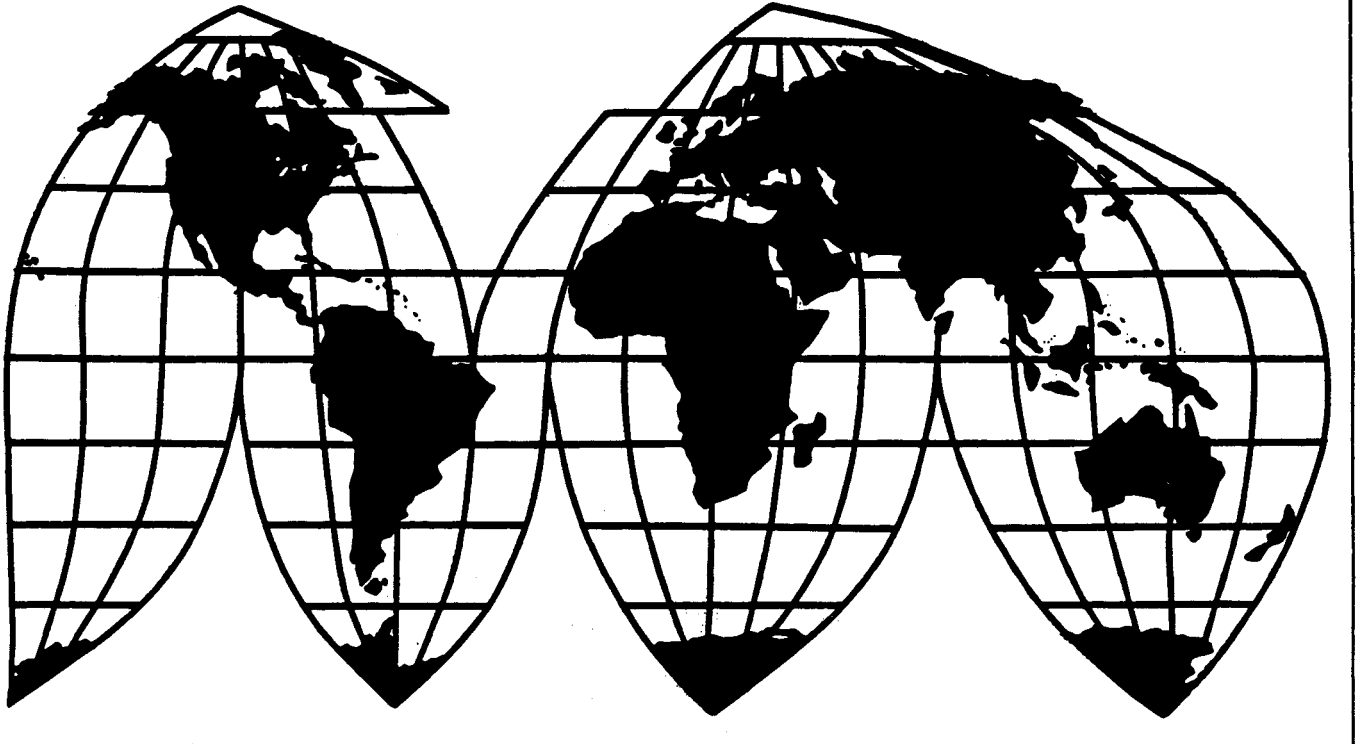
In the Matter of

Certain Recombinantly Produced Human Growth Hormones

Investigation No. 337-TA-358

Publication 2869 **March 1995**

U.S. International Trade Commission



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U.S. International Trade Commission

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In the Matter of

CERTAIN RECOMBINANTLY PRODUCED HUMAN GROWTH HORMONES

Investigation No. 337-TA-358

NOTICE OF COMMISSION DETERMINATIONS (1) NOT TO REVIEW THOSE PORTIONS OF THE ADMINISTRATIVE LAW JUDGE'S INITIAL DETERMINATION DISMISSING THE COMPLAINT WITH PREJUDICE AND TERMINATING THE INVESTIGATION AS A SANCTION FOR COMPLAINANT'S DISCOVERY ABUSE; (2) TO TAKE NO POSITION ON THE REMAINDER OF THE INITIAL DETERMINATION; TERMINATION OF INVESTIGATION BASED ON A FINDING OF NO VIOLATION OF SECTION 337 OF THE TARIFF ACT OF 1930.

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission (Commission) has determined not to review the portion of the presiding administrative law judge's (ALJ's) final initial determination (ID) in the above-referenced investigation dismissing the complaint with prejudice as a sanction for complainant's misconduct during discovery, and to take no position on the remainder of the ID in accordance with Beloit Corporation v. Valmet Oy, TVP Paper Machines, Inc., and the United States International Trade Commission, 742 F. 2d 1421 (Fed. Cir. 1984). Notice is also given that the Commission has denied complainant Genentech's motion to supplement the record, and also denied Genentech's motion for leave to reply to an opposition to Genentech's motion to supplement the record.

FOR FURTHER INFORMATION CONTACT: Scott Andersen, Esq., telephone 202-205-3099, or Cynthia Johnson, Esq., telephone 202-205-3098, Office of the General Counsel, U.S. International Trade Commission.

SUPPLEMENTARY INFORMATION: The Commission instituted this investigation on September 29, 1993, based on a complaint filed by Genentech, Inc. of South San Francisco, California. 58 Fed. Reg. 50954. The following six firms were named as respondents: Novo Nordisk A/S of Denmark; Novo Nordisk of North America, Inc. of New York; Novo Nordisk Pharmaceuticals, Inc. of New Jersey; ZymoGenetics, Inc. of Seattle, Washington (collectively, the Novo respondents); Bio-Technology General Corp. of New York; and Bio-Technology General Corp. (Israel) Ltd. (collectively, the BTG respondents). The Commission also provisionally accepted Genentech's motion for temporary relief. Id. The Commission terminated the temporary relief proceedings as to the Novo respondents on the basis of a consent order. 58 Fed. Reg. 60672 (November 17, 1993).

The ALJ held an evidentiary hearing on temporary relief from December 13 through December 18, 1993. On January 26, 1994, the ALJ issued an ID denying Genentech's motion for temporary relief. The temporary relief ID was adopted by the Commission on February 25, 1994.

On March 2, 1994, the ALJ designated the permanent phase of the investigation "more complicated".

The evidentiary hearing on issues concerning permanent relief commenced on April 11, 1994, and concluded on April 24, 1994. On July 28, 1994, the ALJ issued an ID delaying the issuance of his final ID on permanent relief until November 29, 1994. On August 22, 1994, the Commission determined not to review that ID.

On August 29, 1994, the BTG and Novo respondents individually moved for an order imposing sanctions against complainant Genentech for alleged discovery abuse and reopening the record for the reception of additional documentary evidence. In his final ID, issued on November 29, 1994, the ALJ granted the motion for sanctions, and denied the requests to reopen the record. In the ID, the ALJ dismissed the complainant with prejudice and terminated the investigation as a sanction for Genentech's misconduct during discovery. Additionally, the ALJ issued an opinion ruling on the merits of the investigation based on the evidentiary record as it closed on April 24, 1994.

On December 12, 1994, complainant Genentech and the Commission investigative attorney filed petitions for review of the ID. The Novo respondents filed a contingent petition for review. On December 19, 1994, all parties filed responses to the petitions for review.

On December 12, 1994, complainant Genentech filed a motion to supplement the Commission record. Responses to Genentech's motion were filed by the BTG respondents, the Novo respondents, and the IA. The Commission denied Genentech's motion on the basis that the record, as defined by interim rule 210.43(a), already includes the documents at issue. On December 20, 1994, Genentech moved for leave to reply to the BTG respondents' opposition to Genentech's motion to supplement the record. The Commission denied Genentech's motion for leave to reply as moot in view of its denial of Genentech's motion to supplement the record.

This action is taken under the authority of section 337 of the Tariff Act of 1930, 19 U.S.C. § 1337, and Commission interim rule 210.53, 19 C.F.R. § 210.53.

Copies 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.

By order of the Commission.

Donna R. Koehnke

Donna R. Koehnke
Secretary

Issued: January 17, 1995

PUBLIC VERSION

UNITED STATES INTERNATIONAL TRADE COMMISSION
Washington, D.C.

In the Matter of	)	
	)	
Certain Recombinantly Produced	)	Investigation No. 337-TA-358
Human Growth Hormones	)	
	)	

Initial Determination

Paul J. Luckern, Administrative Law Judge

Pursuant to the Notice of Investigation published on September 29, 1993, (58 Fed. Reg. 50954-55), this is the administrative law judge's final initial determination under Commission interim rule 210.53. The administrative law judge hereby determines that the investigation should be terminated and the complaint dismissed with prejudice pursuant to Commission interim rule 210.36(b) as a sanction for complainant's conduct in violation of Commission interim rule 210.30(d)(2) and ground rules 4(ix) and 5, resulting in an incomplete record and violation of the due preocess rights of the respondents. Accordingly, the administrative law judge finds no violation of subsection (a)(1)(B)(i) of the Tariff Act of 1930, as amended (19 U.S.C. § 1337), in the importation into the United States, the sale for importation, or the sale within the United States after importation, of certain recombinantly produced human growth hormones.

In the alternative, should the Commission determine that the conduct of complainant is not sanctionable, and that a final determination can be made on the incomplete record as it was closed on April 24, 1994, the administrative

law judge has included in this initial determination an opinion based on that record which finds that there would be, under those circumstances, a violation of said subsection (a)(1)(B)(i) by each of the respondents.

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ABBREVIATIONS

CB	Complainant's Initial Posthearing Brief
CBR	Complainant's Post Hearing Reply Brief
CFF	Complainant's Proposed Findings of Fact
CPX	Complainant's Physical Exhibit
CX	Complainant's Documentary Exhibit
CRFF	Complainant's Proposed Rebuttal Findings of Fact
FF	Findings of Fact
PEO	Permanent Exclusion Order
RBRFF	BTG's Proposed Rebuttal Findings
RBB	BTG's Initial Post Hearing Brief
RBPX	BTG's Physical Exhibit
RBX	BTG's Documentary Exhibit
RNB	Novo's Documentary Exhibit
RNBR	Novo's Post Hearing Reply Brief
RNPX	Novo's Physical Exhibit
RNX	Novo's Documentary Exhibit
RNFF	Novo's Proposed Findings of Fact
RT	BTG's Proposed Finding of Fact
SB	Staff's Initial Post Hearing Brief
SBR	Staff's Post' Hearing Reply Brief
SX	Staff's Documentary Exhibit
TEO	Temporary Exclusion Order
TEO FF	Findings of Order No. 64
Tr	Transcript
RNB	Novo's Initial Post Hearing Brief

I. PROCEDURAL HISTORY

On September 21, 1993, pursuant to subsection (b) of section 337 of the Tariff Act of 1930, as amended, the Commission instituted an investigation, following the filing of an amended complaint by complainant Genentech, Inc. (Genentech), to determine whether there is a violation of subsection (a)(1)(b) of section 337 in the importation into the United States, the sale for importation, or the sale within the United States after importation of certain recombinantly produced human growth hormones made abroad by processes covered by claims 1, 2, 3, 5, 6, 10, or 11 of U.S. Letters Patent 4,366,246 (the '246 patent), claims 1, 2, 4, or 5 of U.S. Letters Patent 4,342,832 (the '832 patent), claim 2 of U.S. Letters Patent 4,601,980 (the '980 patent) or claims 1, 2, 5, 6, 7, 10, 11, 30, or 38 of U.S. Letters Patent 5,221,619 (the '619 patent) and whether there exists, or is in the process of being established, an industry in the United States as required by section (a)(2) of section 337. Also, pursuant to Commission interim rule 210.24(e)(8), Motion Docket No. 358-1 for temporary relief was provisionally accepted and referred to an administrative law judge.

The Commission in its notice of investigation, pursuant to Commission interim rule 210.58(b)(1), further delegated to the presiding administrative law judge the authority to compel discovery, take evidence, and hear argument with respect to the public interest in this investigation, as appropriate, and directed the judge to file with the Commission recommended findings of fact on the issue within 14 days after filing the initial determination, under Commission interim rule 210.53(a), on whether there is a violation of section 337 for purposes of permanent relief.[1]

The notice of investigation, published on September 29, 1993 (58 Fed. Reg.

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[1] Included with this initial determination, as Section IX, are recommended findings of fact concerning public interest.

50954-55), named as respondents Novo Nordisk A/S, Novo Nordisk of North America, Inc., Novo Nordisk Pharmaceuticals, Inc., and Zymogenetics (Novo respondents or Novo) and Bio-Technology General Corp. and Bio-Technology General (Israel) Ltd. (BTG respondents or BTG).

