Indian Patent Law: 2005
Key Concerns and Recommendations

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PRESENTATION OUTLINE

I. Pharma Innovation Process

II. Regulatory Data Protection

III. Incremental Innovation

IV. Compulsory license

V. Pre –grant opposition

VI. Counterfeit medicine

VII. Patent office infrastructure

PHARMA INNOVATION PROCESS

PHARMA INNOVATION PROCESS

- **Discovery research:**
  Identifies a molecule with specific and potentially biologically useful characteristics as a candidate drug

- **High risk!**

  - **only 5 in 5,000 compounds that are screened enter pre-clinical testing**

  - **only 1 drug in 5 that enters human trials is approved as both safe and effective**

PHARMA INNOVATION PROCESS

Patent protection

- **patents applied for early in a drug discovery programme - often before a candidate drug has been identified - to stop a competitor getting protection first**

- **only available for inventions that satisfy the criteria of being *new,* involve an *inventive* step and are industrially applicable**

- **as in most high-technology R&D, in the case of pharmaceuticals as well, spectacular breakthroughs -so-called “first-in-class products” or new active substances originating from pioneering approaches are rare.**

PHARMA INNOVATION PROCESS

Patent protection

- More usually, products that provide additional therapeutic benefit occurs as a series of incremental improvements in safety, efficacy, and utility standards within the same general "class" of medicines rather than a quantum leap
- Change often occurs in molecules that may seem trivial but they bring about significant change in benefits to patients
- No ‘EVER GREENING’

PHARMA INNOVATION PROCESS

- **Drug development: takes the simple active agent through a complex multi-stage process to a pharmaceutical formulation which is safe and effective for man**

- **Involves numerous steps with stringent testing in animals and man - consumes bulk (70%+) of R&D budget**

- **Clinical trials are the most complex, costly and time consuming aspect of any drug development program Failure of the drug can occur up to the last moment of clinical evaluation**

PHARMA INNOVATION PROCESS

Regulatory Approvals

- **After successful *in vitro* and animal testing, permission must be obtained from the Regulatory Authority to test candidate drug in people in clinical trials**
- **Clinical assessment is in three main phases and the drug must be reassessed and approved by the RA before next testing phase**
- **Drug manufacturer can then apply to the RA for formal approval to sell the drug**
- **All safety and clinical trial results must go to the RA as a Regulatory Dossier of many thousands of pages of proprietary data for a decision whether to approve the new drug**

PHARMA INNOVATION PROCESS

- **pre-clinical tests – ‘in-vitro’ and animal studies If useful and safe, the drug company asks the regulatory authority for permission to test the drug in people. The company must submit all documents and data on pre-clinical studies as well as a detailed plan or protocol for the trial**

clinical trials

- **Phase I: small number of people to see what dose is safe**
- **Phase II: larger number of participants using the appropriate dose over a longer period of time to see if the drug is working and whether it has any long-term side effects**
- **Phase III: researchers give the drug to a much larger group of people over several months or years to see whether the drug remains useful or has any side effects that only show up after a longer period of time**
- **Phase IV: researchers continue to study the drug even after it has been approved: 'post-marketing' trials.**

PHARMA INNOVATION PROCESS

DEMONSTRATION OF SAFETY & EFFICACY: COSTLY & TIME CONSUMING

- **Cost (per drug)**
  - **Today: USD over 1 billion**
  - **1991: USD 231 million**
- **Time: US marketing approval**
  - **1960s: 8 years**
  - **1990s: 14.2 years**
- **Average number of clinical trials and patients has more than doubled since early 1980s**
  - **1981 – 1984: 30 trials / 1,321 patients**
  - **1994 – 1995: 68 trials / 4,237 patients**
- **All data submitted in the process is proprietary**

REGULATORY DATA PROTECTION

Regulatory Data Protection

- **A key component underpinning the high investment R&D based agrochem, biotech and pharmaceutical industries is RDP**

- **RDP - period during which test and clinical trial data of one company may not be used or referred to in an application by another company to obtain a marketing authorization**

