production to be exported
 - Product must be clearly identified as having been produced under this system – through labelling/marketing/colouring/packaging/shaping
 - Details of shipment must be placed on website by licensee-distinguishing features
 - Exporting member to notify TRIPS council about CL conditions- very detailed info- names of licensee, products and quantities, destination, duration of licence,

Measures to prevent diversion/re-exportation

- Exporting members obliged to attach conditions to licence
 - Only the amount necessary to meet the needs of the importer can be manufactured
 - Entire production should be exported to the importing member
 - Clear identification requirements- specific labelling, marking, special packaging, and/or special colouring, shaping of products-
 - Provided that these are feasible and do not impact on price
 - Importing member-
 - Put in place measures to prevent re-exportation
-
- System too complex. Bureaucratic
 - Not an effective / expeditious solution to LDC problems

Indian Patents Act

- 92A. Compulsory licence for export of patented pharmaceutical products in certain exceptional circumstances.—
- (1) Compulsory licence shall be available for manufacture and export of patented pharmaceutical products to any country having insufficient or no manufacturing capacity in the pharmaceutical sector for the concerned product to address public health problems, provided compulsory licence has been granted by such country or such country has, by notification or otherwise, allowed importation of the patented pharmaceutical products from India.



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- (2) The Controller shall, on receipt of an application in the prescribed manner, grant a compulsory licence solely for manufacture and export of the concerned pharmaceutical product to such country under such terms and conditions as may be specified and published by him.

COMFORT LETTERS

- A number of LDCs have introduced the practice of “comfort letters” - to procurement authorities and generic suppliers indicating they were taking advantage of paragraph 7 flexibility not to enforce patents.
- Some take a short cut of simply issuing procurement letters stating that “the government approves procurement of a generic medicine irrespective of its IP status.”
- This appears to be a result of misreading World Bank Procurement Guidelines
- However, it is not adequate merely to say that LDCs were exempted from implementing TRIPS

Comfort Letters

- The fact that LDCs do not have to enforce pharmaceutical patents is not self-executing
- The transition period **gives LDCs** freedom to choose whether or not to protect trademarks, patents, geographical indications etc
- **If they** choose to protect it – then they have to apply the provisions on non-discrimination

Comfort Letters

- This lax procedure is being questioned by Republicans in the US Congress
- Pressure is being exerted on the Global Fund to tighten up its due diligence standards (the ones that require compliance with international and national law).
- There is need for explicit national legal authorization allowing procurement letters, informal compulsory licences, non-enforcement of existing patents on medicines etc.

The best approach would be to repeal patent rights for any pharmaceutical products – hoping that the waiver will be extended beyond 2016

TRIPS PLUS MEASURES

- Most countries that do business with the US and other developed countries are members of the WTO
 - And obliged to comply with the TRIPS
- But they sometimes enter into bilateral agreement or Free Trade Agreements that require them to abide by stricter rules than the TRIPS requires (TRIPS-PLUS rules)
 - In return for trade benefits
- These agreements may adversely affect access to medicines

Examples of TRIPS+ measures

- Limitation of uses of compulsory licences – to emergencies and public non-commercial use
- Test data exclusivity- (data that companies use to get regulatory approval for their medication)
 - TRIPS does not provide for data exclusivity- it only provides for the protection of test data against unfair competition. But countries are coerced to guarantee exclusive use of data for 5 years

TRIPS+

- Patent term extensions-
bilateral agreements
sometimes require states to
extend patent terms
beyond 20 years to
compensate for the time
lost in obtaining
marketing approval
- Bilateral agreements may
prevent parallel
importation and the use of
the Bolar exception



Anticounterfeiting

- Art. 51 defines “**Counterfeit trademark goods**” as goods, including packaging, bearing without authorization a **trademark**
 - which is identical to the trademark validly registered in respect of such goods,
 - or which cannot be distinguished in its essential aspects from such a trademark
 - **and which thereby infringes the rights of the owner of the trademark in question under the law of the country of importation.”**
- Counterfeits are goods that violate trademark laws and calculated to confuse or deceive consumers.
- But there is a growing tendency to equate generics with counterfeits
- *Ochieng&Ors v The A-G*, Petition #409/2009.
- Kenya passed an **Anti-Counterfeit Act**, 2008 which effectively equated generics to counterfeit
- “The court ordered Kenya’s Parliament to review the act and to remove ambiguities that could result in arbitrary seizures of generic medicines under the pretext of counterfeits. ”

Fight
Counterfeits



NOT Generic
Drugs



THANK YOU

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