A hearing on complainant's Motion No. 358-1 for temporary relief commenced on December 13 and concluded on December 18.[2] Said motion was denied in Order No. 64, an initial determination (TEO ID), filed on January 26, 1994, which found that complainant had not proven it would suffer irreparable harm in the absence of temporary relief (Order No. 64 at 102). The TEO ID was adopted by the Commission on February 25, 1994.[3]

Order No. 82, which issued on March 2, 1994, pursuant to Commission interim rules 210.53(c) and 210.59, designated the permanent phase of this investigation "more complicated" and concluded that the initial determination on permanent relief would be due no later than July 29, 1994.[4]

On April 8 complainant orally moved to amend the notice of investigation and complaint (Tr. at 43) by withdrawing claim 38 of the '619 patent. In an initial determination filed herewith (Order No. 146) complainant's oral motion

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[2] The hearing involved only the BTG respondents. The Novo respondents had previously entered into a consent order with respect to the TEO proceedings. See Order No. 22 (Oct. 19, 1993).

[3] Notice of Commission Determination To Adopt the Administrative Law Judge's Initial Determination Denying The Motion Of Complainant For Temporary Relief, 59 Fed. Reg. 10165 (March 3, 1994).

[4] The Commission, in a notice dated April 4, 1994, determined to review and modify the initial determination (Order No. 82) by striking a statement concerning the statutory deadline for Commission action on the ground that the statement was not consistent with section 337(b), which provides that the statutory deadline in "more complicated" investigations is eighteen (18) months after the date of institution. It did state however that while the statutory deadline for completion of the investigation is March 29, 1995, the Commission expects to complete this investigation prior to that deadline. In all other respects, the Commission adopted Order No. 82 as the determination of the Commission.

was granted.

The evidentiary hearing on issues concerning permanent relief commenced on April 11, 1994 and concluded on April 24, 1994, with the closing of the record (PEO hearing). Closing arguments, following the filing of post-hearing submissions, were had on June 9 and 10, 1994.

On May 23, 1994, BTG moved for an order to reopen the PEO record and admit into evidence a deposition exhibit and a news release that were admitted in the TEO Proceeding (Motion Docket No. 358-117). BTG's Motion No. 358-117 is granted.[5]

Order No. 132, which issued on July 28, 1994, delayed the issuance of any final initial determination on permanent relief until November 29, 1994, at the latest. On August 22, the Commission determined not to review that initial determination.

On August 29, 1994, each of BTG and Novo moved for an order imposing sanctions against Genentech and reopening the administrative record for the reception of additional documentary evidence. (Motion Docket Nos. 358-133 and 358-130 (BTG) and Nos. 358-131 and 358-132 (Novo)). Motions Nos. 358-133 and 358-131 for sanctions are granted, while Motion Nos. 358-130 and 358-132 to reopen the record are denied. See Section VI, infra.

II. JURISDICTION

BTG argued that the Commission does not have jurisdiction over BTG's importation of accused human growth hormone products because its importation transactions are allegedly shielded from a determination of patent infringement pursuant to 35 U.S.C. § 271(e)(1) or the common law research-use defense.[6] It

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[5] Neither of said exhibits is cited in the opinion (Section VII, infra).

[6] 35 U.S.C. §271(e)(1) generally exempts from a determination of infringement acts that are reasonably related to the FDA approval process.

asserted that there is no evidence that BTG imported human growth hormone into the United States other than for clinical trials and for basic research, and since there has been no act of infringement, the Commission lacks jurisdiction (RBB at 64 to 66). Complainant and the staff argued that the Commission does have jurisdiction over BTG in this investigation.

BTG's contention that the Commission has no jurisdiction is rejected. In Amgen Inc. v. U.S.I.T.C., 902 F.2d 1532, 14 USPQ2d 1734, 1736-37 (Fed. Cir. 1990) (Amgen) the Federal Circuit stated that:

> As is very common in situations where a tribunal's subject matter jurisdiction is based on the same statute which gives rise to the federal right, the jurisdictional requirements of section 337 mesh with the factual requirements necessary to prevail on the merits. In such a situation the Supreme Court has held that the tribunal should assume jurisdiction and treat (and dismiss on, if necessary) the merits of the case.

Id. at 1737-38, citing Bell v. Hood, 327 U.S. 678, 682 (1946); Jackson Transit Authority v. Local Division 1285, Amalgamated Transit Union, AFL-CIO-CLC, 457 U.S. 15, 21 (1982); Do-Well Machine Shop v. United States, 870 F.2d 637, 639-49 (Fed. Cir. 1989). Accordingly, the Court reversed the Commission's determination that it lacked jurisdiction and held that the Commission should have "assumed jurisdiction, and, if the facts indicate that Amgen cannot obtain relief . . . the Commission should have dismissed on the merits." Id at 1739. The two exceptions to this general rule, where the claim is "immaterial and is brought solely for the purpose of obtaining jurisdiction in a particular forum" and where the claim is "wholly insubstantial and frivolous," were found not to exist in that case. Id. at 1738.

The allegations in the complaint regarding BTG's importation are found to be neither "immaterial" nor brought solely to obtain jurisdiction in the Commission, nor to be "wholly insubstantial and frivolous." BTG has admitted that it has imported human growth hormone into the United States although it

argued that it was imported only for clinical trials and for basic research. The administrative law judge finds that affirmative defenses based on 35 U.S.C. §271(e)(1) and the common law research use doctrine do not present a barrier to the Commission's exercise of jurisdiction. Here, as in Amgen, jurisdiction is based on the importation of a product that allegedly was made by an infringing process. The issue of infringement is an issue that relates to the merits of the case; and is "not material to the issue of jurisdiction." Amgen, 902 F.2d at 1536. Hence the Commission has subject matter and in rem jurisdiction because the alleged unfair acts and unfair methods involve importation and sale in the United States of recombinantly produced human growth hormone alleged to be manufactured abroad by processes covered by certain claims of the '832 patent, the '980 patent and '619 patent and the 246 patent.[7]

Also the Commission has in personam jurisdiction based on the appearance of counsel for all parties.

III. PARTIES

Complainant Genentech is a Delaware corporation having its principal place of business at 460 Point San Bruno Boulevard, South San Francisco, California 94080. (CX 62). Respondent Bio-Technology General Corp. is a Delaware corporation having its principal place of business at 70 Wood Ave. South, Metro Park Financial Center, 2nd Floor, Iselin, New Jersey 08830. (CX 48, p. 2). The company's production activities are carried out through its wholly-owned subsidiary, respondent Bio-Technology General (Israel) Ltd. in Rehovot, Israel. (CX 195, p. 2). Respondent Novo Nordisk A/S is a Danish limited liability company located in Bagsvaerd, Denmark. Respondent Novo Nordisk of North America, Inc., is a Delaware corporation, having its principal place of business

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[7] The merits of BTG's defense under 35 U.S.C. §271(e)(1) and the common law research defense are discussed in Section VII, C infra.

in New York, New York. Respondent Novo Nordisk Pharmaceuticals, Inc. is a Delaware corporation, having its principal place of business in Princeton, New Jersey. Respondent Zymogenetics, Inc. is a Washington corporation having its principal place of business in Seattle, Washington. (CX 321; Tr. (PEO) at 1802).

IV. PRODUCTS INVOLVED

The PEO proceeding involves complainant's NUTROPIN and PROTROPIN products, BTG's BIOTROPIN product, and Novo's NORDITROPIN product. Complainant alleged that NUTROPIN and PROTROPIN are both brands of human growth hormone produced by complainant using recombinant DNA technology of the patents in issue and that BTG's BIOTROPIN and Novo's NORDITORPIN infringe certain claims of the patents in issue.[8]

V. IMPORTATION

BTG has imported recombinantly produced human growth hormone into the United States which complainant has accused infringe certain claims in issue.

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[8] Complainant, at the PEO hearing, alleged that Novo and BTG have imported recombinantly produced human growth hormones that have been made abroad by processes covered by the following claims of the patents in issue:

The BTG respondents

'619 patent
claims 1, 2, 5, 6, 7 10, 11, and 30

'832 patent
claim 1, 2, 4, and 5

'980 patent
claim 2

The Novo respondents

'619 patent
claims 1, 2, 6, 7, and 10

'832 patent
claims 1, 2, 4, and 5

'980 patent
claim 2

'246 patent
claims 1, 2, 3, 5, 6, 10, and 11

(See BTG Prehearing Brief at 54, et seq.).

(See, e.g., CX 321, at 9-11).

VI. BTG'S MOTION NO. 358-133 AND NOVO'S MOTION NO. 358-131 FOR SANCTIONS AND BTG'S MOTION NO. 358-130 AND NOVO'S MOTION NO. 358-132 TO REOPEN[9]

BTG, in its Motion No. 358-133 for sanctions filed on August 29, 1994, argued at 2, 3 that on the record the imposition of sanctions on Genentech is warranted given the adverse effects of Genentech's actions upon BTG's ability to use various materials at the PEO hearing and in BTG's post-hearing submissions; and hence the administrative law judge should find the following sanctions:

> (1) Rule by initial determination that the determinations as to the validity, enforceability, and infringement by BTG with respect to the '832, '980, and '619 patents[10] in the investigation be rendered against Genentech pursuant to interim rule 210.36(b)(5);
>
> (2) Rule that for the purposes of this investigation, all findings necessary to support denial of relief are taken as established adversely to Genentech pursuant to interim rule 210.36(b)(2); and

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[9] BTG moved to reopen the record to put into evidence RBX 414, 415, 416, 417, 418, 419, 420, 421, 422, 423, 424, 425, 426, 427, 428, 429, 430, 431, 432, 433, 434, 435, 436, 437, 438, 439, 440, 441, 445, 446, 447 and 448. By letter dated September 9, 1994, BTG withdrew its offer of RBX 422. RBX 442, 443 and 444, listed in BTG's motion, were produced during discovery in this investigation, prior to the commencement of the hearing on permanent relief, under ITC production numbers GZ 125/001703-001705, GZ 55/1248-1249 and GZ 55/1245-1246, respectively.

Novo has moved to reopen the record to put into evidence RNX 157, 158, 159, 161, 162, 163, 165, 166, 167, 168, 169 and 170. RNX 160 and 164, listed in Novo's motion, were produced during discovery in this investigation, prior to the hearing on permanent relief, under ITC production numbers GZ 100 2007\2017 and GZ 83 1639-1657, respectively. In its opposition at 10 Genentech argued that Novo's request to admit GLP 02789-02790 should be denied because said document had been produced to Novo during the discovery period under ITC production No. GZ 68 2280-2281. It does not appear that Novo has in fact offered any document bearing the GLP numbers 02789-02790.

[10] The '832, '980 and '613 patents are the only patents asserted against BTG.

(3) Order Genentech to pay BTG's reasonable expenses, including attorney's fees, in connection with BTG's efforts to obtain the improperly withheld documents pursuant to Rule 210.33(c) of the Final Rules of Practice and Procedure.

Novo, in its Motion No. 358-131 for sanctions, filed on August 29, 1994, argued that concealment, lack of candor, frivolous legal argument and continuing evasion have characterized Genentech's conduct concerning the "GLP" documents; that it is indisputable that weeks before the PEO hearing commenced Genentech knew, or upon any reflection would have recognized, that it no longer had any cognizable claim of privilege in the "GLP" documents as a result of a district court's March 22, 1994 decision in an Indiana multi-district litigation involving Genentech, Eli Lilly & Company (Lilly) and the University of California (UC); and that at a minimum, Genentech had a duty to bring the decision of the district court to the attention of respondents. It is argued that at no time, whether before, during or after the PEO hearing, did Genentech bring the March 22 district court opinion to the attention of respondents, the staff or the Commission. Novo argued that Genentech's pattern of deception and evasiveness was violative of all standards of conduct applicable to this investigation and warrants the most stringent sanction, viz. dismissal of the complaint; and that Genentech should not be allowed to continue to use this tribunal to achieve its own ends after so abusing the integrity of this investigation and unfairly prejudicing respondents.

A. Background

On March 16, 1993, complainant Genentech filed a complaint alleging violations of subsection (a)(1)(b) of section 337 of the Tariff Act of 1930, as amended. Letters supplementing the complaint were filed on March 30, March 31, April 5, April 6, April 9, April 12 and April 22. On August 18 complainant

filed an amended complaint (FF 630). The Commission on September 21, 1993 instituted an investigation, under section 337, involving certain claims of the '246 patent, '832 patent, '980 patent and '619 patent and naming BTG and Novo as respondents and provisionally accepted a motion for temporary relief filed by Genentech. (FF 631 and Procedural History, supra). The notice of investigation was published in the Federal Register on September 29, 1993 (FF 632).

In litigation in the United States District Court for the Southern District of Indiana, complainant Genentech has charged Lilly with infringement of the '980, '832 and '246 patents, in issue in this investigation. In that litigation, pending since 1987, Lilly contends that certain of Genentech's patents, including the '980, '832 and '246 patents, are invalid (FF 634). Consolidated with that litigation is a federal district court litigation between Lilly and Genentech involving the remaining '619 patent in issue in this investigation (FF 635). (The consolidated litigation is hereafter referred to as the "MDL litigation.") UC is also involved in the consolidated litigation.

Included as counsel in this investigation for Genentech is not only counsel from the law firm of Fish and Richardson but also John F. Kidd, Esq. of the law firm of Rogers & Wells. Mr. Kidd is Genentech's lead counsel in the MDL litigation. He also participated in opening argument in April 1994 at the hearing on permanent relief in this investigation. In addition, Stephen Raines, Genentech's Vice President, Intellectual Property, is listed as "Of Counsel" for Genentech in this investigation. Also, Raines signed an "Agreement to Abide By the Terms of The Protective Order (Order No. 2)" in this investigation, which was served on February 17, 1994. Raines further testified at the hearing on permanent relief on April 22, and was present for at least a portion of that hearing (FF 636).

