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WESFACCA Memorandum

TO: Patent, Trademark & Copyright Law Committee

FROM: M-E. M. Timbers, Program Coordinator
(203-348-7331, Ext. 2719)

RE: Luncheon Meeting - October 24, 1984
"THE PATENT RESTORATION LAW"

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We are pleased to announce that on Wednesday, October 24th, Karl Jorda, Esq., Corporate Patent Counsel for Ciba-Geigy, will be speaking on the passage of the Patent Restoration Law (Waxman-Hatch bill). Such passage reflects the climax of 10 years of efforts, and investigations into, the United States, brandname drug industry, in which efforts Mr. Jorda has participated. Copies of the new law will be handed out at the meeting.

Please make reservations as soon as possible by calling Mary-Ellen Timbers at 203-348-7331 ext. 2719. The cost will be $14.00 (Fourteen Dollars) (choice of butterfly steak or filet of sole).

Date: October 24, 1984

Place: Manero's, Steamboat Road, Greenwich

Time: Reception: 12:00 noon (cash bar)
Lunch will begin promptly at 12:30 p.m. and will conclude by 2:00 p.m.

cc: Charles R. Hann
Earl M. Wunderli
Lee M. Hirsch

PATENT TERM RESTORATION
P.L. 98-417
RECENT HISTORY

1) Drug Regulatory Reform Acts in 95th Congress

(Patent Term extension as offset to compulsory licensing)

(H.R. 11447 - Symms)

2) ABA-PTC Section Resolution - August 78

3) NACA and PMA patent extension questionnaires in 1979

4) CMA patent extension draft bill early 1980

5) S.2892 (Bayh, 96th Congress - 6/27/80)

H.R. 7925 (Kastenmeier - 8/19/80)

"Patent Term Restoration Act of 1980"

6) S.255 (Matthias, 97th Congress - 1/27/81

H.R. 1937 (Kastenmeier - 2/18/81)

"Patent Term Restoration Act of 1981"

S.255 passed Senate on voice vote 7/9/81

H.R. 1937 - hearings in Fall - OTA Study

Six Kastenmeier Amendments - Negotiations all through 1982 - Became H.R. 6444 - Approved by House Judiciary Committee - Defeated in House by 5 votes on 9/15/82

7) S.1306 (Matthias, 98th Congress - 5/17/83)

H.R. 3502 (Synar - 6/30/83)

"Patent Term Restoration Act of 1983"

[H.R.3605 (Waxman - 7/19/83) - "Drug Price Competition Act"]

8) S.1538, S.2748, S.2926
H.R. 3605
P.L. 98-417 - 9/24/84
"Drug Price Competition and Patent Term Restoration Act of 1984"

9) H.R. 5529 (Glickman - 4/26/84)
"Agricultural Patent Reform Act of 1984"

# STATEMENT IN SUPPORT OF A PROPOSED BILL AUTHORIZING OPTIONAL EXTENSION OF TERM OF PATENTS RELATING TO CERTAIN REGULATED PRODUCTS

March 1968

STAUFFER CHEMICAL COMPANY
299 Park Avenue
New York, N. Y.
10017

Iver C. Macdougall
Director, Law Department

## Patent Extension Act

Provides for restoration of a portion of the patent term lost as the result of FDA premarket testing and approval requirements for prescription and nonprescription human drugs, food additives, color additives, and prescription and nonprescription medical devices. Extension of the term of a product, use, or process patent for these federally regulated products is authorized.

Five requirements for extension of the patent term of a product:

1) the patent must not have expired,

2) the patent must not previously have been extended,

3) a patent extension application must be submitted,

4) the product must have been subject to regulatory review before its commercial marketing or use, and

5) the particular commercial marketing or use must be the first such marketing or use permitted by the regulatory statute or, in the case of manufacturing processes involving recombinant DNA technology, the permitted process must be the first permitted commercial marketing or use of the product manufactured with that particular process.

The scope of the patent extension is never broader than the scope of NDA approval.

For each regulatory review period for a product, the owner of record of the patent or its prepresentative must select one, and only one, patent to be extended. Thus, the owner may select a product, process, or use patent. The patent selected may be an earlier or later patent. The only limitation is that the particular marketing or use of the product permitted as a result of the regulatory reivew period must be the first such marketing or use of the product involved.

The scope of the patent extension is never broader than the scope of NDA approval.

The rights covered by the patent during its primary term are are equally covered during the period of extension.

## Patent Extension Procedure

- File application in USPTO (Patent Office) within 60 days from NDA/regulatory approval.

- USPTO notifies FDA (Secretary, HHS) with copy of application within 60 DAYS.

- FDA notifies USPTO within 30 days of the regulatory review period, publishes notice in FEDERAL REGISTER.

- DUE DILIGENCE review by HSS if, within 180 DAYS of FEDERAL REGISTER publication, petition submitted "upon which it may reasonably be determined that the applicant did not act with due diligence".

  "Due diligence" is defined as:

  that degree of attention, continuous direct effort, and timeliness as may reasonably be expected from, and are ordinarily exercised by, a person during a regulatory review period.

- Review for DUE DILIGENCE completed by FDA Commissioner within 90 DAYS, if required, published with "factual and legal basis" in FEDERAL REGISTER.

- Informal hearing can be requested within 60 days of publication of DUE DILIGENCE review.

- Hearing held within 30-60 days of request, upon notice to all parties.

- Final non-appealable determination made within 30 days of hearing and published in FEDERAL REGISTER.