- **RDP is an intellectual property right**
  - ✓ **recognized in the GATT TRIPS Agreement**
  - ✓ **Independent right from patents: separate sections in Part II of TRIPS Agreement**

Regulatory Data Protection

- **Protection under TRIPS Article 39.2 is distinct from that under Article 39.3**
- **If it were not for the obligation to provide test data to governments to establish safety and efficacy and gain marketing approval, data generated at considerable cost, time and risk would be considered a trade secret**
- **As such, it would be protected by TRIPS Article 39.2 against unauthorized acquisition or use "in a manner contrary to honest commercial practices"**
- **However, regulatory data is indeed published by Government in public interest and therefore the need for special protection under TRIPS Article 39.3**

Regulatory Data Protection

- **TRIPS Article 39.3**

"Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products, which utilize ***new chemical entities***, the submission of undisclosed information or other data, the origination of which involves a ***considerable effort,*** shall ***protect such data against unfair commercial use***. In addition, Members shall protect such data against disclosure, except where necessary to protect the public, or unless steps are taken to ensure that the ***data is protected against unfair commercial use***."

Regulatory Data Protection

- **Obliges WTO members to protect data**

✓ **“against unfair commercial use “**

✓ **“against disclosure”**

except (1) in public interest, or (2) when originator does not take steps to ensure that the data is protected against unfair commercial use

Regulatory Data Protection

Rules 122 A & B of the Indian Drugs and Cosmetics Rules, 1945 provide that the Drug Controller General of India, in order to grant marketing approval for the import and /or manufacture of a new drug, can exercise his discretionary power in waiving the requirement of submission of clinical dossier in the public interest based on "data available from other countries."

Further, the submission of certain other data relating to animal toxicology and related studies etc "*may be modified or relaxed in case of new drugs approved and marketed for several years in other countries if he is satisfied that there is adequate published evidence*

Regulatory Data Protection

Reddy Report recommendations includes significant discriminatory provisions under GATT (violation of National treatment provisions) and TRIPS

- **5 years RDP for traditional medicines**
- **3 years RDP for agrochem**
- **calibrated approach for pharmaceuticals**

❖ **minimum standards of DP i.e., prevention of unauthorized disclosure and unauthorized use through explicit legal provisions in Drugs and Cosmetics Act, 1940**

❖ **after an indefinite transition period – higher standards can be considered i.e., 5 years of non-reliance by DCGI on data submitted by originator for obtaining marketing approval for a new drug which is a new chemical entity and actually relied upon by the Drug regulator for that approval**

Regulatory Data Protection

RECOMMENDATIONS

- **recognize RDP as an IP and as an outstanding obligation (*w.e.f.* Jan 1, 2000) within the meaning of TRIPS Article 39.3**
- **recognize that the provision includes two obligations – protection against disclosure and protection against unfair commercial use**