Beginning in October 1993, BTG propounded discovery requests on Genentech in this investigation seeking information regarding the '832 patent, '980 patent and '619 patent that were asserted against it by Genentech (FF 637). Novo, beginning in November 1993, propounded discovery requests on Genentech in this investigation seeking information regarding all of the patents in issue, viz. the '246 patent as well as the '832 patent, the '980 patent and the '619 patent, because all four patents were asserted against it by Genentech (FF 638). Discovery was ongoing in the MDL litigation concurrently with the discovery in this investigation (FF 646).

In the MDL litigation, early in November 1993 Genentech "inadvertently" produced approximately sixteen (16) boxes of documents to UC and Lilly bearing "GLP" bates numbers. A "substantial" portion of those documents were alleged to be privileged. Within twenty-four (24) hours after Genentech learned that it had "inadvertently" produced the GLP documents, Genentech filed a motion in the MDL litigation for return of the documents with the GLP bates numbers. The parties in the MDL litigation thereafter conducted discovery (including depositions) concerning the facts and circumstances of Genentech's "inadvertent" production of the materials, which discovery was completed in early January, 1994. The parties then extensively briefed the issue and by early February 1994, the matter was submitted to Judge Dillin in the MDL litigation for decision (FF 646).

During December 1993, Genentech conducted a review of the "inadvertently" produced documents to UC and Lilly, withdrew its claim of privilege with respect to three boxes (approximately 9,000 pages) of documents, and in late December 1993 Genentech produced to Lilly and UC copies of the documents as to which Genentech was no longer claiming privilege (FF 658).

A hearing on complainant's motion for temporary relief commenced on

December 13, 1993, and concluded on December 18. See Procedural History, supra.

Order No. 25, which issued on October 20, 1993, set the commencement of the evidentiary hearing on the permanent relief phase of this investigation for March 21. Order No. 82, which issued on March 2, 1994, delayed the commencement of the evidentiary hearing until April 11. Said hearing concluded on April 24, 1994, at which time the record was closed. Initial post-hearing submissions were filed on May 23, and reply post-hearing submissions on June 3. Closing arguments were had on June 9 and 10 (FF 650).

Taking of discovery after a scheduled discovery completion date has been permitted in this investigation. Thus, while the discovery completion date in the TEO phase of this investigation was December 6, 1993, at least the deposition of Gottesman and Blech, which were admitted into evidence at the TEO and PEO hearings, were taken after the TEO discovery completion date had passed. Moreover, while the discovery completion date for the PEO phase of this investigation was March 18, 1994, at least the following depositions, which were also admitted into evidence at the PEO hearing, were taken after the PEO discovery completion date had passed: Kleid, Chamberlin, Lin, Goodman, Goedell, and Heyneker. In addition, during the hearing on permanent relief, the administrative law judge ruled that certain proffered evidence of complainant would be admitted into evidence provided that Novo, after the April 24 closing date for the hearing, was given the opportunity to examine certain witnesses. Complainant subsequently withdrew its proffer of said evidence (FF 651).

Because identical patents are involved in the MDL litigation and in this investigation, Genentech knew by at least in March 1994, that certain documents generated in the MDL litigation were responsive to discovery requests propounded by the respondents in this investigation, and that such documents were being produced to BTG and Novo under the protective order in this investigation (FF

642).

On March 22, 1994, Judge Dillin denied Genentech's motion in the MDL litigation for the return of 12,000 pages of inadvertently produced documents to Lilly and UC (the "GLP" documents). In the opinion denying Genentech's motion (MDL opinion) Judge Dillin did "not find a subject matter waiver ... [and hence] the waiver [applied]... only to the documents actually produced" (FF 644). Genentech did not seek any appeal of Judge Dillin's denial of its motion (FF 645). Judge Dillin's opinion was published at 30 USPQ2d 1881 on June 27, 1994 (FF 644). Genentech never informed Novo, BTG or the staff about the issuance of the MDL opinion (FF 645).

BTG's counsel, in a letter dated Friday, July 8, 1994, and faxed to Genentech's counsel, referred to the MDL opinion "just published this week" and represented that from the facts available to BTG, BTG believes that many, if not all, of the approximately 12,000 documents involved in the MDL opinion were covered by BTG's discovery requests to Genentech and are relevant to the issues in this investigation; and that BTG's records indicate that no additional documents, such as the ones at issue in the MDL opinion were produced to BTG after issuance of the MDL opinion on March 22, 1994, and that if production were not made, then Genentech is in violation of the administrative law judge's ground rule 4(ix) (FF 653) in effect in this investigation. It was requested, in the July 8 letter, that Genentech confirm that the 12,000 documents referred to in the MDL opinion were in fact produced to BTG, and that if said documents were not produced, but had been withheld on the ground of privilege, that they be produced to BTG immediately so that BTG can determine whether it will need to make a motion to reopen the record to introduce any documents that it concludes should have been part of the record in this investigation (FF 652).

Genentech's counsel, in a fax letter dated Friday, July 8, 1994,

responding to BTG's July 8 letter, stated that Genentech is "presently looking into the matters raised in your letter and will get beck to you early next week" (FF 654).

In a fax letter to complainant's counsel dated Tuesday, July 12, 1994, BTG stated that it had heard nothing from Genentech since "your fax letter of July 8, 1994, stating that you are looking into the matter of Genentech's withheld documents in view of the MDL order [MDL opinion]"; that it is very important that BTG receive Genentech's documents in issue in the MDL opinion since the period during which the administrative law judge may decide the case is rapidly drawing to a close;[11] and that accordingly, unless BTG received copies of the withheld documents by the close of business on July 13, BTG would move before the administrative law judge for appropriate relief (FF 655).

Genentech's counsel, in a July 13 fax letter to BTG's counsel in response to BTG's July 12 letter, represented that "no one is more anxious than Genentech to resolve the issue involving the MDL documents and avoid any potential delay in these proceedings," and that "Genentech and its counsel have been diligently pursuing the matter and we intend to have a formal response to both you and counsel for Novo before the week's end." (FF 656).

In a July 14 letter of Genentech's counsel to counsel for BTG and Novo, responding to the letter of July 8 of BTG's counsel, it was represented that "there is no basis for re-opening the ITC record to include any of these documents" from the MDL litigation that were involved in Judge Dillin's March 22 opinion because the opinion "did not obligate Genentech to produce the privileged materials in this investigation" (FF 657). It was also represented

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[11] At that time, pursuant to Order No. 82, the final initial determination on permanent relief was due on July 29, 1994.

that during "the last three days" Genentech had conducted an "exhaustive review" of the approximately 9000 pages of documents it produced to Lilly and UC in late December 1993, and no longer claimed were privileged, and determined that approximately 70 percent of those documents were unrelated in any way to growth hormone and/or to the issues relating to the patents in issue in this investigation; that with respect to the remaining approximately 2,900 pages of growth hormone-related documents, all but 60 pages of them were duplicate of documents previously produced to Lilly and UC in the MDL litigation and also produced in this investigation; and that as to the remaining 60 pages of non-privileged growth-hormone-related materials, it was believed they were produced in this investigation, although that had not been established for certain, and in order to avoid any further delay in fully resolving the issues raised by BTG's counsel's July 8 letter, "we voluntarily produce copies of these 60 pages herewith" (FF 658). At a July 26 conference Genentech's counsel Eccleston represented that the sixty documents enclosed with Genentech's July 14 letter to BTG and Novo were responsive to discovery requests of respondents in this investigation and that "we're pretty sure they have been produced [during discovery in this investigation]". Genentech's counsel Kidd represented that:

> some of these [60] documents have been continuously showing up, and I know they've been produced because I've been sitting in a lot of depositions. . . But I think they have been [produced], Mr. Ross thinks they have been and the Fish & Richardson firm thinks that they have been.

(FF 659). Kidd, however, thereafter represented that "[a]nd it turned out that these last 60 pages were the ones that we just couldn't come up with" (FF 659). In a July 28 letter to the administrative law judge, Genentech's counsel represented that it still had not been able to determine that all of the remaining 60 pages were produced during discovery, although it was confirmed that at least some of the 60 pages were produced and that the balance of the

remaining pages contains information that is merely cumulative of materials provided to BTG and Novo during discovery (FF 672).

On July 14, 1994, BTG filed Motion No. 358-119 for an order compelling "immediate" production of the GLP documents which (1) in all likelihood were called for by BTG's discovery requests, (2) were found to be not privileged in the MDL opinion and (3) apparently were not produced by complainant in this investigation (FF 660). On July 15, Genentech's counsel in a telephone conference represented that with respect to the documents involved in BTG's Motion No. 358-119 to compel "they are responsive to at least some of BTG's document requests, but we also believe that there's a good likelihood that they have already been produced to BTG" (FF 661).

Genentech's counsel, at the July 15 conference, argued that the waiver in the MDL opinion is:

> for a limited, a very limited purpose of the multidistrict litigation and as to the four corners of the document.
>
> It doesn't apply beyond the multidistrict litigation; it doesn't apply to the ITC; it doesn't apply to other parties, other than UC and Lilly. [FF 661]

BTG argued that what Genentech's counsel said made absolutely no sense; that the documents were found not to be privileged by the district court because there had been a production, and therefore the privilege had been waived; that only as to "other documents dealing with the same subject matter" was there no waiver"; that there is nothing in the MDL opinion that says that the waiver as to the documents involved in the MDL opinion meant that said documents could only be seen by UC and Lilly attorneys; and that counsel for Genentech is on record, both in pleadings, as well as in phone conferences with the administrative law judge, as stating again and again that Genentech has no problem providing documents that were the subject to the MDL protective order

to counsel in this investigation under the protective order, provided Lilly and UC had not asserted some kind of confidentiality (FF 661).

On July 15, 1994, Genentech also filed an opposition to BTG's Motion No. 358-119 to compel. It again argued that the MDL opinion did not hold that complainant had waived its privilege for all purposes, but rather that it held that there had been only a limited waiver of privilege as to UC and Lilly in the MDL litigation (FF 662). Genentech, in an August 22 response to Order No. 136, which issued on August 16, repeated its argument that the GLP documents were privileged and BTG and Novo were not entitled to see them because of the very limited nature of the MDL waiver found by the MDL Court and because of the protective order in place in the MDL litigation (FF 680).

Order No. 129, which issued on July 15, ordered that the GLP documents in issue in BTG's Motion No. 358-119 be made available for inspection no later than Tuesday, July 19. Genentech filed no motion for reconsideration of Order No. 129, nor did it request interlocutory review of Order No. 129 (FF 663).

On July 21, pursuant to Order No. 129, each of BTG and Novo filed motions to reopen the record for admission of additional evidence involving the GLP documents produced pursuant to Order No. 129 and for sanctions and to delay the issuance of the initial determination, then due on July 29, until November 29, 1994, at the latest (FF 665). The underlying reason for the motions was to permit sufficient time for the respondents and the administrative law judge to examine and analyze "newly produced evidence" that had been "improperly" withheld by Genentech (FF 665).

On July 25, Genentech opposed the motions filed by the respondents on July 21. Genentech argued that the documents which the respondents saw "for the first time last week," were attorney work product and/or privileged attorney-client communications; that for the most part, those documents contain merely

the analyses, musings, ruminations and thought processes of Genentech's counsel and would-be counsel; that those documents do not constitute "new" evidence, nor do they refer to evidence previously unknown to BTG and Novo and any underlying factual information even present in said documents was available to BTG and Novo during discovery; and that it is the eleventh hour in these proceedings and the final initial determination is due in "only a few days." Genentech, however, also argued that if the administrative law judge does grant respondents' motions to reopen the record, the administrative law judge should adhere to the district court's ruling in the MDL litigation that there has been no subject matter waiver and that any waiver extended only to the four corners of the documents that have been produced which would not preclude the administrative law judge from allowing further depositions, affidavits, or trial testimony concerning each of the documents, which Genentech expects will be necessary in the event that the record is reopened (FF 665).

In the conference before the administrative law judge on July 26, Genentech's counsel represented that because of the protective order in the MDL litigation, any privilege attached to the documents ordered to be produced pursuant to Order No. 129 starting on July 19, was "just waived with the purpose of the MDL litigation" and that "[w]e at [sic] the lead counsel didn't even know about [sic] that this order [MDL opinion] had issued. Because Genentech really believed that it was just a waiver in the case. And we were just completely unaware of this" (FF 668). Genentech's counsel also represented that "[t]here's nothing that they [respondents] have requested that they're entitled to that they have not gotten," and that "[e]verything we could do internally has been done ... [although] [w]e have not checked with Lilly" (FF 669, 670). Novo, by letter to the administrative law judge dated July 27, 1994, stated that the July 26 conference called into question whether complainant had fully complied with

discovery requests in this investigation; that none of at least fourteen relevant documents attached to Novo's motion to reopen filed July 21 were produced to Novo "before last week"; and that only one of the 14 documents was listed in the Duplan sheets[12] provided to Novo pursuant to ground rule 5(i)(b) (FF 671). Genentech's counsel, in a July 28 letter to the administrative law judge, represented that with respect to the non-privileged GLP documents missing from Genentech's earlier productions to BTG and Novo, "we have been able to locate those documents at Genentech. They are being sent from Genentech to Rogers & Wells [complainant's counsel], and will be produced to respondents in New York by close of business today" (FF 672). In a letter to counsel for BTG and counsel for Novo dated July 28, Genentech's counsel represented that "[b]y the end of business today, we will send you (1) the documents which you contend were 'missing' from last week's production; (2) more legible copies of certain documents produced last week; and (3) certain additional pages of purportedly 'incomplete' documents produced last week" (FF 673). Those items (1), (2) and (3) were sent by letter dated July 29 (FF 679).

