

Highlights of the Patent Amendment Act 2005 with reference to Pharmaceuticals

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THE NATURE OF PHARMACEUTICAL INNOVATION

Radical v. Incremental Innovation

RADICAL INNOVATION

A new product, process or system that results from a technological breakthrough

INCREMENTAL INNOVATION

- ✘ Involves technical modifications of an existing product, process or system that results in some improvement or enhancement thereto.

CLINICAL VALUE OF INCREMENTAL PHARMACEUTICAL INNOVATION

- ✘ Increased effectiveness over prior known drug products

SOCIAL AND ECONOMIC VALUE OF INCREMENTAL PHARMACEUTICAL INNOVATION

- ✘ Crucial revenue to support new drug discovery programs
- ✘ Mitigate the risks of new drug development
- ✘ Basis for the discovery of breakthrough drugs

RADICAL INNOVATIONS – LIMITATIONS

- ✘ Side-effects
- ✘ Extremely costly and highly risky

PHARMACEUTICAL PRODUCTS UNDER INDIA'S PATENT LAWS PRIOR TO 2005

- ✘ Precluded the patenting of pharmaceutical products

TRIPS AGREEMENT

- ✘ The terms of the TRIPS Agreement required India to provide patent protection for pharmaceutical products by January 2005. India purported to comply with TRIPS obligations through a number of patent law amendments culminating in the passage of the Patents (Amendment) Act, 2005.

2005 AMENDMENT

- ✘ The Act for the first time introduces pharmaceutical product patents.
- ✘ The Act attempts to balance the competing interests of a variety of stakeholders

SECTION 5 PATENT ACT

- ✘ In the case of inventions being claimed relating to food, medicine, drugs or chemical substances, only patents relating to the methods or processes of manufacture of such substances could be obtained.

SECTION 3(D): NEW FORMS OF KNOWN PHARMACEUTICAL SUBSTANCES

- ✘ Incremental pharmaceutical innovations—including new forms of known pharmaceutical substances—are not patentable unless they result in significantly enhanced “efficacy” of the active substance.

DRAWBACK OF SEC. 3(D)

- ✘ Discourages R&D into such innovations
- ✘ Incentives for incremental innovation can lead to decreases in costs and increased access to medicines

LIMITATION OF ENHANCED EFFICACY REQUIREMENT

- ✘ Functional drawbacks

NOVARTIS CASE

- ✘ The challenge to the amended section was mainly on two grounds namely,
 - ✘ (a) it is not compatible to the TRIPS; and
 - ✘ (b) it is arbitrary, illogical, vague and offends Article 14 of the Constitution of India.
- ✘ Novartis contended that the provision gives uncontrolled discretion to the Controller to decide as to whether there is an enhancement in the known efficacy or not.
- ✘ The Madras High Court ruled that the amendment was constitutional

NOVARTIS CASE – INTELLECTUAL PROPERTY APPELLATE BOARD

Novartis was not entitled for a patent on two grounds

It fails to satisfy the requirements under
Section 3(d)

Excessive pricing

GLOCHEM INDUSTRIES V CADILA HEALTHCARE LTD.

- ✘ What has to be examined is the enhancement of known efficacy of stated substance in the context of better therapeutic effect.

RATIONALE FOR SECTION 3(D)

- ✘ To prevent patent “evergreening”

ALTERNATIVES TO SEC. 3(D)

- ✘ Rigorous application of the existing patentability requirements
- ✘ Novelty
- ✘ Non Obviousness
- ✘ Industrial Application

SECTION 3(D)

- ✘ The following is not patentable:
- ✘ Discovery of *a new form of a known substance* that does not result in the enhancement of the known efficacy of that substance
- ✘ *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.
- ✘ Exclusion from patentable subject matter is meant to apply broadly to all derivatives
- ✘ Of a known substance unless they differ “significantly” with respect to “efficacy”:

OPPONENTS V PROPONENTS OF SEC. 3(D)

- ✘ Opponents - Product patents would reduce access to life-saving drugs
- ✘ Would permit patent evergreening.
- ✘ Development of drug products tailored to the needs of Indian patients
- ✘ Proponents - Section was necessary to prevent patent evergreening

TRIPS AGREEMENT V SEC. 3(D)

- ✘ Art 27.1 - Non-discrimination among types of invention
- ✘ Indian Patents Act's categorical exclusion of incremental pharmaceutical innovation from patentable subject matter is in conflict with the international consensus reflected in the TRIPS Agreement.

IMPLICATIONS OF SECTION 3(D) FOR INCREMENTAL PHARMACEUTICAL INNOVATION IN INDIA

- ✘ Restriction of patentability to new chemical entities alone is likely to benefit only MNCs which have the resources and the experience to develop new chemical entities.

REFORMING PATENT ACT

- ✘ If India is to take advantage of the benefits and opportunities presented by incremental pharmaceutical innovation, reform of Section 3(d) is necessary.

COMPULSORY LICENSING

- ✘ Compulsory license is issued for various public interest reasons where the patent owner refused to make the invention available.
- ✘ Compulsory license can be granted after the expiration of three years from the grant of the patent on the ground that
 - ✘ Reasonable requirements of the public have not been satisfied,
 - ✘ Patented invention is not available to the public at a reasonably affordable price,
 - ✘ Patented invention is not worked in the territory of India.

COMPULSORY LICENSING - AMENDMENT ACT OF 2005

- ✘ Automatic compulsory licensing provisions

EXPORT OF PHARMACEUTICAL PRODUCTS UNDER COMPULSORY LICENSING

- ✘ Sec. 92 (A) allowed export of pharmaceutical products under compulsory licensing where the importing country “has by notification or otherwise allowed importation of the patented pharmaceutical products from India”.
- ✘ Amendment Act caps a ‘reasonable’ period of negotiations at six months.

BOLAR PROVISION:

- ✘ Where a potential competitor uses an invention to undertake acts necessary for obtaining regulatory approval before the expiry of the patent term.
- ✘ Amendment of 2002 Excluded from infringement “the act of making, using or selling a patented invention” for the purpose of obtaining information to be submitted to a regulatory authority.
- ✘ The 2005 Act expanded this provision to bring even the act of ‘importing’ within its ambit.

PARALLEL IMPORTS:

- ✘ To prevent market division
- ✘ Price discrimination on a regional or international scale.
- ✘ Section 107A “ it was not an infringement to import a patented product provided such import was from an exporter who was “duly authorised by the patentee to sell or distribute the product”.
- ✘ Patents (Amendment) Act, 2002 - Enables importation of a patented product by any person from a person who is duly authorised by the patentee to sell or distribute it.
- ✘ Amendment of 2005 allows import from a person duly authorised under the law to produce, sell or distribute the product.

IMPLICATIONS OF THE AMENDMENT:

- ✘ impact on the world market
- ✘ rational use of TRIPS flexibilities
- ✘ Effective regulatory mechanism for checks and balances on the availability,
- ✘ access and price of essential drugs
- ✘ build capacity for research and development of indigenous drugs.
- ✘ New use of traditional knowledge based products

THANK YOU