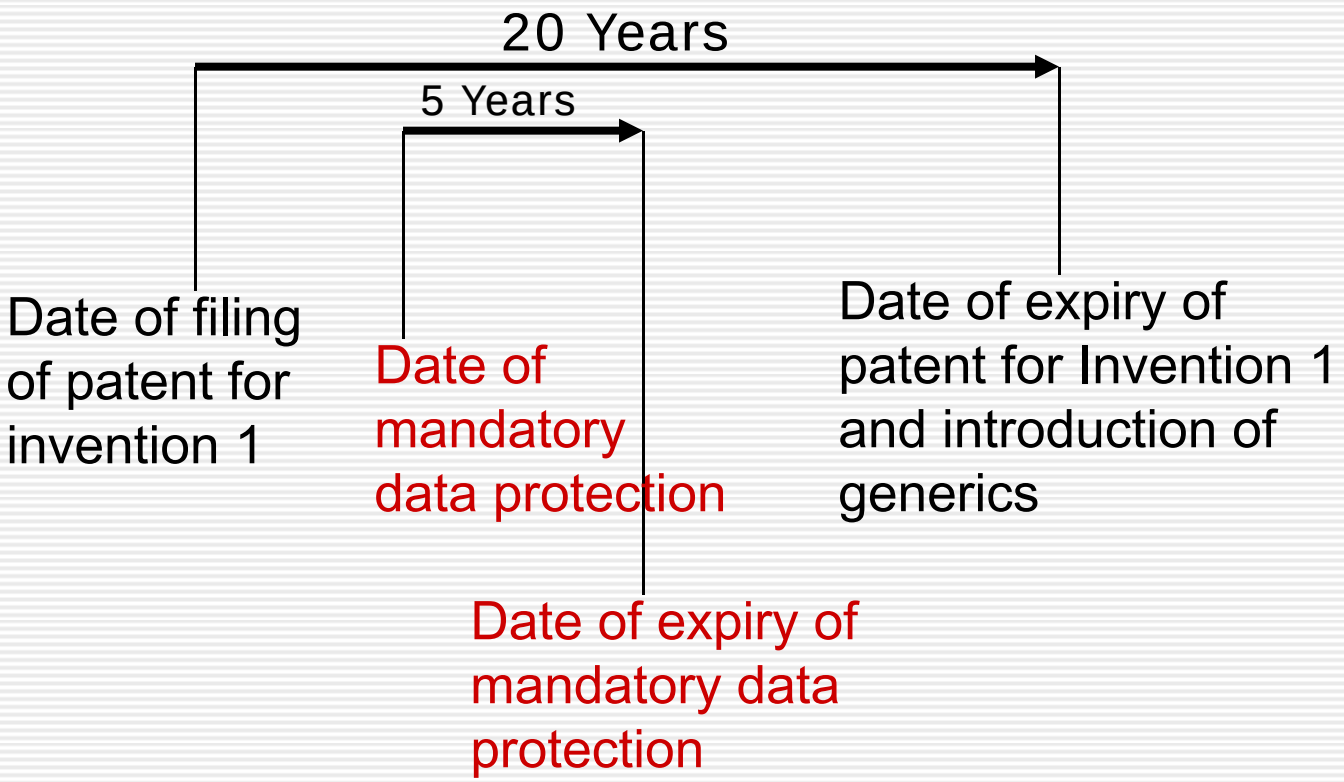
Regulatory Data Protection

RECOMMENDATIONS

- **Ensure a minimum five-year exclusivity period for new drug products (beginning from the date of market approval of the innovative product in the country where the product is approved)**
- **strengthen the regulatory system to ensure safety, quality and efficacy of medicines - crucial for life and health of the human beings – bioequivalence does not mean clinical equivalence**
- **incentivize research in biologics and new *personalised and predictive* medicines that accommodate genetic profiling, pharmacogenetics, novel diagnostics and gene therapy**

MANDATORY DATA PROTECTION IS 'EVERGREENING'…A MISCONCEPTION

Scenario 1



*Anyone is free to use the patent of invention 1 when the patent term expires. There is no extension of patent term with mandatory data protection of the innovator for a specified period