On July 28, 1994, the administrative law judge, in view of the production of documents by Genentech to Novo and BTG commencing on July 19, issued Order No. 132 (an initial determination) granting respondents' motions filed on July 21 to the extent that he delayed the issuance of any final initial determination on permanent relief from July 29, 1994, until November 29, 1994, at the latest. The November 29, 1994, date is the latest date under which the administrative law judge must act under the statutory definition of "more complicated" (FF 674).

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[12] The term "Duplan sheets" refers to privileged documents list such as explained in Duplan v. Deering Milliken, Inc., 184 USPQ 775 (D.S.C. 1975) (Duplan).

Order No. 133, which also issued on July 28, 1994, denied without prejudice respondents' motions filed on July 21, to the extent that they requested reopening the record and sanctions, on procedural grounds in view of the fact that neither BTG nor Novo specifically identified any documents which it wanted admitted into evidence. Order No. 133 concluded that if any of the respondents intend to renew said motions to reopen and for sanctions it should be done no later than August 19, and gave complainant until August 29 to respond to any such renewed motions filed by respondents (FF 676, 677).

Order No. 134, which issued on July 28, 1994, directed complainant to respond by August 4 to certain issues raised by the respondents at the July 26 conference concerning Genentech's production of documents which commenced on July 19 (FF 678). Order No. 134 concluded that if there are still outstanding issues with respect to the production ordered by the administrative law judge pursuant to Order No. 129, a party should notify the administrative law judge in writing no later than August 5, subsequent to discussions with complainant and a telephone conference thereafter will be scheduled (FF 678). Letters dated August 5 from each of BTG and Novo were received by the administrative law judge raising questions concerning Genentech's production which commenced on July 19 (FF 686, 687).

On August 8, the administrative law judge conducted a telephone conference with the parties pursuant to Order No. 134 and the August 5 letters received from counsel for Novo and BTG. As stated at the telephone conference on August 8 and in Order No. 135, which issued on August 8, 1994, the administrative law judge reopened the record for discovery by respondents and the staff "in connection with documents produced by complainant pursuant to Order No. 129" (Order No. 135 at 1) (FF 689(a)).

On August 12, the administrative law judge received motions to compel from

BTG and Novo, pursuant to Order No. 135, as a result of discovery served by respondents also pursuant to Order No. 135. In issue in the motions to compel, inter alia, was whether Genentech identified on its Duplan sheets, which were received by respondents prior to the hearing on permanent relief, all of its documents that were responsive to discovery requests of respondents but that were not produced to respondents prior to the hearing. Under ground rule 5 in effect in this investigation respondents were entitled to complete Duplan lists before hearing. It is a fact that Genentech did not identify on its Duplan sheets, which were received by respondents prior to said hearing, all of its documents that were responsive to respondents' discovery requests (see FF 690).

Order No. 136, which issued on August 16, responding to respondents' motions to compel, found certain discovery responses incomplete (FF 693). Accordingly, Order No. 136 ordered Genentech to complete certain discovery requests of BTG and Novo by August 22. In view of the incomplete responses of Genentech, Order No. 136 extended the August 19 date for the filing by respondents of any renewed motions to reopen and for sanctions to August 29. A date of September 2 was set for complainant to respond to any such renewed motions (FF 693). Genentech replied to the staff's response to the renewed motions on September 12.

B. Respondents' Motions for Sanctions

1. Genentech's Arguments

In the "Consolidated Memorandum of Genentech, Inc. In Opposition to Respondents' Motion For Sanctions and Motions to Reopen the Proceedings," which was filed on September 2, 1994 (opposition), Genentech argued with respect to "the recourse of sanction to remedy the GLP situation" that

> the only appropriate course is to reopen the record to give respondents (and the Staff) a reasonable opportunity (a) to show why any truly new evidence should be admitted into the record, and

> upon that showing, and (b) to admit the evidence in a hearing in which the parties have the opportunity to argue how that new evidence is relevant to their "claim," in the context of a hearing where Genentech produces whatever witnesses are ordered by the Administrative Law Judge ... and where the new evidence may properly be considered by all parties.

Opposition at 2-3 (emphasis in original).

In "Genentech's Reply To The Staff's Response To Respondents' Motion's To Reopen The Record And For Sanctions," which reply was filed on September 12, 1994, Genentech argued at 2-3 that the staff has attempted to put its own interpretation on certain of the GLP documents; that the staff would have the administrative law judge ignore certain documents on the ground of relevance, and has distilled bits and pieces from other documents, and given the staff's own view on why the documents may be relevant to some issues in this investigation; and that the administrative law judge now has before him a "potpourri" of possible interpretations of the GLP documents from which he can pick and choose, none of which has been put into context by any live witnesses having actual knowledge of the documents. Hence, Genentech argued that any interpretation of the GLP documents would be based on pure speculation and inference. Genentech further included, as an Appendix A to its opposition, "Genentech's Proposed Rebuttal Findings to Novo's Proposed Facts/Adverse Inferences From the GLP Documents."

Genentech has also argued (opposition at 17-19) that the sanctions sought by respondents would not be available under Rule 37(b) of the Federal Rules of Civil Procedure, because Genentech has not defied a specific discovery order, and hence no sanction under Commission interim rule 210.36(b) is available.

Genentech argued further (opposition at 20) that any sanction of dismissal is draconian, punitive and implicates due process concerns; that there are limitations on a court's discretion to impose sanctions under Rule 37(b) of the

Federal Rules of Civil Procedure which sanctions must be "just" and must be specifically related to the particular "claim" which was at issue in any discovery order. Genentech also argued (opposition at 24, 31) that under the sanctions specifically authorized by Commission interim rule 210.36(b)(5), the rule has the following language not found in Rule 37(b):

> It shall be the duty of the parties to seek, and that of the administrative law judge to grant, such of the foregoing means of relief or other appropriate relief as may be sufficient to compensate for the lack of withheld testimony, documents, or other evidence.

Hence it argued that the language of said rule does not permit sanctions to be imposed except to make up for unavailable evidence. Genentech also argued (opposition at 24-25) that any relief must be the minimum necessary to accomplish the purpose of the interim rule of compensating for a lack of evidence, and a hearing in which all of the parties have the opportunity to develop the record with respect to the GLP documents produced by Genentech would be such a measure of relief; and that evidentiary sanctions are highly disfavored because they frustrate the statutory obligation to make statutory determinations on the basis of a "fully developed factual record."

2. Ruling

a. Monetary Sanctions

At the outset, BTG's request in its Motion No. 358-133 that Genentech be ordered as a sanction to pay BTG's reasonable expenses, including attorneys fees, in connection with BTG's efforts to obtain the GLP documents is denied. This investigation was instituted on September 21, 1993. The Commission's final rule 210.33(c), relied upon by BTG, expressly applies only to those section 337 investigations "that are instituted after August 31, 1994." 59 Fed. Reg. 39020 (Aug. 1, 1994). Costs and attorney's fees are not available under the Commission's interim rules which apply to this investigation. Thus, the

Commission's 1988 comments on Commission interim rule 210.36 state that "[t]he Commission will determine at a later date whether to publish proposed rules governing issuance of orders directing the payment of costs and attorneys fees as a sanction for abuse of discovery." Interim Rules Governing Investigations and Enforcement Procedures Pertaining to Unfair Practices in Import Trade, 53 Fed. Reg. 33043, 33052 (Aug. 29, 1988) (1988 Comments). No such rule was proposed by the Commission until it published proposed final rule 210.33 in late 1992. 57 Fed. Reg. 52830, 52879 (Nov. 5, 1992). In addition, concerning the Commission's authority to award monetary sanction under its interim rules, the Commission stated in Certain Concealed Cabinet Hinges and Mounting Plates, Inv. No. 337-TA-289 (Hinges) that "while express authority to make such awards was granted by Congress in the 1988 amendments to section 337, specifically 19 U.S.C. 1337(h), the Commission declined to implement its authority to award attorneys fees in promulgating the interim rules." Hinges, Commission Opinion at 14 (1989).[13]

b. Due Process in Section 337 Investigations

Any section 337 investigation must be conducted pursuant to the Administrative Procedure Act (APA), 5 U.S.C. § 500, et. seq.[14] The APA requires, inter alia, (1) that the Commission provide parties with the opportunity "for

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[13] Genentech argued (opposition at 5) that "in addition to the relief or sanctions of the reopened hearing with Genentech required to produce witnesses, Genentech does not oppose reimbursing Novo and BTG their reasonable expenses in reassembling for a hearing on the documents." Genentech did not refer to respondents' costs to obtain the improperly withheld GLP documents. Genentech, however, appears to recognize that some sanction is warranted. As found by the administrative law judge, costs and attorney's fees are not available under the Commission interim rules.

[14] Section 337(c) provides that "[e]ach determination under subsection (d) [concerning permanent relief] ... of this section shall be made on the record after notice and a opportunity for a hearing in conformity with the provisions of subchapter II of subchapter 5 of Title 5." 19 U.S.C. § 1337(c) (1994).

submission and consideration of facts," 5 U.S.C. § 554(c)(1); (2) that the Commission may take depositions or have depositions taken "when the ends of justice would be served," 5 U.S.C. § 556(c)(4); and (3) that a party is entitled to present his case, submit a rebuttal case, and conduct cross-examination as necessary for a "full and true disclosure" of the facts, 5 U.S.C. § 556(d). It is "a basic obligation of the ALJ to develop a full and fair record." Smith v. Secretary of Health Education and Welfare, 587 F.2d 857, 860 (7th Cir. 1978) (emphasis added), citing Daniels v. Mathews, 567 F.2d 845 (8th Cir. 1977). Moreover, if an agency has adopted rules for discovery it is bound by those rules and must ensure that its discovery procedures meet the requirements of due process. McClelland v. Andrus, 606 F.2d 1278, 1285-86 (D.C. Cir. 1979) (McClelland).[15] In McClelland, the D.C. Circuit held that "violence" could be done to "our conception of fair procedure and due process" by denying discovery of a report that it found "might identify individuals that appellant may wish to call as witnesses" and "may lead appellant to additional evidence supportive of his claims." McClelland, 606 F.2d at 1286.

Due process "mandates that a judicial proceeding [in a federal district court] give all parties an opportunity to be heard on the critical and decisive allegations which go to the core of the parties' claim or defense and to present evidence on the contested facts." Complaint of Bakers' Trust Company, 752 F.2d

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[15] The Commission's interim rules were promulgated to allow the parties to take broad discovery in order to develop the relevant issues. The ability of a party to take discovery on the issues presented in an investigation in preparation for the hearing is a significant due process consideration. Hinges, Order No. 31 at 6-7 (April 28, 1989) (denying motion to add respondent one month before discovery completion) and Order No. 41 at 3 (May 9, 1989) (heavy burden on party seeking to amend complaint where due process rights to full participation and discovery are prejudiced). See also Certain Track Lighting System Components, Including Plug Boxes, Inv. No. 337-TA-286, Order No. 23 at 3 (March 10, 1989) ("Due process requires fairness in preparation for trial as well as fair opportunity for both sides to make a good evidentiary record").

874, 890 (3rd Cir. 1984) (Bakers' Trust) (emphasis in original). A district court, however, faced with the post-trial production of a large number of documents responsive to earlier propounded discovery requests generally can delay issuance of its decision; order the parties to conduct any additional discovery on the documents as necessary; assess the fees and costs incurred in such additional discovery against the party responsible for the late production; and conduct a supplementary trial on the late-produced documents, with fees and costs incurred in such a proceeding assessed against the responsible party, and with the court's decision to issue sometime thereafter. As already stated, supra, in a section 337 investigation under the interim rules, the administrative law judge does not have the authority to award costs and fees to a party victimized by the discovery misconduct of another party. Moreover, the deadline for the completion of a section 337 investigation is fixed by the applicable statute and cannot be extended. Pursuant to Commission interim rule 210.53(a), the final initial determination of the administrative law judge in this investigation must be filed with the Commission no later than November 29, 1994.[16] Complainant Genentech has been aware of the statutory deadline since the notice of the investigation was published in the Federal Register on September 29, 1993.[17] Hence, Genentech's conduct and the respondents' respective motions for sanctions must be viewed not only in the light of the APA, but also in the light of the deadlines imposed by section 337.

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[16] The administrative law judge knows of no statutory authority whereby said date may be extended.

