DRUG REGULATION

WHY DRUG REGULATION?

- Modern medicine has come with a cost;
- While modern medicine cures it also has toxic side effects;
- The thalidomide tragedy in the sixties was a turning point in drug regulation;

DRUG REGULATORY LAW REFORMED TO BRING IN RIGOROUS CLINICAL TRIALS

- Regulatory across the world require three phases of clinical trials before approval is granted;
- Phase I generally on health volunteers to check for toxicity, side effects;
- Phase II is on a small number of patients to determine whether the drug is working on the disease;
- Phase III is on a large number of patients in order to see whether the Phase II results stand true for a large number of patients;
- Phase IV is called the pharmaco-vigilance phase – post approval monitoring;

REGULATORY PATHWAY FOR GENERIC MEDICINE

- Generic drugs have to establish only that their drug is bioequivalent;
- Bioequivalence studies generally carried out on healthy volunteers;
- Many ethical issues in India in relation to these drugs;

DRUG REGULATORY FRAMEWORK IN INDIA

- Only DCGI can approve new drugs;
- Generic drugs can be approved by state regulators;
- Clinical trials are regulated by the DCGI

BAYER V. UNION OF INDIA: PATENT LINKAGE CASE

- Bayer sought to argue that the DCGI could not grant approval to any drug if the same was covered by a valid patent;
- Form 44 appended to the Drugs & Cosmetics Rules, 1945 required all generic applicants to disclose the patent status of the drug;
- Section 156 of the Patents Act: Patent to bind Government.—Subject to the other provisions contained in this Act, a patent shall have to all intents the like effect as against Government as it has against any person.

THE BOLAR DEFENSE

[107A Certain acts not to be considered as infringement. -For the purposes of this Act,-(a) any act of making, constructing, [using, selling or importing] a patented invention solely for uses reasonably related to the development and submission of information required under any law for the time being in force, in India, or in a country other than India, that regulates the manufacture, construction, [198] [use, sale or import] of any product;

THE HISTORY OF THE BOLAR DEFENSE

- ***Roche Products, Inc. v. Bolar Pharmaceutical Co.***, 733 F.2d 858 (Fed. Cir. 1984) – patent found to be infringed by the CAFC;
- The US Congress enacted a legislation called the Drug Price Competition and Patent Term Restoration Act over-ruling Roche v. Bolar and clearly allowing for use of a patent to generate regulatory data;
- The Indian JPC that examined the Bill recommended the enactment of a similar provision in Indian law;

THE BOLAR DEFENSE

[107A Certain acts not to be considered as infringement. -For the purposes of this Act,-(a) any act of making, constructing, [using, selling or importing] a patented invention solely for uses reasonably related to the development and submission of information required under any law for the time being in force, in India, or in a country other than India, that regulates the manufacture, construction, [198] [use, sale or import] of any product;

BAYER V. NATCO & ALEMBIC

- Natco was exporting Bayer's patented API to China – same drug was subject to CL proceedings;
- Bayer sued Alembic for patent infringement and filed a writ before the High Court impleading Natco, seeking a writ of mandamus directing the customs to seize the exports;
- Natco pleaded that its export activities would be covered by S. 107A since the API was being exported for regulatory purposes;

BAYER'S ARGUMENTS

(i) that Section 107A of the Patents Act has no application as the acts contemplated thereunder, of making, constructing, using, selling or importing a patented invention, are to be performed within the territory of India and the information from such activity can be submitted with the regulatory authorities either in India or with the countries other than India;

(ii) that Section 107A of the Act does not contemplate export of product per se but is limited to information generated within the territory of India; and,

(iii) that export of a product covered by Compulsory License under the garb of Section 107A of the Act is abuse of the process of law;

DOES THE PROVISION PERMIT EXPORT?

[107A Certain acts not to be considered as infringement. -For the purposes of this Act,-(a) any act of making, constructing, [using, selling or importing] a patented invention solely for uses reasonably related to the development and submission of information required under any law for the time being in force, in India, or in a country other than India, that regulates the manufacture, construction, [198] [use, sale or import] of any product;

THE COURT'S RULING

- The words 'sale/selling' thus, as per their literal/natural/textual meaning are without any geographical limitations and in Section 107A are not to be understood as within India' only and if such sale/selling were to involve transfer of the patented invention/product to a country other than India though would also qualify as export/exporting but would not cease to be sale/selling.

- There is nothing in the language of Section 107A to suggest that only the information generated / collected in India could be transported out of India and not the patented invention. Information generated in India, unless accepted under the law of any other country for granting regulatory approvals for manufacture, sale and import in that country, would be of no use. There is nothing in the language of Section 107A to indicate that the legislature applied itself that the regulatory laws of countries other than India would accept the information generated and collected in India.