REGULATORY REVIEW AND INNOVATION

IN THE CHEMICAL INDUSTRY

History of Pre-Marketing Regulation legislation

1. Food & Drug Act

   1962 Kef added efficacy applicable to drugs, animal drugs, food additives, etc.

2. FIFRA

   Applicable to insecticides, pesticides

3. Toxic Substances Act

   Applicable to: (get examples of chemicals to be sold)

Trends in Research for products subject to premarketing regulatory approval

1. All in highly sophisticated fields where analytical technology growing in sophistication

2. Biosciences better recognize possible long term effects and new biological effects with unknown consequences

3. Resultant cost in time and money for testing to satisfy self and regulatory agency

Effect of Trends

1. In industry generally

   A. Control on extent project can be carried forward with measurement of probable success - pert[illegible] charts - committees

   B. Number of projects which can be supported - selectivity - which projects to proceed with

2. On small business

   A. Selectivity acute from funding limitations - how much will one project cost vs. another

   B. Time to plan next test requires results of current tests to see if warrant going on -- Cause of greater delay for small company -- big ones can run simultaneously

   C. Financing required

3. Individual inventors, e.g., university professor

   A. Cost of research almost impossible to fund

      1) can't interest bank for sums involved and start new company

      2) major undertaking by licensee company requires higher degree of scrutiny and projection of success before company will take on

4. On all -- Erosion of patent life

Possible Considerations to counteract effect

1. Things can't do first

   A. Can't stop growth of sophistication of analytical technology - don't want to - company's and public's interest

B. Can't roll back clock on regulation - don't want to - Company's and public-can improve pace of approval and create atmosphere where approval gets credit vs. fear of criticism for mistake

2. Can consider program of government payment for testing to satisfy govent regulation

A. Administrative nightmare to establish agency to discern which project is worthy of support and for how much

B. Tremendous cost to taxpayer

3. Can rely on proven incentives related to free enterprise profit motive

A. Tax treatment of research and development (Text from Sagurton)

B. Improvements in Patent System

1) Restoration of patent term for products subject to pre-marketing regulatory review

Ways to accomplish Patent Life Restoration

1. Hold grant of patent until regulatory review completed successfully

A. Benefits

1) Simple to administer - only thing required is notice to Commissioner to withhold grant and second notice re approval

2) Full seventeen year term assured

B. Disadvantages

1) Product may never receive regulatory approval and patent expiration delayed for no public benefit

2) Fundamental purpose of patent law - to get information to public to enable further research to build on technology - is defeated

3) Totality of patent scope is extended in chemical field- patent often covers many compounds in generic claim, eg, 1000 and only one goes thru regulatory process. Public deprived of right to develop product based on one of the 999 until patent expires

4) No protection to public against dilatory action in obtaining regulatory approval

2. Extend any patent covering product for an arbitrary period, e.g., 7 years since patent term length now can be considered an average deemed correct for all inventions regardless of their type

A. Advantages

1) Again simple to administer -- only thing required is notice to Commissioner of approval

B. Disadvantages

1) Determination of arbitrary period depends upon assessing current experiences of delay for drugs, insecticide, etc. and the projecting anticipated delays as science sophistication and future regulatory criteria develop - an almost impossible task

2) Extension for fixed term -- is deterrent to regulatory agency efforts to shorten period of review - would make no difference

3. As in countries outside United States provide system that patentee shortly before patent expiration may petition court for extension of patent where patent life has been lost due to regulatory review requirements

   A. Advantages

      1) Finding of court that patent extension appropriate is res judicata in patent infringement action during extended term

   B. Disadvantages

      1) Extremely expensive based on experience in South Africa and Great Britain

      2) Happens late in patent life and advice of potential extension given to public so late in term that can seriously disrupt product development plans to compete with patentee at normal expiration

      3) Neither patentee nor public has assurance as to disposition of petition by court and thus planning is difficult

4. Extend patent rights applicable to product subject to regulatory review to seventeen years after regulatory approval but not to exceed fixed period such as 24 years from original patent grant

   A. Advantages

      1) Scope of rights extended would be applicable only to product subject to regulatory review

      2) Maximum period of patent life protects against dilatory action

   B. Disadvantage

      1) Measurement solely on basis of approval date may not be in

reasonable relationship to the period that is appropriately considered that in which the regulatory agency is a factor- much research is done to reach conclusion that submission to regulatory agency is appropriate

Certain principles become apparent from foregoing -- needed to provide equitable restoration of patent rights innovator can expect and to adequately protect the public interest

1. Patent should be granted after normal examination procedure so public has benefit of publication of technology at earliest possible time

2. Patent life extension should be applicable to types of patents which provide proprietary rights to a specific product

3. Products involved should be those specifically designated in legislation requiring regulatory review before commercialization, e.g., Food & Drug law, FIFRA, Toxic Substances, and should be specifically defined

4. Extension should have maximum length to assure to public diligence of the patentee before the regulatory agency

5. Rights derived from the extension should provide continuing exclusivity only for the product which has been subject to regulatory approval - any other subject matter included within the scope of the patent should fall into the public domain at normal expiration date

6. Procedure should be as simple as can be designed, requiring no need for review by P.T.O. of proceedings before regulatory agency. Since patent rights extended provide to patentee only the right to bring infringement action against unlicensed copying of the product approved, public has protection of courts review of propriety of the extension in any infringement litigation.

Appropriate legislation to accomplish foregoing attached as Exhibit

1. Establishes type of patents covered - ones covering product (product patent) and ones covering use of product (use patent)

2. Specific products involved are defined by relating to regulatory legislation

3. Maximum term of extension is seven years since evidence exists that a period that long can be supported statistically and the period is short enough to demand diligence

4. Regulatory review period is defined for each type product with objectively measured starting and ending date. Starting dates are acts which require considerable research by patentee before regulatory agency is approached

5. Procedure established simple and requires no significant expenditure of P.T.O. time or funds

   Explain

   Notification at time of approval eliminates P.T.O. files from being

burdened with filings relative to products which never receive regulatory approval.

Attorney certification of dates and scope of patent extension requested relieves P.T.O. of judgemental review and binds patentee at the court.