[17] At least one commentator has stated that the attractiveness of section 337 investigations to complainants is "chiefly attributable to the relatively quick decision attainable under the statutory time limits." Donald K. Duvall, Unfair Competition and the ITC § 1.4 at 9 (1994 ed.). However, the rapid adjudication of section 337 investigations is not to be accomplished at the expense of a respondent's right to a fair opportunity to respond to a complainant's allegations and to present its case.

The administrative law judge finds, infra, that there was gross negligence on the part of Genentech in not identifying certain GLP documents on Duplan lists submitted to the respondents before the April 11 commencement of the hearing on permanent relief, and in not commencing production of the GLP documents until ordered to do so by the administrative law judge on July 19, and that such gross negligence justifies the severest disciplinary measures available under Commission interim rule 210.36(b), viz. an order of dismissal. In this investigation it is inarguable that there are material issues of fact in dispute to which the GLP documents relate, and that said GLP documents may have led respondents to the discovery of additional evidence supportive of their claims. Genentech's failure to commence production of the GLP documents subsequent to the issuance of the MDL opinion, until ordered to do so by the administrative law judge, has violated irreparably the due process rights of respondents.

c. Authority to Impose Sanctions Pursuant to Commission Interim Rule 210.36(b)

The Tariff Act of 1930, as amended, states as follows:

> **(h) Sanctions for abuse of discovery and abuse of process**
>
> The Commission may by rule prescribe sanctions for abuse of discovery and abuse of process to the extent authorized by Rule 11 and Rule 37 of the Federal Rules of Civil Procedure.

19 U.S.C. § 1337(h)(1994) (emphasis added).[18] In August 1988, the Commission promulgated its interim rules, including Commission interim rule 210.36(b),[19]

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[18] Subsection (h) was added to section 337 by section 1342(a)(5) of the Omnibus Trade Act of 1988, Pub.L. 100-418.

[19] Commission interim rule 210.36(b) provides as follows:

> **(b) Failure to comply with order compelling discovery.** If a party or an officer or agent of a party fails to comply with an order including, but not limited to, an order for the taking of a
>
> (continued...)

which are in effect in this investigation. In the Commission's 1988 comments to the interim rules, it stated the following with respect to Commission interim rule 210.36:

> **Section 210.36**
>
> ...section 1342(a)(5)(B) of the Omnibus Trade Act created a new subsection (h) of section 337, which authorizes the Commission to prescribe rules for imposing sanctions for abuse of discovery in

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[19](...continued)

> deposition or the production of documents, an order to answer interrogatories, an order issued pursuant to a request for admissions, or an order to comply with a subpoena, the administrative law judge, for the purpose of permitting resolution of relevant issues and disposition of the investigation without unnecessary delay despite the failure to comply, may take such action in regard thereto as is just, <u>including, but not limited to</u> the following;
>
> (1) Infer that the admission, testimony, documents, or other evidence would have been adverse to the party;
>
> (2) Rule that for the purposes of the investigation the matter or matters concerning the order or subpoena issued be taken as established adversely to the party;
>
> (3) Rule that the party may not introduce into evidence or otherwise rely upon testimony by the party, officer, or agent, or documents, or other material in support of his position in the investigation;
>
> (4) Rule that the party may not be heard to object to introduction and use of secondary evidence to show what the withheld admission, testimony, documents, or other evidence would have shown;
>
> (5) Rule that a motion or other submission by the party concerning the order or subpoena issued be stricken or <u>rule by initial determination that a determination in the investigation be rendered against the party</u>, or both. Any such action may be taken by written or oral order issued in the course of the investigation or by inclusion in the initial determination of the administrative law judge. It shall be the duty of the parties to seek, and that of the administrative law judge to grant, such of the foregoing means of relief or other appropriate relief as may be sufficient to compensate for the lack of withheld testimony, documents, or other evidence. If in the administrative law judge's opinion such relief would not be sufficient, the administrative law judge shall certify to the Commission a request that court enforcement of the subpoena or other discovery order be sought.

(Emphasis added).

section 337 investigations to the extent sanctions could be imposed by a Federal District Court under Rule 37 of the FRCP.

The Commission rule governing sanctions for abuse of discovery is § 210.36. It has not been revised, for the following reasons. The existing provisions of § 210.36 provide sanctions that are comparable to those available under FRCP 37, except that there is no provision for a sanction order directing payment of a party's costs and attorneys' fees.

1988 Comments, 53 Fed. Reg. at 33052 (emphasis added).[20] Thus it is clear that the Commission intends for Commission interim rule 210.36(b) and Rule 37(b) of the Federal Rules of Civil Procedure to be coextensive.[21]

The administrative law judge finds that Genentech has violated Commission interim rule 210.30(d)(2) and two of his ground rules which guarantee respondents' due process rights, viz. ground rules 4(ix) and 5. Commission interim rule 210.30(d)(2) imposes a duty to supplement responses to discovery requests as follows:

(2) A party is under a duty to seasonably amend a prior response if he obtains information upon the basis of which --

* * *

(ii) He knows that the response, though correct when made, is no longer true, and the circumstances are such that a failure to amend the response is in substance a knowing concealment.[22]

Ground rules 4(ix) and 5, of which complainant had notice on September 22,

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[20] In its opposition at 17, Genentech agreed that Congress in 1988 amended Section 337, such that the Commission may prescribe sanctions to the extent that the federal courts may impose sanctions under Rule 37.

[21] While Commission interim rule 210.36(b) refers to "Failure to comply with order compelling discovery," supra, the Commission's comments indicate that the Commission intends sanctions to issue under Commission interim rule 210.36(b) just as sanctions would issue under Rule 37(b), which rule covers the failure to comply with any "order to provide or permit discovery" and is not limited to orders compelling discovery pursuant to a motion to compel.

[22] Commission interim rule 210.30(d)(2) was based on the language of Rule 26(e)(2) of the Federal Rules of Civil Procedure before that rule was amended in 1993.

1993,[23] compel certain conduct by the parties during the discovery phase of an investigation. Thus ground rule 4(ix) provides as follows:

> (ix) A duty to timely supplement all discovery responses upon obtaining information rendering a response substantially incomplete or incorrect is hereby imposed by the administrative law judge pursuant to Commission interim rule 210.30(d)(3). [Emphasis added.]

Ground rule 4(ix), which supplements Commission interim rule 210.30(d)(2), ensures that the party upon whom a discovery request is served cannot conceal responsive information which renders a prior response substantially incomplete or incorrect. Ground rule 5 provides for a procedure for the identification of documents with respect to which "there is no objection to production ... other than that the document is subject to a claim of privilege," whereby certain information relevant to the document and the claimed privilege is set forth in a privileged document list as in Duplan, supra.[24] (FF 691).

Genentech has argued that it was neither obligated nor able to produce the GLP documents because (1) under the MDL opinion the waiver of privilege applied only to the MDL litigation since the district court judge did not find that there was a "subject matter waiver" of the privilege (FF 657, 661, 662, 666, 668, 681), and (2) Genentech's lead counsel in this investigation was unaware of the issuance of the MDL opinion (FF 668).

Genentech's reliance on the lack of any subject matter waiver is unsupported by federal case law on point, as well as confusing and misleading.

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[23] Ground rule 4(ix) and 5 were put into effect in this investigation with the issuance of Order No. 1 on September 22, 1993, and have remained unaltered throughout the course of the investigation.

[24] Ground rule 5 puts the requesting party on notice of documents which are responsive to discovery requests and which would be produced to the requesting party, but for a claim of privilege, thus enabling the requesting party to challenge, if desired, the propriety of the privilege claimed prior to any hearing and/or before the record is closed. Genentech's conduct as to certain of the GLP documents, before issuance of the MDL opinion, denied respondents that opportunity.

The issue, which Genentech has failed to address, is whether the privilege that was claimed in the GLP documents actually disclosed to Lilly and UC, which privilege was deemed by the district court to have been waived, is also waived as to the respondents in this investigation, and not whether there was any "subject matter waiver."[25] As stated in Order No. 129, which issued on July 19, Genentech has cited nothing in the MDL opinion or elsewhere indicating that the waiver of privilege found by Judge Dillin as to the GLP documents was limited to UC and Lilly.[26] Moreover, it is clear that confidentiality is essential to the maintenance of the attorney-client privilege, Ethan Horwitz and Lester Horwitz, Patent Litigation: Procedure and Tactics § 5.01[4][iii] (1994), citing Duplan, supra, and when such confidentiality is breached, the privilege should be deemed to have been waived as to any future litigation. See e.g., Chubb v. National Bank, 224 USPQ 1002 (D.D.C. 1984); In re Natta, 163 USPQ 680 (D. Del. 1969).

The administrative law judge also rejects Genentech's second argument that its lead counsel in this investigation didn't even know that the MDL opinion had issued. Genentech's lead counsel in the MDL litigation, who is listed as counsel for Genentech in this investigation, and who participated in opening

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[25] The doctrine of subject matter waiver applies where a claimed attorney client privilege in a document or other communication is deemed to have been waived and the court further finds that, as a result, any claimed attorney-client privilege in all other documents or communications dealing with the same subject matter is also deemed to have been waived. See e.g., International Telephone and Telegraph Corp. v. United Telephone Company of Florida, 60 F.R.D. 177, 185-86 (M.D. Fla. 1973). Federal courts have held that the inadvertent disclosure of certain privileged documents does not result in the general waiver of privilege in other undisclosed documents on the same subject matter. See e.g., Champion Int'l Corp. v. International Paper Co., 486 F.Supp. 1328 (N.D. Ga. 1980); Golden Valley Microwave Foods v. Weaver popcorn Co., 18 USPQ2d 1867 (N.D. Ind. 1990); International Digital Sys. v. Digital Equip. Corp., 120 F.R.D. 145, 146 n.2 (D. Mass. 1988).

[26] Genentech sought neither reconsideration nor interlocutory review of Order No. 129.

argument in April 1994 at the hearing in this investigation on permanent relief, acknowledged receipt of the MDL opinion (FF 636). Moreover, Genentech's Vice President for Intellectual Property is "Of Counsel" for Genentech in this investigation, and was active at the hearing on permanent relief in this investigation (FF 636). Hence, at least certain counsel for Genentech active in this investigation, as well as Genentech's own in house counsel, knew about the issuance of the MDL opinion and either knew or should have known about the significance of that opinion for this investigation. In addition, Genentech knew at least by March 1994, that documents generated in the MDL litigation were relevant to issues in this proceeding (FF 642, 643). Moreover, Genentech was very much involved with the GLP documents in the MDL litigation while discovery was being pursued by Genentech in this investigation (FF 646).

Had Genentech produced the GLP documents after issuance of the MDL opinion, respondents would have had the opportunity to conduct any additional discovery, including discovery depositions, necessitated by their production, and would have had the opportunity to complete the record and prepare fully for any hearing or continuation of said hearing.[27] Instead, as a result of Genentech's failure to comply with Commission interim rule 210.30(d)(2) and ground rules 4(ix) and 5, respondents were precluded from conducting such discovery and from offering the GLP documents into evidence at the hearing on permanent relief. What effect the GLP documents would have had on this

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[27] In at least two previous investigations of this administrative law judge large numbers of relevant documents were either produced or discovered near the end of the discovery period and, as a result, the hearing dates were delayed. Certain Integrated Circuit Telecommunication Chips and Products Containing Same, Including Dialing Apparatus, Inv. No. 337-TA-337, Order No. 86 at 1, 14 n.8, 18 (Oct. 14, 1992); Certain Aramid Fiber, Inv. No. 337-TA-194, Order No. 13 at 10-11, 13 (Oct. 31, 1984). In addition, even in this investigation, discovery was taken after the discovery cut-off date (FF 651).

investigation, either in themselves or in leading to the discovery of other admissible evidence, is unknown. It is known that GLP documents responsive to respondents' discovery requests were not produced by Genentech during the discovery period. Accordingly, the administrative law judge finds, as a result of Genentech's conduct, that the record as it now stands is incomplete.

While Genentech has acknowledged the duty to supplement discovery imposed by Commission interim rule 210.30(d)(2) and ground rule 4(ix) (FF 666), it has also maintained that it was under no duty to supplement its discovery requests under the instant circumstances because: (1) the duty to supplement discovery responses extends only until the close of discovery, which was March 18, whereas the MDL opinion issued on March 22, after the close of discovery; (2) the new information did not render Genentech's discovery responses substantially incomplete or inaccurate; and (3) Genentech did not knowingly conceal any information (FF 666).