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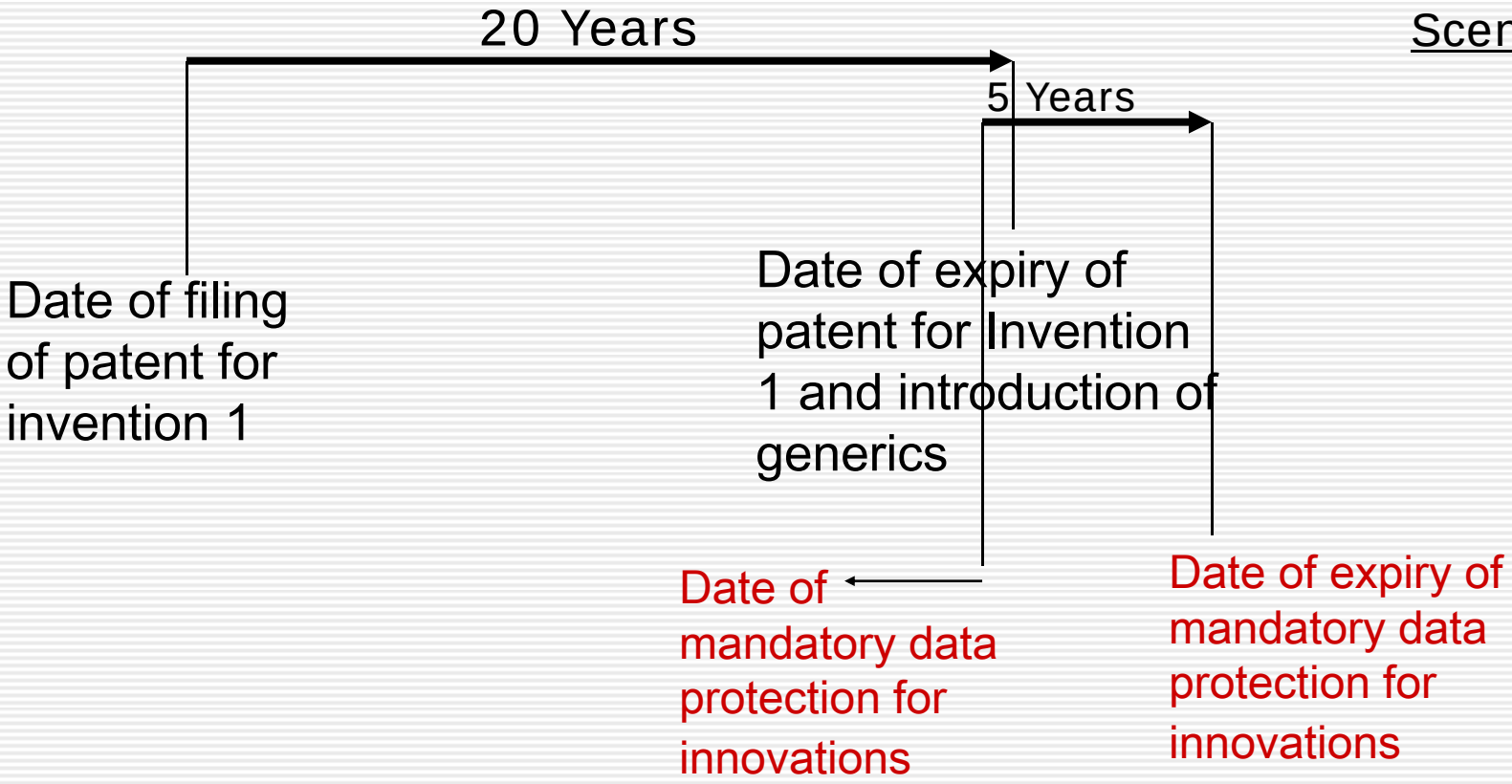

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“Incremental Innovation”
Section 3 (d)

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- **Section 3(d) of the Act creates additional hurdles to satisfy 'inventive step' and falls short of India's obligations under TRIPS Article 27 which expressly require Members to grant patents on inventions that are new, involve inventive step, and are industrially applicable**
- **Besides prohibiting patent protection for a new use of a known substance, stipulates that a new form of a known substance like a salt, ester, ether, polymorph, and other derivatives of a known substance is excluded from patent coverage, if it does not show <u>significantly enhanced efficacy</u> compared to the known substance.**
- ***Pari Materia* to Article 10(2) (b) of Directive 2004/27/EC of the European Parliament relating to medicinal products for human use**

Section 3 (d)

