

8. Implement, monitor and update the water conservation plan

The CVP contractors listed below have developed water conservation plans which Reclamation has evaluated and preliminarily determined meet the requirements of the Criteria.

- Arvin Edison Water Shortage District.
- Bella Vista Water District.
- Colusa County Water District.
- Corning Water District.
- Dunnigan Water District.
- Gravelly-Food Water District.
- Monterey County Water Resources Agency.

- Proberta Water District.
- San Juan Water District.
- Santa Barbara, City of.
- Santa Barbara, County of.
- Tea Pot Dome Water District.
- The West Side Irrigation District.
- Thomes Creek Water District.
- Westside Water District.

Public comment on Reclamation's preliminary (i.e., draft) determinations at this time is invited. Copies of the plans listed above will be available for review at Reclamation's Mid Pacific (MP) Region Office and MP's area offices. If you wish to review a copy of the plans, please contact Ms. Reifsnider to find the office nearest you.

Dated: March 28, 1995.

Franklin E. Dimick,

Assistant Regional Director.

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INTERNATIONAL TRADE COMMISSION

[Investigation No. 337-TA-349]

Certain Diltiazem Hydrochloride and Diltiazem Preparations; Notice of Commission Decision to Review Portions of an Initial Determination

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has determined to review certain portions of the initial determination (ID) and Order No. 52 issued by the presiding administrative law judge (ALJ) on February 2, 1995, in the above-captioned investigation.

FOR FURTHER INFORMATION CONTACT: Cynthia P. Johnson, Esq., Office of the General Counsel, U.S. International Trade Commission, telephone 202-205-3098.

SUPPLEMENTARY INFORMATION: On February 1, 1995, the presiding ALJ

issued his final ID finding that there was no violation of section 337. He found that claim 1 of U.S. Letters Patent 4,438,035 ('035 patent) was not infringed by any of respondents' processes, that claim 1 was invalid as obvious under 35 U.S.C. 103, and that the '035 patent was unenforceable because of complainants' inequitable conduct during reexamination proceedings before the U.S. Patent and Trademark Office. In a separate order (Order No. 52), issued on the same date, the ALJ granted respondents' motion for evidentiary sanctions. In that order, he stated that because there is a Commission preference for decisions on the merits based on all the evidence adduced, and because he believes that the same conclusions of law regarding infringement would be appropriate whether or not the sanctions of Order No. 52 are applied, he was imposing sanctions on complainants only as alternate relief, i.e., only if the Commission determines based on all the evidence of record that respondents have infringed claim 1 of the '035 patent.

On February 21, 1995, complainants filed a petition for review of the ALJ's final ID. They also filed a separate petition for review of Order No. 52. On the same day, the Commission investigative attorneys (IAs) filed a petition for review of the ALJ's finding that a domestic industry exists.

On March 6, 1995, the IAs, the Fermion respondents, and the Profarmaco respondents filed oppositions to complainants' petition for review. Respondent Gyma Laboratories also filed an opposition to petition for review indicating that it principally relies on and concurs in the response filed by the Profarmaco respondents.

Having examined the record in this investigation, including the ID and Order No. 52, the Commission has determined to review the issues of (1) claim interpretation, (2) whether claim 1 of the '035 patent is infringed by respondents' processes; (3) whether claim 1 of the '035 patent is invalid as obvious under 35 U.S.C. § 103; (4) whether the '035 patent is unenforceable; and (5) Order No. 52. The Commission has determined not to review the remainder of the ID. The Commission regards the ID as including Order No. 52. The Commission has also denied complainants' motion for leave to file the affidavit of James Gambrell, and denied complainants' request for an oral hearing. With regard to the Gambrell affidavit, the Commission believes that reopening the record to accept the affidavit at this late stage of

the investigation would not be appropriate.

On review, the Commission is particularly interested in answers to the following questions:

(1) Is claim 1 of the '035 patent entitled to any range of equivalents? If not, why not? If so, does the range of equivalents cover (1) use of methyl ethyl ketone, the next higher homolog of acetone, as a solvent when used with potassium hydroxide as a base, or (2) use of potassium carbonate and toluene as the base-solvent combination? Why?

(2) What is the status of the Abic group of respondents? Have they settled their differences with complainants? If so, will a motion to terminate the Abic group of respondents from the investigation be forthcoming?

(3) Is there any suggestion or motivation in the prior art references as a whole applied in the ID to combine those references so as to render obvious under 35 U.S.C. 103 the invention claimed in claim 1 of the '035 patent?

(4) Was there a sale in the United States of the product produced by the Tanabe trade secret KOH/DMSO process within the meaning of 35 U.S.C. 102(b)? Is there applicable case law relevant to complainants' contention that sales of a product for the sole purpose of FDA approval do not constitute an "on sale" bar within the meaning of 35 U.S.C. 102(b)? The Commission is interested in an analysis, based on the evidence of record, of whether sales made solely for purposes of FDA approval constitute an "on sale" bar, taking into account the analysis set forth by the Federal Circuit in considering whether a prior use or sale is a statutory bar in, e.g., *Pennwalt Corp. v. Akzona Inc.* (and cases cited therein) 740 F.2d 1573 (Fed. Cir. 1984). The Commission is also interested in any evidence of record relevant to complainants' contention that the only sales in the United States of Tanabe's trade secret KOH/DMSO process were for purposes of FDA approval. If the Tanabe KOH/DMSO process is found to be prior art, what suggestion or motivation, if any, is there in the prior art that the use of DMSO as a solvent would have rendered the solvents of claim 1 of the '035 patent obvious under 35 U.S.C. 103? Finally, assuming that the Tanabe KOH/DMSO process is prior art, was it more pertinent than the references before the examiner during the reexamination proceedings?