Contrary to Genentech's argument, the duty to supplement discovery requests extended at least until the close of the record upon completion of the hearing, especially where the withholding party had been aware of the information, as Genentech was aware of the MDL opinion, prior to the record being closed. Nothing in Commission interim rule 210.30(d)(2) or in Rule 26(e) of the Federal Rules of Civil Procedure limits the duty to supplement to the end of any discovery period. The Notes of the Advisory Committee on Rules state, with respect to the 1993 amendment to Rule 26(e), that "[t]he obligation to supplement disclosures and discovery responses applies whenever a party learns that its prior disclosure or responses are in some material respect incomplete or incorrect." In addition, as Genentech is aware, the discovery cut-off date

set by this adminiustrative law judge is not set in stone but may be extended,[28] and discovery has been allowed in this investigation beyond the discovery completion dates (FF 651). Moreover, hearing dates themselves are flexible. Thus, until the final initial determination is filed with the Commission, any party may move to reopen the record, and discovery may be conducted on any issue at the discretion of the administrative law judge. Havenfield v. H. & R. Block, Inc., 509 F.2d 1263 (8th Cir. 1975) (Havenfield), cited by Genentech (FF 666), is inapposite. In Havenfield, the Eighth Circuit held the district court did not abuse its discretion in disallowing the filing of a supplemental discovery response pursuant to a local rule that prohibited the filing of supplemental discovery responses after the close of discovery, absent good cause. Havenfield, 509 F.2d at 1271-72. There is no "local rule" at the Commission explicitly or in practice limiting the duty to supplement. Moreover, in Havenfield the defendant sought to supplement its own previous discovery responses in order to improve its position in the litigation, i.e. to set forth the new information for its own benefit, and the Court found that in delaying three and one-half to four months before attempting to supplement the appropriate discovery responses, the defendant "was not acting seasonably." Havenfield, 509 F.2d at 1272.

The administrative law judge rejects Genentech's argument that the admittedly new information in this investigation did not render its previous responses incomplete or inaccurate. As stated, supra, in placing a document on a Duplan-type privilege document list, a responding party avers that the document thus listed is responsive to a discovery request and that the only basis on which production of the document is withheld is a claim of privilege.

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[28] See e.g., Order No. 68 (Feb. 10, 1994).

Thus, when the United States District Court for the Southern District of Indiana held in the MDL opinion that the GLP documents were no longer privileged, this holding clearly rendered Genentech's previous responses involving those documents inaccurate (assuming arguendo Genentech had listed all of the GLP documents on its Duplan sheets), i.e. Genentech's assertion of privilege. Whether the content of the GLP documents represents significant or "truly new" evidence is immaterial to the issue of whether Genentech's previous discovery responses were inaccurate. The administrative law judge finds that upon issuance of the MDL opinion the GLP documents to which that opinion applied were no longer privileged, and that Genentech was under a duty to supplement discovery responses in which it asserted a privilege as to those documents.

Genentech's argument, supra, that its failure to disclose the MDL opinion and produce the GLP documents did not amount to a "knowing concealment" is also rejected. As the Seventh Circuit has stated:

> The strong term "knowing concealment" is designed, in recognition of the burden that a general duty of supplementation would impose in complex litigation, to protect a party who is reasonable in believing either that the change that has made his answer no longer accurate is known to his opponent or that it is a matter of no importance.

Fortino v. Quasar Company, 950 F.2d 389, 396 (7th Cir. 1991), citing Johnson v. H.K. Webster, Inc., 775 F.2d 1, 8 (1st Cir. 1985). Applying the standard in Fortino to Genentech's conduct, the administrative law judge finds that there was no basis for a reasonable belief on Genentech's part that the respondents in this investigation would have obtained knowledge of the issuance of the MDL opinion in March 1994. There is nothing in the record to show that either BTG or Novo was informed by any party in the MDL litigation, or by anyone else, about the issuance of the MDL opinion, or that they had any knowledge about it, until after its publication on June 27. To the contrary, when respondents

became aware of the MDL opinion through its publication, respondents promptly attempted to obtain from Genentech the GLP documents (FF 652), but were rebuffed by Genentech about a week later on July 14 (FF 657), at which time the final initial determination on permanent relief was due on July 29.

Genentech also has failed to show that it reasonably believed that the MDL opinion was a matter of no importance. To the contrary, in its opposition filed on September 2, Genentech argued for a hearing on the GLP documents, with no opportunity for discovery depositions on the documents by respondents.[29]

BTG and Novo, in their Motion Nos. 358-130 and 358-132 to reopen, have each asserted that at least certain of the GLP documents are significant to certain issues in this investigation. Novo, also in its Motion No. 358-132, at footnote 3, argued:

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[29] Genentech proposed (opposition at 36) the following procedural schedule:

Mon., Sept. 19: Identification by respondents and Staff of their previously-identified GLP documents, sponsoring witnesses, and any other witnesses who are expected to give testimony relative to each document;

Wed., Sept. 21: Identification by Genentech of rebuttal documents and witnesses;

Thurs., Sept. 29: Commencement of "GLP hearing" (length to be determined by Administrative Law Judge -- assumed, for scheduling purposes, to end on Tuesday, Oct. 4; and assumed that all "requested" witnesses can be available for the hearing); order of presentation -- Respondents, Staff, Genentech;

Fri., Oct. 14: Post-hearing briefs by respondents and Staff (with proposed findings of fact) in support of (a) why their respective GLP documents should be admitted into the record, and (b) how those documents should impact their claims; and

Tues., Oct. 18: Reply brief by Genentech (with rebuttal findings of fact) (case then under submission to the Administrative Law Judge).

> While a number of documents are of potential significance or could have been the basis for further discovery or deposition questions, Novo Nordisk has made a great effort to winnow these documents, such that those annexed hereto constitute only those which Novo Nordisk believes are sufficiently significant, on their face, to warrant reopening the record to admit them in the absence of any further discovery. Had Genentech timely produced the GLP documents, Novo Nordisk, in all likelihood, would have relied on, or otherwise utilized, more, perhaps many more, of the GLP documents. [Emphasis in original].

Due process requires that the respondents should not be limited to considering the GLP documents "on their face," and requires that respondents should have had at least the opportunity for further discovery, including depositions, on the documents and the opportunity to offer them into evidence at the evidentiary hearing on permanent relief. Had Genentech timely produced the GLP documents, respondents would have had those opportunities and been afforded due process.

d. Sanctions Are Warranted Under Commission Interim Rule 210.36(b)

As noted, supra, the administrative law judge finds that because Genentech has violated Commission interim rule 210.30(d)(2) and his ground rules 4(ix) and 5, sanctions under Commission interim rule 210.36(b) are warranted. He rejects, as without merit, Genentech's argument that no sanction is available under Commission interim rule 210.36(b) or Rule 37(b) of the Federal Rules of Civil Procedure because it has violated no discovery orders contemplated by the those rules (opposition at 17-18, 23-24; reply at 6). Commission interim rule 210.30(d)(2) is a rule imposing a certain duty to supplement discovery responses, and ground rules 4(ix) and 5 are discovery orders of the administrative law judge. Federal Courts have held that Rule 26(e) of the Federal Rules of Civil Procedure, which imposes a duty to supplement discovery responses under certain circumstances, does not require that there be an order compelling discovery in place before a court may impose sanctions for violation of the duty to supplement. Alldread v. Grenada, 988 F.2d 1425, 1436 (1st Cir.

1993); Thibeault v. Square D Company, 960 F.2d 239, 245 (5th Cir. 1992). Moreover, if Genentech's illusory argument that it should be spared sanctions because Genentech did not defy a specific order compelling discovery were accepted, then parties in section 337 investigations would be able, through grossly negligent failure to produce requested documents whose privileged status has been lost and/or grossly negligent failure to identify privileged documents, to proceed with a hearing and post-hearing submissions and then argue that an initial determination on the merits should issue, as Genentech argued on July 25 (FF 665), irrespective of the non-production of responsive documents even though its conduct precluded the requesting party from filing a timely motion to compel. In other words, in the absence of compliance by Genentech with Commission interim rule 210.30(d)(2) and ground rules 4(ix) and 5, the respondents did not know, and could not have been expected to know, that there was even a basis for filing a motion to compel. Despite the fact that the MDL opinion issued on March 22, 1994, which was more than two weeks before the start of the permanent relief hearing on April 11, Genentech made no attempt to inform the other parties in the investigation about the MDL opinion. The respondents were thus unable to bring any motion to compel production of the GLP documents until they first learned of MDL the opinion, not through any notification by Genentech, but through publication of the MDL opinion on June 27. Further, when respondents did become aware of effect of the MDL opinion, Genentech, although aware that final initial determination was then due on July 29 and that the maximum statutory deadline for any final initial determination was November 29, refused to commence production of the GLP documents until so ordered by the

administrative law judge on July 15 (FF 663).[30]

In addition, there is precedent in Commission practice for the application of sanctions under Commission interim rule 210.36(b) in the absence of an order compelling discovery issued under Commission interim rule 210.36(a). In Certain Composite Diamond Coated Textile Machinery Components, Inv. No. 337-TA-160, Order No. 43 (March 29, 1984) (Diamond Coated Machinery), the complainant had inspected certain documents in February 1984 and requested that a number of them be photocopied by respondents. Respondents initially agreed, but later refused to provide copies of the materials, arguing that the documents contained the confidential information of a third party. In its proposed agenda for a discovery conference in early March 1984, complainant stated that the respondents be ordered to produce the documents at issue, but the administrative law judge "did not consider the motion" based on the assurance of respondents' counsel that the documents would be produced. By the time of the hearing in late March 1984, respondents had still not produced the requested documents (again asserting the third party status of the documents, as well as asserting a relevance objection) and complainant filed a motion for sanctions, which motion the respondents argued should be summarily denied in the absence of any preceding motion to compel under then Rule 210.36(a). Diamond Coated Machinery, Order No. 43 at 2-4.

The administrative law judge in Diamond Coated Machinery granted the complainant's motion for sanctions. The administrative law judge stated that the respondents had expressed no objection at the discovery conference to the

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[30] Indeed, Genentech even opposed Motion Nos. 358-120 and 122 of respondents BTG and Novo, respectively, to delay issuance of the final initial determination on permanent relief, which was due on July 29 (FF 662). See Order No. 132 (July 28, 1994).

production of the documents and "thereby precluded complainant from seeking timely relief such as motion to compel." Id. at 4. The administrative law judge went on to state the following regarding the effect of said conduct on the party seeking discovery:

> Whether intentional or not, respondents have misled complainant right up through the March 13 conference, thus prejudicing complainant in its ability to take further steps to obtain the desired discovery. Had respondents given timely notice of their position, complainant may have been able to obtain discovery of the disputed documents (see e.g., Societe Internationale Pour Participations Industrielles et Commerciales, S.A. v. Rogers, 357 U.S. 197 (1958)) or found alternative means to obtain its equivalent. ... respondents forestalled and prevented complainant from making a timely motion to compel, as well as pursuing any alternate discovery procedures as might have been available. Such dilatory conduct comes at least within the spirit of Rule 210.36 and warrants the issuance of sanctions.

Id. at 5-6 (emphasis added).

As in Diamond Coated Machinery, Genentech's conduct in this investigation has affected the ability of the respondents to make a complete record and to fairly prepare for the hearing. Here Genentech, in violation of ground rule 5, initially failed to list all of the GLP documents responsive to respondents' discovery requests on its Duplan list (FF 690). Thus, with respect to those documents, respondents were completely unaware that those documents (1) were responsive to some of their requests and (2) were withheld only on the basis of a claim of privilege. Respondents were thus altogether precluded from even attempting to obtain discovery of those documents. Later, upon issuance of the MDL opinion, Genentech, in violation of Commission interim rule 210.30(d)(2) and ground rule 4(ix), failed to produce said documents to respondents and failed even to update its Duplan list to put respondents on notice that the documents

were no longer privileged.[31] Moreover, while in Diamond Coated Machinery the complainant at least knew of the existence of the discoverable documents prior to the hearing and sanctions were still issued in that investigation, the respondents in this investigation did not know about the discoverable documents until some two months after the hearing, and only then through publication of the MDL opinion rather than by notification from Genentech.

Genentech's attempts to distinguish Diamond Coated Machinery are rejected.[32] The fact that Diamond Coated Machinery was decided prior to the addition of section 337(h) to the statute is irrelevant. As stated above, upon amendment of the statute in 1988, the Commission issued new rules (the so-

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[31] Referring to the 60 documents produced to respondents by Genentech on July 14, which documents were responsive to certain of respondents' discovery requests and with respect to which Genentech's previous claims of privilege had been withdrawn without notice to the respondents prior to July 14 (FF 666), Genentech has argued that the portion of said documents not produced to respondents prior to July 14 are merely cumulative of documents and information that had been produced already to respondents, and add nothing to the investigation (FF 666). Although it is unclear what portion of said documents were produced to respondents during the discovery period, it is clear that all of said documents should have been produced as soon as Genentech's claims of privilege were withdrawn. Whether such documents are "cumulative" of documents already produced is not for Genentech to determine unilaterally. Even if none of the 60 documents above are any part of the basis for the sanctions requested by respondents, Genentech's failure to produce each of said documents during the discovery period is further confirmation of Genentech's inattentive approach to discovery of the GLP documents prior to July 1994.