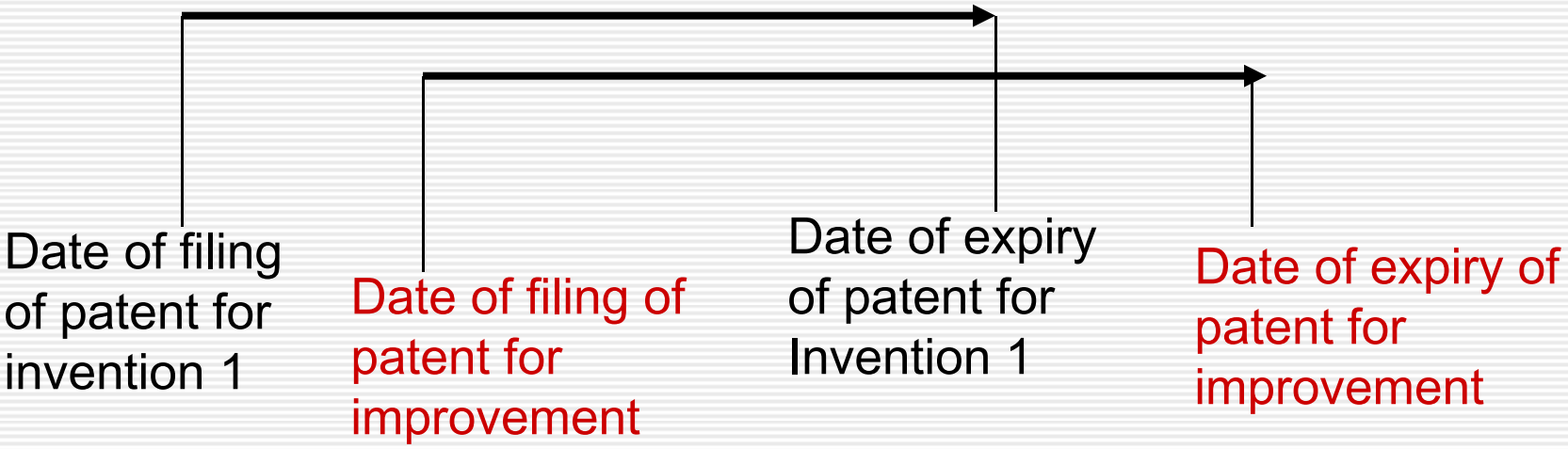
- **The wisdom behind 3(d) was to introduce stricter tests for establishing "inventive step" in order to discourage frivolous claims aimed at "evergreening" – it is disallowing good patents**
- **considerable concern to us that in the absence of any guidelines the term 'efficacy' is being construed in a 'drug regulatory' sense by the Patent office**
- **not only are the Patent examiners ill equipped to appreciate efficacy standards, but the patent applicants also find it difficult to satisfy efficacy requirements at the stage of filing and prosecution of patent applications**
- **'efficacy' is being interpreted differently by different patent offices on same facts and circumstances – resulting in varying outcomes for patent applicants**

Section 3 (d)

RECOMMENDATION

- ❑ amend Sec 3(d) to remove additional hurdles for patentability of pharmaceutical inventions and allow second use patents
- ❑ in the meanwhile, provide guidelines for interpretation and scope of the term "efficacy" either in the Manual or in an Explanation to either the provision on "inventive step" OR to Sec. 3(d) of the Patent Act
- ❑ accept and implement the Mashelkar Committee Report
- ❑ guidance is required for clarity and transparency in the system and to avoid unnecessary litigation for our already overburdened judiciary

EVERGREENING…A MISCONCEPTION



Anyone is free to use the patent of invention 1 when the term for that is over. The innovator or anyone else who has patent for the improvement will have rights to his patent only. There is no extension of patent term as per the Indian Patent Act

COMPULSORY LICENSE

COMPULSORY LICENSE

- **Current CL provisions continue to**

  1. **favor parties that are not patent owners**

  2. **favor Indian based manufacturers**

  3. **trigger grounds for imposition of CL for virtually any use of the exclusive rights granted by a patent**

COMPULSORY LICENSE

Local working requirements

- ***ambiquous*- while the words *"manufacture in India"* are deleted, the words *" patented invention has not been worked in India"* has been newly inserted.**

- **There remain several examples of importation discrimination outside the Compulsory Licensing provisions**

RECOMMENDATIONS

- **restrict issuance of CL to National Emergency, Extreme Urgency, and public non-commercial use,** and **cases where there is an anti competitive finding**

- **amend provisions (Sec. 84 [7]) that provide grounds for triggering CL by competitors for Commercial benefits**

