

**PARA 6 OF DOHA DECLARATION
&
INDIA'S RESPONSE**

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The Real basic problem

The gravity, magnitude & the urgency of the problem

- *"HIV/AIDS will soon become the worst epidemic of infectious disease in recorded history, eclipsing both the bubonic plague of the 1300's and the influenza epidemic of 1918-1919, which killed more than 20,000,000 people worldwide."*
- *"More than 34,300,000 people in today are living with HIV/AIDS.*
- *95 percent living in the developing world."*

The Real basic problem

The gravity, magnitude & urgency of the problem

Future generation

- Among children age 14 and under worldwide: -
 - more than 3,800,000 have died from AIDS,
 - more than 1,300,000 are living with the disease;
 - in 1 year alone--1999--an estimated 620,000 became infected, - 90 percent were babies born to HIV-positive women.
- *"Worldwide, there have already been an estimated 18,800,000 deaths, of which more than 80 percent occurred in sub-Saharan Africa."*
- *"By the end of 1999, 13,200,000 children have lost at least one parent to AIDS, including 12,100,000 children in sub-Saharan Africa, and are thus considered AIDS orphans."
(extracts from US Bill)*

Delay dangerous

Man made problem - Absurd Patent Law

Its gravity, magnitude & the urgency

Plight of developing countries under product patent -

- Many AIDS/HIV drug patented
- AZT imported & marketed by MNC patentees at US \$ 10,000 per patient.
- With no generic drug industry in developing & LDCs to compete MNCs maintain prices
- Not even 1% of AIDS victims in developing countries can afford - 99% dying untreated.

Depend on India's generic supplies for requirements

Man made problem - Absurd Patent Law Its gravity, magnitude & the urgency

Generic production in India - the hope & expectation

- These drugs not patented in India
- CIPLA produced & offered it at US \$350/-

Can India under product patent
continue to help?

DOHA DECLARATION

- Accepts the gravity, magnitude & urgency of the health problem
- Asserts primacy of public health over commercial interests,
- Recognises members rights & urges all nations to take all measures necessary & grant CL to provide healthcare to their people, treating TRIPS flexible.

The Para 6 problem

Deeply concerned, that access to such medicines would be denied to people in developing & LDCs WTO Ministerial Conference at Doha recognises

"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"

And instructs the TRIPS Council to find an expeditious solution to this problem - but fails.

Aug. 30 Decision of WTO Council unworkable

INDIA'S RESPONSE

Under product patent

Patent's Amendment Ordinance/Act '05

Limit the problem :-

- Grant only for genuine inventions 9000 patent claims ('Me-too' drugs) by limiting - possible candidates - about 300 NDAs
- Defining - 'invention' - 'inventive-step', 'pharmaceutical substance'.
- Excluding patents for 'new use', salts, esters, new forms etc of same entities.

Protection against wrongful grants:-

- Pre & post grant opposition, revocation.

Facilitate generic production for quicker response:-

- Experiments & Clinical trials permitted.
- In se. 86 time for patentees response limited to six months.

INDIA'S RESPONSE

Sec. 90(i) relating to compulsory licence amended:

Clauses (vii) and (viii) redrafted to clarify:

- CL granted for pre-dominant purpose of supply in Indian market, the licensee may export the patented product, Similar facility of export also permitted when licence granted to remedy anti-competitive practice

This is a good provision - will help in stock piling in anticipation of export order & CL.

The words - 'if needed in both the clauses should be deleted as unnecessary & create doubts & disputes'.

INDIA'S RESPONSE

Sec. 92A good beginning but needs improvement

Significant points:-

- More practicable than Aug. 30 Decision of WTO Council
- No requirement of eligible importing country
- Pharmaceutical product - brought coverage, i.e. not restricted to AIDS/HIV pandemics etc.
- No requirement of CL if no patent protection in importing country
- However, no guidelines provided for terms & conditions to be prescribed & reasonable royalty to be fixed by the Controller.
- It also leaves the matter open for royalty claimed in both the countries.
- Guidelines must be clearly defined.

Guidelines for terms & conditions

- Should provide for repeat supplies for the same product to the same party under the same CL.
- Should prescribe reasonable royalty as not exceeding 2% of net ex-factory value.
- Should avoid any other restrictive conditions - particularly those prescribed by Aug. 30 Decision.

Rationale & justification for royalty

- For fixing royalty the facts - that the patentee, by maintaining the price at levels which only about 1% of the affected population can afford, & avoiding to reduce the price, has of his own volition, left large market & demand unserved in either or both countries.
- This means that the economic value of authorization is nil from the consumers to be covered by CL & also there is no loss to him by grant of CL.
- In sec. 92A scheme royalty may be claimable at both ends???

Rationale & justification for royalty

- Canada has recently amended its Act to provide for rate of royalty payable specified for each country & only in the importing country. For India the rate is 1.6%.
- In USA the royalty has been fixed at even 1% in some cases.
- Any royalty not exceeding 2% can be justified as reasonable royalty & also as *'adequate remuneration ...taking into account the economic value of the authorization.'*

The procedure for CL under 92A Patent Rules (amended in 2005) 96-102

Unjustified imposition

Rule 96 prescribes elaborate procedure:-

- provides for prima-facie rejection by Controller
- Publication to invite opposition as per sec. 87(2) (which allows for opposition by the patentee and also by any person interested).
- Hearing of opposition
- Time frame which will delay the grant at least by one year.
- No appeal is provided for applicant for CL. The decision of the Controller would be final.
- **None of these provisions are required by sec. 92A or Art. 31 of TRIPS.**

Suggestions

- Provide simpler & faster procedure for CL u/s. 92A.
- Not to accept any of the restrictive conditions of Aug. 30 Decision.
- Reasonable royalty to be fixed - not exceeding 2%.
- To avoid restrictions by way of data protection or data exclusivity in Drug Rules.
- Not to agree to any amendments of PCT or harmonization PLT/SPLT.

Suggestions

Suggest to all developing & LDCs :-

- LDCs exempted from TRIPS Patent provisions must not give up or compromise.
- Not to extend any TRIPS plus patent protection under Free Trade or Regional Agreements.
- To reject Aug. 30 Decision.
- To adopt stricter standard for patentability.
- To adopt royalty for CL - not exceeding 2%.
- Not to accept data exclusivity or data protection restrictions.
- Not to agree any amendments of PCT or harmonization PLT/SPLT.

Thank You