[32] In its reply to the staff's response to the motions for sanctions Genentech attempted to factually distinguish Diamond Coated Machinery, arguing that its order is inapplicable to this investigation because it was issued before the 1988 amendment to the statute that permits sanctions for discovery abuses only to the extent permitted by Rule 37 (reply at 7); that in Diamond Coated Machinery sanctions were imposed upon respondents' failure to provide certain promised discovery, with the administrative law judge "equating" respondents' promise in response to a "timely motion to compel" with an order compelling discovery (id.); and that in this investigation, unlike Diamond Coated Machinery, any motions to compel "were entertained and complied with," and "there is no missing discovery" since all GLP documents have been produced to respondents (reply at 7-8). Genentech further argued that in Diamond Coated Machinery the situation "was not exposed until the hearing," and the administrative law judge there determined that at that stage it was too late for a motion to compel (reply at 8).

called "interim rules") to bring Commission practice into compliance with the amended statute. At that time the Commission stated that the rule published as interim rule 210.36 was unchanged from the existing rule 210.36, under which Diamond Coated Machinery was decided, and stated that further "[t]he existing provisions of § 210.36 provide sanctions that are comparable to those available under FRCP 37." 1988 Comments, 53 Fed. Reg. at 33052. If Commission interim rule 210.36 permitted discovery sanctions beyond those permitted under Rule 37 of the Federal Rules of Civil Procedure, then the Commission would have had to amend it in order to comply with section 337(h).

In addition, the focus of Diamond Coated Machinery is that the administrative law judge there, as admitted by Genentech in its reply at 9, determined that because of the conduct of the producing party it was too late for a motion to compel. The salient fact in that case, as in this investigation, is that the party in possession of the documents, by its own conduct, "precluded [the other party] from seeking timely relief such as a motion to compel or other alternative discovery." Diamond Coated Machinery at 4, supra.

Commission interim rule 210.30(d)(2) and ground rules 4(ix) and 5, with clarity and specificity, compel certain conduct by the parties during the course of discovery, and are not general or ambiguous. Thus, they are distinguishable from the orders involved in, for example, R.W. Int'l Corp. v. Welch Foods, Inc., 937 F.2d 11, 15 (1st Cir. 1991) (R.W. Int'l Corp.), cited by the complainant in its opposition.[33] The order in issue in R.W. Int'l Corp. was the district

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[33] In support of the proposition that Genentech has violated no orders contemplated by Commission interim rule 210.36(b) or Rule 37(b), Genentech cited R.W. Int'l Corp., citing Badalamenti v. Dunham's, Inc., 896 F.2d 1359, 1362 (Fed. Cir.), cert. denied sub nom., Hyde Athletic Industries, Inc. v. Badalamenti, ___ U.S. ___, 111 S.Ct. 142 (1990) (Badalamenti); Salahuddin v. Harris, 782 F.2d (continued...)

court's "Scheduling Order" in which the court gave certain instructions concerning the scope of discovery, the parties were directed to state certain facts regarding their costs, earnings, profits, etc., and certain discovery deadlines were set. When the plaintiff subsequently failed to respond to discovery requests of defendant, and plaintiff's sole shareholder refused to answer certain questions during his deposition, the district court dismissed the case, finding that plaintiff had willfully violated its "discovery orders." The First Circuit reversed, finding that an order "to answer specific ... questions" could not be implied from the Scheduling Order. R.W. Int'l Corp., 937 F.2d at 13-14, 16. The First Circuit stated that whether plaintiff's failure to produce documents was sanctionable under Rule 37(b)(2) of the Federal Rules of Civil Procedure depended on whether plaintiff had defied a "sufficiently explicit" order, and held that the district court's Scheduling Order was not such a "sufficiently explicit" order, but rather a "general directive," containing "sweeping generalities," "fraught with ambiguities," and "broad brush." Id. at 16-18.

Commission interim rule 210.30(d)(2) and ground rules 4(ix) and 5, unlike the Scheduling Order in R.W. Int'l Corp., do not address any vaguely defined categories of documents or discovery requests, but unambiguously apply, respectively, to any and all discovery requests that are rendered incomplete or incorrect by later acquired information and the identification of any and all documents with respect to which any party claims a privilege. Thus, the First Circuit's criticism that an order to answer a particular deposition question or

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[33](...continued)
1127, 1131 (2d Cir. 1986) (Salahuddin); 4A J. Moore & J. Lucas, Moore's Federal Prac. ¶ 37.03[2], at 37-62 to 37-64 (2d ed. 1991); 8 C. Wright & A. Miller, Federal Prac. & Proc. § 2289 at 790 (1970)); and GFI Computer Indus., Inc. v. Fry, 476 F.2d 1, 3 (5th Cir. 1973) (GFI).

produce a particular document cannot be implied from a "general order" such as the district court's Scheduling Order, is found not to apply to Commission interim rule 210.30(d)(2) and ground rules 4(ix) and 5.[34]

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[34] Badalamenti, Salahuddin and GFI, supra, are similarly inapposite. Neither Badalamenti nor Salahuddin apply because neither case directly involves Rule 37(b)(2) of the Federal Rules of Civil Procedure. In Badalamenti, it was discovered during proceedings on remand that the plaintiff had failed to produce certain documents that were responsive to a Rule 30(b)(5) document request which had been served on plaintiff by defendants with a notice of deposition during the initial proceedings. Defendants moved for, and were granted, sanctions under Rule 37(d) which applies only to a complete failure of a party to attend at his own deposition or serve answers to interrogatories or respond to a request for inspection. No sanctions were sought or awarded pursuant to Rule 37(b) which applies only to a failure at all of a party to attend at his own deposition or serve answers to interrogatories or respond to request for inspection. On appeal the Federal Circuit reversed, holding that although plaintiff's response to the document request was inadequate and failed to include responsive documents, plaintiff had responded and thus could not be sanctioned under Rule 37(d). Badalamenti, 896 F.2d at 1363. The Court's only references to Rule 37(b), cited by Genentech, is that "Rule 37(b) provides for sanctions where a party fails to comply with a discovery order" and "[t]he district court in this case acknowledged that sanctions under this subdivision were unavailable because there was no discovery order that was violated." Badalamenti, 896 F.2d at 1362. This reference by the Court to Rule 37(b)(2) is the merest dicta. Moreover, unlike the plaintiff in Badalamenti, Genentech in this investigation has clearly violated Commission interim rule 210.30(d)(2) and ground rules 4(ix) and 5 of Order No. 1.

In Salahuddin the district court had ordered the plaintiff's deposition pursuant to Rule 30(a) of the Federal Rules of Civil Procedure, and upon plaintiff's refusal to answer certain questions during the deposition the district court dismissed the case as a sanction pursuant to Rule 37(d). The Second Circuit reversed the dismissal and also discussed the applicability of Rule 37(b) to the case, noting that the defendants originally sought sanctions for Salahuddin's deposition conduct under Rule 37(b)(2). The Second Circuit held that although a court order under Rule 37(a) was in effect at the time of the plaintiff's deposition, said order "did not specify what matters could or could not be inquired into at the deposition or what procedures were to be followed if a dispute arose over the manner of conducting the deposition." Salahuddin, 782 F.2d at 1131. The Court further noted that the district court "had the power under Rule 37(a) to direct Salahuddin to answer specified questions but it failed to do so," and declined to imply any such order from the Rule 30(a) order. Salahuddin, 782 F.2d at 1131-32. The Court thus held that "[t]here was no violation of a court order upon which to base Rule 37(b) sanctions."

Salahuddin is distinguishable from the instant investigation in two respects. First, in Salahuddin, like Badalamenti, the issue before the Court

(continued...)

e. Appropriateness of Dismissal As A Sanction Under Commission Interim Rule 210.36(b)

The sanction of dismissal is appropriate in this investigation where, as a result of Genentech's conduct, the record is incomplete and where Genentech's failure to comply with Commission interim rule 210.30(d)(2) and ground rules 4(ix) and 5 is found to amount to gross negligence. Under the language "including, but not limited to" in Commission interim rule 210.36(b), the administrative law judge has broad discretion as to what sanction he may issue, including the rendering of a determination against a party. Commission interim rule 210.36(b)(1)-(5). In addition, Rule 37(b), on which Commission interim rule 210.36(b) is modeled, expressly provides for the entry an order "dismissing the action or proceeding." See Fed. r. Civ. P. 37(b)(2)(C).

In Societe Internationale Pour Participations Indusrielles et Commerciales, S.A. v. Rogers, 357 U.S. 197 (1958) (Societe) the Supreme Court held that, in view of the due process implications in the denial of a party'ys right to be heard, Rule 37 does not authorized dismissal of a case "when it has been established that failure to comply has been due to inability, and not to willfullness, bad faith, or any fault." Societe, 357 U.S. at 212. In that case the Supreme Court accepted the arguments of a Swiss party that it was unable, despite extensive efforts at compliance with a court order, to produce the

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[34](...continued)
of Appeals was the application by the district court of sanctions pursuant to Rule 37(d) of the Federal Rules of Civil Procedure and not Rule 37(b)(2). Second, to the extent that Salahuddin does apply to Rule 37(b)(2) sanctions, the order in that case, like that in R.W. Int'l Corp., lacks the specificity of ground rule 5 at issue.

In additions the GFI case, cited by Genentech, does not apply to this investigation because it was found in that case that the order of the district court that the party against whom sanctions were entered was accused of violating had been "issued under an erroneous view of the facts," and thus could not serve as the basis for a default judgement. GFI, 476 F.2d at 5. Commission interim rule 210.30(d)(2) and ground rules 4(ix) and 5 were not issued in error, unlike the order in GFI.

douments at issue due to the threat of criminal prosecution under Swiss law relating to production of such documents. Id. at 211-12. Interpreting the meaning of the "fault" standard enunciated in Societe, the Second Circuit has held that "fault" covers at least gross negligence. Cince Forty-Second Street Theater, Inc. v. Allied Artists Picture corp., 602 F.2d 1062, 1067 (2d Cir. 1979).

Negligence has been described in the context of tort law as the failure to conform to an expected standard of conduct or duty of care resulting in somme harm to another. W. Page Keeton, Prosser & Keeton on the Law of Torts § 30, at 164 (5th ed. 1984) (Prosser & Keeton). Gross negligence "signifies more than ordinary inadvertence or inattention, but less than perhaps conscious indifference to the consequences," and "differs from ordinary negligence only in degree." Prosser & Keeton § 34, at 212 (footnotes and citations omitted). The degree of care owned depends upon the circumstances present.[35] Thus, in a section 337 investigation, in which the time available for discovery is relativley condensed and the time available for completion of the investigation is short and fixed by statute, and in this investigation in particular where the investigation had already been declared "more complicated" prior to issuance of

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[35] Prosser & Keeton describe how the standard of care owed by one to anther may alter in accordance with the circumstances involved as follows:

> The amount of care demanded by the standard of reasonable conduct must be in proportion to the apparent risk. As the danger becomes greater, the actor is required to exercise caution commesurate with it. Those who deal with instrumentalities that are know to be dangerous ... must exercise a greate amount of care because the risk is great. They may be required to take every reasonable precaution suggested by experience or prudence.

Prosser & Keeton § 34, at 208 (footnotes and citations omitted).

the MDL opinion,[36] the parties' duty of care in discovery is found to be very high, and each party is expected to "take every reasonable precaution suggested by experience or prudence" in the conduct of discovery. With specific regard to the conduct of discovery, the Second Circuit in Cine, in dismissing the case pursuant to Rule 37(b) based on the party's gross negligence, held that gross negligence was present "where counsel clearly should have understood his duty to the court." Cine, 602 F.2d at 1068 (emphasis added).

The administrative law judge finds that Genentech clearly should have understood its duty under Commission interim rule 210.30(d)(2) and ground rules 4(ix) and 5. Moreover, given the heightended duty of care Genentech was obligated to observe, the administrative law judge finds that Genentech's conduct after issuance of the MDL opinion is grossly negligent in (1) its failure to identify all of the GLP documents responsive to the respondents' discovery requests, in violation of ground rule 5, and (2) its failure to notify respondents' about the MDL opinion and its failure to produce the GLP documents to the respondents after the MDL opinion had issued, in violation of Commission interim rule 210.30(d)(2) and ground rule 4(ix).

The administrative law judge rejects Genentech's argument that the sanction of dismissal is not available to the administrative law judge junder Commission interim rule 210.36(b). While "dismissal" is not expressly provided for in Commission interim rule 210.36(b), the interim rule does expressly provide for its equivalent, viz. that an administrative law judge may rule "that a determination in the investigation be rendered against the party." Commission interim rule 210.36(b)(5). Moreoer, Rule 37(b), which the Commission has stated is "comparable" to Commission interim rule 210.36(b), does expressly

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[36] See Order No. 82 (March 2, 1994).

provide for the issuance of an order "dismissing the action or procedding or any part thereof" as a sanction for abuse for discovery. Fed. R. Civ. P. 37(b)(2)(C).

Dismissal is appropriate not only because of the due process owed to respondents, but also because of its important deterrent value. In Naational Hockey League v. Metropolitan Hockey Club, 427 U.S. 639 (1976), the Supreme Court articulated the significance of deterrence in the application of Rule 37 sanctions, not only with respect to the individual parties involved, but also with respect to future parties. The Court held that:

> There is a natural tendency on the part of reviewing courts, properly employing the benefit of hindsight, to be heavily influenced by the severity of outright dismissal as a sanction for failure to comply with a discovery order. It is quite reasonable to conclude that a party who has been subjected to such an order will feel duly chastened, so that even though he succeeds in having the order reversed on appeal he will nonetheless comply promptly with future discovery orders of the district court.
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> But here, as in other areas of the law, the most severe in the spectrum of sanctions provided by statute or rule must be available to the district court in appropriate cases, not merely to peanlize those whose conduct may be deemed to warrant such a sanction, but to deter those, who might be tempted to such conduct in the absence of such a deterrent. If the decision of the Court of Appeals remained undistrubed in this case, it might well be that these respondents would faithfully comply with all future discovery orders entered by the District Court in this case. But other parties to other lawsuits would feel freer than we think Rule 37 contemplates they should feel to flout other discovery orders of other district courts.

