PATENT EXAMINATION, WITH PARTICULAR REFERENCE TO THE PHARMACEUTICAL SECTOR

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THE ROLE OF THE PATENT EXAMINER

- The legislature through the patent act establishes the national policy on patents
  - Objectives of the legislation, and specific provisions implementing objectives
    - Criteria of patentability, including specific terms under which assessment is performed
- The role of the patent office is to carry out the policies established by the legislature as reflected in the patent act. This includes:
  - Promulgation of regulations that more precisely establish the rules
  - Typically includes adoption of examination manual that provides guidance taking account of court interpretation

PATENT EXAMINATION IS INFLUENCED BY SUBSTANTIVE AND PROCEDURAL RULES AT THE INTERNATIONAL LEVEL

- The WTO Agreement on Trade-Related Aspects of Intellectual Property Rights ("TRIPS Agreement") establishes basic assessment criteria at relatively high level of abstraction, leaving substantial discretion to Members regarding specific implementation
- Appellate Body decision in *India-Mailbox* case confirmed Member flexibility in implementation
- Panel decision in *Canada-Generic Pharmaceuticals* case confirmed that Members may differentiate among different types of patent subject matter for legitimate reasons
- Efforts at WIPO to more closely harmonize patentability criteria and assessment have not succeeded

SUBSTANTIAL DIFFERENCES EXIST AMONG COUNTRY APPROACHES TO ASSESSMENT OF PATENTABILITY

- Differences include definitions of patentable subject matter (i.e. what can be patented?)
  - Most countries exclude laws of nature and natural phenomenon
    - In *AMP v. Myriad Genetics* (569 U.S. ___ June 13, 2013), US Supreme Court confirmed non-patentability of genes (and their codes) as found in nature
  - Many countries exclude computer software programs, as such, and business methods
  - Prior to TRIPS Agreement, many countries excluded pharmaceutical substances and food products

PATENTABILITY CRITERIA

- Additional criteria are novelty, inventive step, capability of industrial application and sufficiency of disclosure
  - Regarding novelty, issues concern (*inter alia*) what constitutes relevant prior art (e.g., absolute or relative novelty), inherency, duty to disclose
  - Inventive step or nonobviousness generally considered most important assessment criterion: what is the distance between the prior art and the claimed invention? What is the contribution?
  - India's Section 3(d), which requires that pharmaceutical inventions claiming a new form of known compound demonstrate a substantial enhancement in efficacy, is an example of establishment by legislation of benchmark by which to assess contribution

PATENTABILITY CRITERIA

- India's Section 3(d) complies with Article 27.1 of the TRIPS Agreement because the standard legitimately differentiates pharmaceutical products that are intended, by definition, to treat conditions in human beings. Computer software programs or machine tools cannot be assessed on the basis of "therapeutic efficacy", while that standard is unarguably relevant to pharmaceutical products

- The criterion of capability of industrial application or utility has taken on substantially greater importance in the biotechnology area, and with advances in combinational chemistry, as the science community is able to generate new biologic materials and chemical compounds with no indication whether they are useful; early patenting can discourage research
- A new research tool may be useful, but using that tool to identify a potential target area for additional research may not disclose a utility

SUFFICIENCY OF DISCLOSURE

- The patent applicant's written description of the invention must demonstrate that the applicant is in possession of the invention, and has reduced it to practice (or enabled)
- Disclosure, *inter alia*, distinguishes science from science-fiction
- Sufficiency has become a major source of concern with development of genus and "Markush" patents, and selection patents
- A Markush patent that specifies a range of compounds that can be combined in different ways may literally disclose millions of potential permutations. Often it is not clear that these combinations are functional. In addition, these types of broad claims can be followed by secondary "selection" patents which claim a particular unanticipated benefit from one of the many potential combinations
- Argentina has adopted patent examination guidelines sharply curtailing these exotic claiming forms

EXAMINATION PROCEDURES

- Patent examination for pharmaceutical, including biotechnological, products and processes, requires patent examiners trained in the art, often PhD level chemists and biotechnologists
- The USPTO has about 9000 patent examiners, about 4500 at EPO, but also national offices (e.g., German and UK offices well-staffed)
- Patent offices compete with private sector for individuals with high-level training
- Recruitment can be particularly difficult in developing countries where pool of high-level scientists smaller, and in demand from the private sector

INTERNATIONAL WORKSHARING

- Patent Cooperation Treaty (PCT) system provides basis for submission of single application in standard format that is processed through WIPO, with referral to International Search Authority (ISA) and International Preliminary Examination Authority (IPEA)
- Examiners in this system use patentability criteria shown in guidelines maintained by WIPO
  - PCT International Search and Preliminary Examination Guidelines, as in force from October 1, 2015
- When applications enter national phase, national patent office may assess applications according to its own criteria, and require additional documentation

INTERNATIONAL WORKSHARING

- South Africa is party to PCT, but for purpose of allowing South African inventors to submit applications that will be examined and enter the national phase in other PCT parties
- For national phase in South Africa, a Statement on the Use of Indigenous Biological Resource, Genetic Resource, Traditional Knowledge or Use on South African Patents Form P26 is also required to be lodged
- Where the invention for which protection is claimed is based on or derived from an indigenous biological resource, a genetic resource, or traditional knowledge or use, the applicant shall, before acceptance of the application furnish the registrar with proof of his or her title or authority to make use of the indigenous biological resource, the genetic resource, or the traditional knowledge or use

PCT PLUS

- One option for addressing examiner constraints for foreign-based applications is to await screening by PCT IPEA; then carry out supplemental examination based on South Africa standards
- This solution would not apply to domestic applicants that do not pursue international applications under PCT
- Though a large percentage of pharmaceutical industry applications employ the PCT system, some do not
- Vigilance would be required to assure that South Africa examination authority did not become "rubber stamp" for PCT examiners operating under guidelines reflecting originator-country standards

BRICS

- Some other developing/emerging market countries have strong staffing in technical aspects relating to pharmaceuticals
- For South Africa, India is a "logical" possibility for cooperation since (a) the India Patent Office has a substantial staff of examiners trained in pharmaceutical sciences and (b) English is a common language
  - The language issue should not be underestimated
  - Cost-sharing would presumably be expected
- Sharing of examination responsibilities could apply both to PCT applications and direct South Africa applications

BRAZILIAN MODEL

- Brazil includes its health regulatory authority, ANVISA, as part of the patent application assessment process for pharmaceuticals
- ANVISA is considered to have specialized knowledge concerning the state-of-the-art and inventiveness in pharmaceutical sciences. It can refuse consent to patenting
- There has been ongoing litigation and political contest between ANVISA and INPI regarding responsibility for patent assessment
- Medicines Control Council (or other body) in South Africa could perform function similar to ANVISA

PATENT PROSECUTION HIGHWAY

- Worksharing among self-selected groups of country patent offices agreeing that first allowance of claim authorizes accelerated processing in other offices
- Results of search and examination shared
- Initially OECD, but expanding
- Attempt to cope with ever-expanding number of patent applications
  - USPTO received 630,000 applications in 2015
  - About 215,000 PCT applications filed in 2015 with 565,500 national phase entries

ADDITIONAL PROCEDURAL ISSUES

- Third-parties are now generally allowed to provide submissions, at least of prior art, during examination process
- Important question involves pre-grant opposition
- Many countries maintain pre-grant opposition that is designed to limit the improvident grant of patents, and to reduce *ex-post facto* costs
- Should be designed so as not to result in undue delays in the grant of patents, but carefully designed timelines can accomplish this
- Post-grant opposition is common; recently introduced in much stronger form in USA