In connection with final disposition of this investigation, the Commission may issue (1) an order that could result in the exclusion of the subject articles from entry into the United States, and/or (2) cease and desist orders that could result in respondents being required to

cease and desist from engaging in unfair acts in the importation and sale of such articles. Accordingly, the Commission is interested in receiving written submissions that address the form of remedy, if any, that should be ordered. If a party seeks exclusion of an article from entry into the United States for purposes other than entry for consumption, the party should so indicate and provide information establishing that activities involving other types of entry either are adversely affecting it or are likely to do so. For background, see the Commission Opinion, *In the Matter of Certain Devices for Connecting Computers via Telephone Lines*, Inv. No. 337-TA-360.

If the Commission contemplates some form of remedy, it must consider the effects of that remedy upon the public interest. The factors the Commission will consider include the effect that an exclusion order and/or cease and desist orders would have on (1) the public health and welfare, (2) competitive conditions in the U.S. economy, (3) U.S. production of articles that are like or directly competitive with those that are subject to investigation, and (4) U.S. consumers. The Commission is therefore interested in receiving written submissions that address the aforementioned public interest factors in the context of this investigation.

If the Commission orders some form of remedy, the President has 60 days to approve or disapprove the Commission's action. During this period, the subject articles would be entitled to enter the United States under a bond, in an amount determined by the Commission and prescribed by the Secretary of the Treasury. The Commission is therefore interested in receiving submissions concerning the amount of the bond that should be imposed.

Written Submissions

The parties to the investigation are requested to file written submissions on the issues under review. The submissions should be concise and thoroughly referenced to the record in this investigation, including references to specific exhibits and testimony. Additionally, the parties to the investigation, interested government agencies, and any other interested persons are encouraged to file written submissions on the issues of remedy, the public interest, and bonding. Complainants and the Commission investigative attorneys are also requested to submit proposed remedial

orders for the Commission's consideration. The written submissions and proposed remedial orders must be filed no later than the close of business on April 13, 1995. Reply submissions must be filed no later than the close of business on April 20, 1995. No further submissions will be permitted unless otherwise ordered by the Commission.

Persons filing written submissions must file with the Office of the Secretary the original document and 14 true copies thereof on or before the deadlines stated above. Any person desiring to submit a document (or portion thereof) to the Commission in confidence must request confidential treatment unless the information has already been granted such treatment during the proceedings. All such requests should be directed to the Secretary of the Commission and must include a full statement of the reasons why the Commission should grant such treatment. See 19 C.F.R. 201.6. Documents for which confidential treatment is granted by the Commission will be treated accordingly. All nonconfidential written submissions will be available for public inspection at the Office of the Secretary.

This action is taken under the authority of section 337 of the Tariff Act of 1930 (19 U.S.C. 1337) and sections 210.54-.55 of the Commission's Interim Rules of Practice and Procedure (19 CFR 210.54-.55).

Copies of the public version of the ID and all other nonconfidential documents filed in connection with this investigation are or will be available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street S.W., Washington, D.C. 20436, telephone 202-205-2000. Hearing-impaired persons are advised that information on the matter can be obtained by contacting the Commission's TDD terminal on 202-205-1810.

Issued: March 30, 1995.

By order of the Commission.

Donna R. Koehnke,
Secretary.

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INTERSTATE COMMERCE COMMISSION

[Docket No. AB-290 (Sub-No. 169X)]

Norfolk and Western Railway Company—Abandonment Exemption— Between Ferguson Junction and Glen Echo, MO

Norfolk and Western Railway Company (NW) has filed a notice of exemption under 49 CFR Part 1152 subpart F—Exempt Abandonments to abandon its 2.56-mile line of railroad between milepost UD-9.94 at Glen Echo and milepost UD-12.50 at Ferguson Junction in St. Louis County, MO.

NW has certified that: (1) No local traffic has moved over the line for at least 2 years; (2) there is no overhead traffic on the line; (3) no formal complaint filed by a user of rail service on the line (or by a state or local government entity acting on behalf of such user) regarding cessation of service over the line either is pending with the Commission or with any U.S. District Court or has been decided in favor of the complainant within the 2-year period; and (4) the requirements at 49 CFR 1105.7 (service of environmental report on agencies), 49 CFR 1105.8 (service of historic report on State Historic Preservation Officer), 49 CFR 1105.11 (transmittal letter), 49 CFR 1105.12 (newspaper publication), and 49 CFR 1152.50(d)(1) (service of verified notice on governmental agencies) have been met.

As a condition to use of this exemption, any employee adversely affected by the abandonment shall be protected under Oregon Short Line R. Co.—Abandonment—Goshen, 360 I.C.C. 91 (1979). To address whether this condition adequately protects affected employees, a petition for partial revocation under 49 U.S.C. 10505(d) must be filed.

Provided no formal expression of intent to file an offer of financial assistance (OFA) has been received, this exemption will be effective on May 5, 1995, unless stayed pending reconsideration. Petitions to stay that do not involve environmental issues,¹

¹ A stay will be issued routinely by the Commission in those proceedings where an informed decision on environmental issues (whether raised by a party or by the Commission's Section of Environmental Analysis in its independent investigation) cannot be made prior to the effective date of the notice of exemption. See Exemption of Out-of-Service Rail Lines, 5 I.C.C.2d 377 (1989). Any entity seeking a stay on environmental concerns is encouraged to file its request as soon as possible in order to permit the

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