- **provide safeguards enshrined in the Aug 30 Decision (Motta-Menon text) for exports under Section 92A of the Patents Act, corresponding to Para 6 of the *Declaration on the TRIPS Agreement and Public Health* at Doha**

PRE –GRANT OPPOSITION

Pre –Grant Opposition

- Present Patent Law allows both Pre-grant & Post-grant on the same 11 grounds
- Section 25 (1) allows pre-grant opposition to be filed any time after publication and till anytime before the grant of Patent – open ended timeline
- multiple pre-grant oppositions are being filed sequentially by same (related companies) or by different competitors for the same patent application leading to a substantial delay in issuing a decision thereby delaying the grant of a patent
- Frivolous Pre-Grant Oppositions freely eat away the rightful time of exclusivity of the applicant
- Yet, the law does not have any provision for undoing or otherwise making good the loss, in case the opposition fails, due to its own infirmities and patent is granted after a considerable delay

Pre –Grant Opposition

RECOMMENDATIONS

- amend Sec. 25 (1) of the Patents Act to disallow pre-grant opposition
- alternatively, amend Section 25 (1) to allow third parties to file interventions within a defined period (say six months) after the publication of the patent application
- convert a pre-grant application in to a post grant one, if prosecution of application is otherwise complete and the Patent Office as sent letter of ‘order of grant’
- introduce provision in Rules requiring opposition proceedings to conclude within twelve months of their commencement, and that the term of a patent which is issued after an opposition proceeding (i.e., the third party opposer loses) be extended by the period of time beyond this twelve months period

COUNTERFEITING

Counterfeit Drugs

- **A Major Public Health Hazard**

- **DCGI's emphasis on quality of drugs in accordance to Specification does not capture the entire picture on Counterfeit drugs – counterfeit is also an issue of IP Infringement**

- **regulatory requirements for EXPORT of APIs and medicines lax – the exported requires a manufacturing license, a firm export order and an NOC from DCGI**

- **Provisions of the pending legislation on counterfeit drugs will go a long way in plugging loopholes in the current law**

RECOMMENDATIONS

- **Accelerate passage of Bill amending Drugs and Cosmetics Act against Counterfeiting pending in Parliament since May 2005**

- **Standardize and harmonize definition of Counterfeit drugs with international standards – WHO/IMPACT**

- **provide stringent customs measures for import of APIs from countries like China**

- **tighten regulatory control over export of APIs and finished formulations**

WORKING OF THE PATENT OFFICE

Working Of Patent Offices

- **Increase in number of applications each year**

- **GOI proposes to have the Indian Patent Office recognized as International Search Authority (ISA) and International Preliminary Examining Authority (IPEA)**

- **To enable the above – requirement for technology upgradation and human resource development and capacity building**

Working Of Patent Offices

- **Total number of Examiners (all branches): 135 – significant attrition**

- **Out of the above around 100 are available for Examining Applications at any given time**

- **Each examiner is required to Examine 10 new cases per month. Even if 100 Examiners examine their quota of 10 applications a month, total number of cases examined in an year would be 12,000**

- **However, number of applications filed in 2006-07 alone are 28, 882**

- **Backlog for examination at present : 22, 000 applications**

Working Of Patent Offices

- **Examiners and Controllers are required to determine patent application in multiple disciplines, which may effect the quality of prosecution - a Controller with mechanical engineering background is examining a biotech patent**

- **Unlike USPTO and JPO, India has four patent offices as per regional jurisdiction, more or less working independently**

- **Lack of synergies between the four offices: (1) Filing is independent; (2) Prosecution is independent and (3) Grant is independent and only aspect of synchronization is in issuing Patent Numbers after grant**

RECOMMENDATIONS

- **Patent examiners need better training**

- **MORE Patent examiners required – China has 3000 Examiners and we have 135**

- **Examiners should be experts in specific technology areas – biotechnology, chemistry and pharmaceuticals**

- **Patent examiners and Controllers should be better paid and a system of bonuses and other incentives created both for talent retention and encouraging better performance**

- **Detailed guidelines in the form of a Manual (MPPP) necessary to encourage transparency and clarity**

Thank You