## Patent Term Extension Calculation

1. Classify regulatory review period into --

   - IND filing date to NDA filing date (IND Period)
   - NDA filing date to NDA approval date (NDA Period)

2. Deduct from each period any time applicant failed to act with "DUE DILIGENCE".

3. Add one-half the remaining IND period (after "due diligence" deduction) to full NDA period (after "due diligence" deduction).

4. Ignore any extension beyond 14 years from date of NDA approval.

5. Limit any otherwise allowable extensions to:

   5 YEARS - if patent issued after enactment or IND period begins after enactment.

   2 YEARS - patent issued before enactment and IND period begun before enactment.

N.B. Products approved before enactment with patents issued before enactment are not eligible for extension.

## Patent Infringement and Defenses

1. It is no longer an infringement under Title II to make, use or sell a patented invention solely for uses "reasonably related" to the development and submission of information (would include clinical testing, comparative testing) before the FDA. Thus, a party can use all patented process technology and other background patents, potential delivery systems and dosages forms, etc. if "reasonably related" to e.g., a potential ANDA filing. This legislatively overrules the Roche v. Bolar decision.

   Constitutional challenges to Title II can be expected to the extent this Act "takes away" property rights (as per Roche v. Bolar) granted in pre-enactment patents.

2. It will be an infringement to file an ANDA for a patented drug or drug use indication to obtain approval to commercialize before the expiration of the patent. The patent holder will unfortunately only be entitled to injunction relief (unless there is commercialization of the ANDA product). Attorneys fees will be awarded only in exceptional cases.

3. An extension of the patent term may be shortened or invalidated for a material violation by the applicant for patent extension or by the Patent Office. Such a material violation shall be a defense in any action involving infringement of the patent during the period of the extension of its term. This defense must be affirmatively pleaded.

The development of a new product is a three-step process:

- first, an American firm announces an invention;
- second, the Russians immediately claim they made the same discovery twenty years ago;
- third, the Japanese start exporting the product the very next day.

## TIMETABLE: MARKETING EXCLUSIVITY

### ANDA Moratorium Period

10 years - "Feldene" clause -- NDA for NCE approved 1/1/82 to ENACTMENT DATE: 10 YEAR freedom from ANDA's becoming EFFECTIVE.

5 years - Post-enactment NDA for NCE's (first NDA approved after enactment) when NO patent "invalidity/no infringement" certification in ANDA: 5 YEAR freedom from ANDA FILING.

4 years/ 7 1/2 yr. - Post-enactment NDA for NCE's when INVALIDITY NO INFRINGEMENT CERTIFIED IN ANDA: 4 YEAR freedom from ANDA FILING: effectiveness deferred beyond approval up to 7 1/2 YEARS from NDA approval only if pioneer sues with 45 DAYS. (See "Effective Date" on next slide.)

3 years - Post-enactment NDA/Supplemental NDA for OCE's (active ingredient previously approved in any prior NDA) WITH NEW CLINICAL DATA: 3 YEAR freedom from ANDA becoming effective.

2 years - NDA/Supplemental NDA for OCE approved 1/1/82 to ENACTMENT: 2 YEAR freedom from ANDA's becoming effective.

180 days - Grace period - marketing exclusivity for first ANDA application that successful challenges the NDA holder/patent owner. Affects subsequent ANDA applicants.

## "Effective Date" of ANDA Following FDA "Approval"

Depends upon "Patent Certification" option chosen in ANDA:

Option I - No NDA Patent Information:
-- IMMEDIATELY EFFECTIVE --

Option II - Relevant Patents Expired:
-- IMMEDIATELY EFFECTIVE --

Option III - Patent Expiration Stated:
-- EFFECTIVE AT PATENT EXPIRATION DATE --

Option IV - INVALID/NOT INFRINGED patent certification

1. If pioneer NDA holder sues within 45 days from notice:

   -- DELAYED EFFECT --

   - normally 30 months; longer/shorter if a party does not "cooperate" in litigation.

   - if court determines earlier (before 30 months) no infringement; EFFECTIVE ON DECISION OF COURT.

   - if court finds infringement earlier, EFFECTIVE AFTER PATENT EXPIRATION

   - if preliminary injunction issues earlier, EFFECTIVE ON FINAL COURT DECISION.

2. If pioneer NDA holder does NOT sue within 45 days: -- IMMEDIATELY EFFECTIVE --

## TIMETABLE: FILING DEADLINES

### ANDA Approval Process

30 days - period following enactment or patent issuance during which patent information must be filed in NDA.

60 days - Following enactment - FDA must publish list of approved drugs.

45 days - Period during which patent holder must sue ANDA applicant that chooses Option IV for patent infringement.

90 days - FDA review and approval of ANDA petition for drugs which differ from listed drug.

180 days - FDA review must approve or disapprove ANDA.

1 year - From date of enactment for FDA timetable to promulgate regulations.

## Strategy Implications

Following these preliminary matters, an impact analysis of the legislation on marketing and development plans should determine specific responses to the legislative changes.

For example, this legislation must be factored into the decision calculus governing the content and timing of filing an NDA: if an NDA for an NCE is filed for an indication of relatively minor marketing impact, the NDA could be protected under the moratorium provision for five (5) years before submission of an ANDA (i.e., six (6) years of effective exclusivity). A subsequently-filed NDA, for an indication with far greater market potential, would be deemed as an NDA for an OCE; this major indication would only receive three years of protection before an ANDA approval could become effective.

Thus, order of filing an NDA can result in a potential loss of gain of three (3) years of marketing exclusivity.

Strategic planning for filing NDA's must take account of patent status, projected indications and legislated moratorium periods.