National Hockey League, 427 U.S. at 642-43 (emphasis in original). See also Cine, 602 F.2d at 1066 (recognizing the general deterrent effect of Rule 37 dismissal). Thus the dismissal of this investigation serves not only to avoid prejudice to the respondents who have been deprived of their ability to fully and fairly prepare their case, but also to deter such conduct in future

investigation.[37] Deterrence is of particulr concern in the context of complex section 337 investigations in which the maximum statutory limitation is relatively short and fixed, and there can be a temptation to obfuscate or delay discovery, or even to conceal discoverable facts and/or documents.

With respect to the documents respondents wish to have admitted into evidence, Genentech argued that the only appropriate course is to reopen the record to give respondents and the staff a reasonable opportunity to show why any "truly new evidence" should be admitted into this record, and that to admit any GLP document solely on the basis of attorney interpretation and inference is improper where witnesses could be made available to put the documents in proper perspective and context. While the administrative law jduge agrees with Genentech to the extent that the interpretation of any GLP document should not be based solely on attorney interpretation, he does not understand Genentech's use of the term "truly new evidence." The Commission interim rules makes no distinction between "evidence" and "truly new evidence"[38] admissible in an adminstrative hearing under section 337. Moreover, in terms of the impact of the GLP documents on any discovery, the Commission interim rule 210.30(b) provides that it is not ground for objection that the information sought will

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[37] As one commentator has stated, National Hockey League, "which does not present a particularly uncommon instance of discovery abuse, shows that dismissal and default are not exceptional but rather they are simply options available to judes who must respond to conduct which is culpable yet not so blatnatly intentional or one sided as to constitute constructive abandonment." Note, "The Emerging Deterrence Orientation in the Imposition of Discovery Sanctions," 91 Harv. L. Rev. 1033, 1047, 1047 n. 86 (1978).

[38] To the extent that Genentech's phrase "truly new evidence" relates to the reference in Commission interim rule 210.42(b) to the inadmissibility of "unduly repetitious evidence," the administrative law judge judge finds no basis for finding that said GLP documents are "unduly repetitious." To the contrary, in late July 1994 Genentech's lead counsel in the MDL litigation represented to the administrative law judge that there is "no question" that the GLP documents were the "innermost thinkings" and that "strategy" of Genentech's counsel (FF 645).

be inadmissible at any hearing if the information sought appears reasonably calculated to lead to the discovery of admissible evidence. It is not denied by Genentech that there are GLP documents in issue produced by Genentech pursuant to Order No. 129 which were responsive to respondents' discovery requests but yet were not produced to respondents pursuant to said discovery requests, and further were not identified on Duplan lists prior toissuance of the MDL opinion. Thus, it is clear that as a direct result of Genentech's gross negligence and intransigence, the record in this investigation is incomplete.

f. There Is No Violation of Section 337

Commission interim rule 210.36(b)(5) provides that, as a sanction for abuse of discovery, an administrative law judge may "rule by initial determination that a determination in the investigation be rendered against a party." This provision, in substance, is the same as a "dismissal" under rule 41(b) of the Federal Rules of Civil Procedure.[39] Accordingly, on this record, and for the many and varied reasons, supra, the administrative law judge finds, pursuant to Commission interim rule 210.36(b)(5), that there is no violation of section 337 by the respondents.[40]

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[39] Rule 41(b) provides as follows:

> (b) **Involuntary Dismissal: Effect Thereof.** For failure of the plaintiff to prosecute or to comply with these rules or any order of court, a defendant may move for dismissal of an action or of any claim against a defendant. Unless the court in its order for dismissal otherwise specifies, a dismissal under this subdivision and any dismissal not provided for in this rule, other than a dismissal for lack of jurisdiction, for improper venue, or for failure to join a party under Rule 19, operates as an adjudication upon the merits.

[40] In Hinges, as a sanction for abuse of the Commission's pre-institution duty of candor and Commission interim rule 210.5(b), the administrative law judge found that "dismissal of the complant with prejudice" was an appropriate sanction. Hinges, Order No. 118 at 28 (Sept. 28, 1989). He also simultaneously issued on alternative initial determination on the merits finding no violation (continued...)

g. Conclusion

Genentech's conduct with respect to the discovery of the GLP documents is characterized by neglect, obfuscation, delay and disingenuousness. Genentech's inexcusable failure to list all of the GLP documents withheld from production on the basis of privilege on its Duplan list, and its failure to notify respondents about the issuance of the MDL opinion, or to produce to respondents the GLP documents affected thereby, pursuant to Commission interim rule 210.30(d)(2) and ground rules 4(ix) and 5, until ordered to do so by the administrative law judge on July 15 is found to be nothing less than gross negligence deserving of severe sanctions. Genentech has been well aware of the statutory deadline of November 29, 1994, since the notice of investigation was published on September 29, 1993. Moreover, Genentech, as a party in the MMDL litigation, had full knowledge of the MDL opinion. Relying on Frivolous legal argument, Genentech refused to produce voluntarily the GLP documents to respondents in this investigation after issuance of the MDL opinion. Instead it proceeded to try its case before the administrative law judge, allow its witnesses to testify, file voluminous post-hearing briefs and present closing arguments with complete disregard of the GLP documents (FF 666). Moreover

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[40](...continued)
of section 337. Hinges, initial determination at 318 (Sept. 28, 1989). The Commission upheld the administrative law judge's initial determianation on the merits finding no violation of section 337. Hinges, Commission opionion at 19, 23 (January 1990). The Commission also upheld the administrative law judge's dismissal of the investigation, stating that "we terminate the investigation and dismiss the complaint, with prejudice," but did not state whether said dismissal constitued a determination of no violation. Id. at 13. On this poinst see Farrel Corp. v. U.S.I.T.C., 949 F.2d 1147 (Fed. Cir. 1991), cert. denied sub nom. Pomini Farrel v. Ferral Corp., _____ U.S. _____, 112 S.Ct. 1947 (1992) (Farrel), where the Federal Circuit reversed the Commission's termination of an investigation on the basis of a pre-existing arbitration clause, holding that under section 337(c) the Commission's "non-conclusive termination may be based only on those grounds explicitly provided for in the statute [19 U.S.C. § 1337(c)] itself, "viz. a consent order or settlement agreement. Farrel, 949 F.2d at 1153 (emphasis added).

Genentech urged that a final initial determination on permanent relief should issue (FF 666) although all the while it had concealed responsive, and non-privileged GLP documents which may tend to undermine or disprove positions Genentech had taken in this investigation, and reveal or clarify certain facts that support contentions made by the respondents.

Genentech has admitted that the GLP documents were overlooked by Genentech during its production of documents and Duplan sheets in the ITC investigation, and argued that "[b]y way of explanation, but not excuse, the misdirection and mishandling was largely the result of the documents being caught up in the change of Genentech's legal counsel in the MDL litigation" (FF 648), and that while Genentech seriously regrets the mishandling of the GLP documents those documents comprise in their entirety, "both privileged and non-privileged ... about 1 percent of the total number of documents pages made available to respondents" (FF 692).

Discovery in a section 337 investigation is not measured by the quantity of documents produced but rather whether all documents responsive to legitimate discovery requests have been produced. In view of the strict statutory time limits in a section 337 investigation there is a special duty on the parties, and particularly on the complainant, to comply with, and facilitate, discovery in a timely manner within the requirements of the Commission's interim rules and the administrative law judge's ground rules. Certainly, any attempt by a complainant to thwart legitimate discovery is a serious offense which cannot be tolerated.

This is not a case where documents were innocently overlooked after a careful record search since the GLP documents were ultimately produced by Genentech in the separate MDL litigation in a federal district court and were then the subject of contested motions in that court. Counsel for Genentech

involved in this investigation is lead counsel for Genentech in the MDL litigation and Genentech's Vice President for Intellectual Property was active in this investigation. It simply cannot be credibly argued that Genentech's conduct was anything but knowing, and possibly purposeful.

Even when ordered by the administrative law judge to produce the GLP documents Genentech's production was piecemeal. On July 25, Genentech represented that pursuant to its production as ordered by the administrative law judge there were no documents missing from the document production (FF 667), and further took the position that respondents' concern regarding the integrity of Genentech's documents production "could be easily resolved if BTG and Novo request copies of the documents from Lilly and UC" (FF 667). It was the production of Genentech's documents in issue however, not the documents of non-parties Lilly and UC, and it is Genentech that is seeking relief under section 337. Genentech again represented during a conference on July 26, that with respect to Genentech's production of the GLP documents "[e]verything we could do internally has been done . . . [although] we have not checked with Lilly" (FF 670). While Genentech made such representions on July 25 and 26, at that time it still had not been able to confirm whether certain non-privileged documents responsive to respondents' discovery requests had been produced, and had yet to produce all of the documents (FF 672, 673, 678, 682, 684, 685, 686, 688). Thereafter respondents' filed motions to compel (FF 690), citing for example a conclusory affidavit filed by Genentech in response to BTG's Interrogatory No. 130 (FF 694). In its response to Order No. 136 compelling a more difinitive response to Interrogatory No. 130, Genentech acknowledged the inconclusiveness of its earlier response but merely submitted additional conclusory affidavits (FF 694).

In late July Genentech argued that the final initial determination should

issue on July 29, and that eh GLP documents which "respondents did see for the first time last week are attorney work product and/or privileged attorney-client communications [and] [f]or the most part, these documents contain merely the analyses, musings, ruminations and thought processes of Genentech's counsel and would-be counsel" (FF 666). However, Genentech also has characterized the GLP documents in question as the "innermost thinkings" and the "strategy" of its lawyers (FF 645). Moreover those "analyses, musings, ruminations and thought processes," as well as the "innermost thinkings" and "strategy," were found to be non-privileged in the MDL litigation. It is obvious that the foregoing might be very material to issues in this investigation.

In September, with the statutory deadline for the final initial determination less than three months away, Genentech submitted detailed proposed "rebuttal findings" to Novo's proposed adverse inferences from the GLP documents and appeared to recognize the need for a hearing, although taking the position that respondents and the staff have the burden to show why the GLP documents, which were responsive to respondents' discovery requests and were admittedly "new evidence," should be admitted into evidence. It is clear that the due process rights of the respondents have suffered as a result of complainant's misconduct. Even complainant appears to concede, in its filing in September, 1994, that a further hearing would be needed to resolve questions raised by the GLP documents which complainant wrongfully withheld. Any further hearing would, of course, have required at least: (1) that the respondents have the opportunity for additional discovery including depositions, (2) that respondents be given the opportunity for preparation for said hearing, for a hearing and for the filing of post hearing submissions and (3) additional consideration by the administrative law judge subsequent to the post-hearing submissions. All of the foregoing would have taken time which was not available because of Genentech's

misconduct. Thus the misconduct has adversely affected the respondents' opportunity to adequately prepare and present a full defense in this investigation.

Accordingly, the administrative law judge grants BTG's Motion No. 358-133 and Novo's Motion No. 358-131 for sanctions and finds, based on the foregoing, that the complaint should be dismissed with prejudice and the investigation terminated with a finding of no violation.

C. Respondents' Motion To Reopen

Complainant has argued that the administrative law judge now has before him a "potpurri" of possible interpretations of the GLP documents from which he can pick and choose and that any such interpretations would be based on pure speculation and inference. The administrative law judge agrees that speculation should not be the basis for evidentiary findings. Accordingly BTG's Motion No. 358-130 to reopen the record for the admissibility of RBX 414 to 421 and 423 to 441 and 445 to 448, and Novo's Motion No. 358-132 to reopen the record for admissibility of RNX 157 to 159, 161, 162, 163 and 165 to 170 are denied. Had respondents had the opportunity for full discovery of said documents, and adequate time to prepare for a hearing on said documents, they would likely have been admitted int the evidentiary record.

pages 55--528 omitted
See statement on page 529.

X. CONCLUSIONS OF LAW

1. The Commission has in rem jurisdiction and subject matter jurisdiction.

2. The Commission has in personam jurisdiction over the respondents.

3. The investigation is terminated, the amended complaint is dismissed, and there is no violation of section 337 in view of the complainant's violation of Commission interim rule 210.30(d)(2) and ground rules 4(ix) and 5, and the due process rights of respondents.

USITC Publication 2869, Investigation No. 337-TA-358

This publication contains only those portions of the Administrative Law Judge's (ALJ) Initial Determination (ID) dismissing the complaint with prejudice and terminating the investigation as a sanction for complainant's discovery abuse (sections I--VI and X.1., 2., and 3.). The Commission took no position on the remainder of the ID.

A copy of the complete ID as issued by the ALJ and all other nonconfidential documents filed in connection with this investigation are 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.